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

# Final Report of the Multistakeholder Consultations

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

December 2001 — EPS M-464

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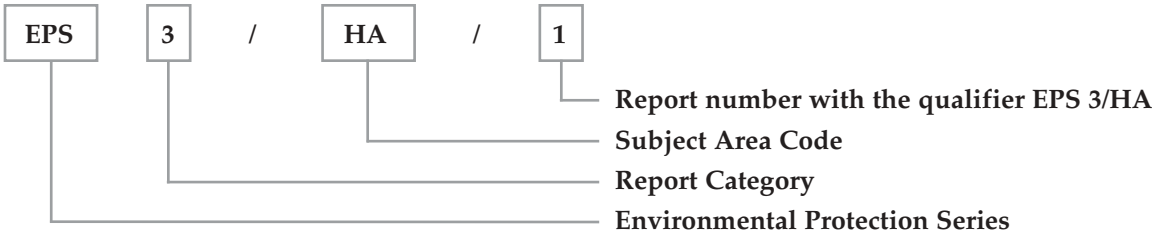


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## Disclaimer

This report is the result of the Multistakeholder Consultations. It is based on the reports prepared by NSN Multistakeholder Table members and technical subcommittees and the deliberations and recommendations that were agreed to at Table meetings. The consultations and the publication of this report were sponsored by Environment Canada; however, the contents of this report do not necessarily reflect the views and policies of Environment Canada. This report will be considered “final” when it is available in both official languages.

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# 1. Introduction

The New Substances Notification (NSN) Regulations for Chemicals and Polymers have been in place under the *Canadian Environmental Protection Act* (CEPA) since July 1, 1994. When the Regulations were promulgated, a commitment was made by Environment Canada and Health Canada to review them following three years of implementation. To fulfil this commitment, these departments established a multistakeholder consultative process in June 1999. Representatives from industry, public advocacy groups (PAG) and the federal government participated in the process.

The NSN Multistakeholder Table (hereafter referred to as the Table or the NSN Table) held eight meetings and numerous subcommittee and other meetings between November 1999 and August 2001 to produce this report. At its first meeting, the Table agreed that the objective of this consultation would be "to identify, discuss and develop consensus recommendations on ways to improve the NSN Regulations and the Program."

This report details the background, context, deliberations and final recommendations of the NSN Multistakeholder Consultations. Section 2 provides the background and context of the consultations, including an introduction to the NSN Regulations and the New Substances (NS) Program and the guiding principles used by the NSN Table in its discussions. The focus of this report and the extensive deliberations of the NSN Table in developing recommendations for improving the Regulations and Program are captured in Section 3. The Table organized its discussions around five themes and several issues relating to each theme. The five themes are:

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

Section 3 provides a description of each theme and associated issues, details about the Table deliberations and, where appropriate, the recommendations of the Table with respect to those themes and issues. The appendices to this report provide background information and references pertaining to the consultation process and the NSN Regulations and NS Program.

# 2. Background and Context of Multistakeholder Consultations on the NSN Regulations and NS Program

The NSN Regulations apply to chemicals, polymers and inanimate and animate products of biotechnology. These consultations did not address or make recommendations related to animate products of biotechnology because this was beyond their scope.

For the purposes of this report, the term "substances" will include only chemicals, polymers and inanimate products of biotechnology.

## 2.1 Introduction to the NSN Regulations

CEPA[1] was promulgated in 1988. Following a five-year review, it was replaced with a revised Act (CEPA'99) on March 31, 2000. Unless expressly stated to the contrary, all references to CEPA in this report are to CEPA'99. One of the objectives of CEPA is to ensure that no new substance is imported into or manufactured in Canada without a formal review, prior to market introduction, of its potential risks to human health and to the environment. The "Substances and Activities New to Canada" provisions in Part 5 of CEPA[2] are the authority under which the NS Program performs the risk assessments and manages chemicals and polymers when risks are identified. The NSN Regulations, which came into effect on July 1, 1994, are the principal means by which the authority is enacted.

The NSN Regulations require importers and manufacturers to notify Environment Canada of substances and activities new to Canada. The information that notifiers must submit to government is described in regulatory "schedules." The notification packages typically include test data relating to physicochemical properties, environmental fate and behaviour and/or toxicity. A detailed description of the NS Program, including the role of the Domestic Substances List (DSL) and the Non-Domestic Substances List (NDSL), is available on Environment Canada's NS Program web site at **www.ec.gc.ca/substances**.

Environment Canada is responsible for the administration of the NS Program, the assessment of potential risks to the environment, development and implementation of controls, compliance promotion and enforcement. Health Canada carries out the assessment of potential risks to human health. Notifiers are responsible for providing the information packages and any associated costs. NS Program costs are currently borne by Environment Canada and Health Canada; however, a cost recovery initiative is being pursued[3] to recover some of the costs from notifiers. Table members agreed that, because of this other initiative, cost recovery would not be part of its deliberations. However, the Table recognizes that fees associated with cost recovery may need to be reexamined depending on the extent of the amendments to the NSN Regulations.

Multistakeholder consultations and review of the NS Program, procedures and practices have been, and continue to be, critical to the successful implementation of the NSN Regulations. The current NSN Regulations incorporate recommendations of the Environmental Contaminants Act Amendments Consultative Committee,[4] a multistakeholder body. When the NSN Regulations were promulgated, a commitment was made on the part of Environment Canada and Health Canada to review the NSN Regulations following three years of their implementation. This exercise fulfils this promise.

## 2.2 Focus of the Consultations on the NSN Regulations and NS Program

In June 1999, Environment Canada and Health Canada established a multistakeholder consultative process to work towards common understanding of the NSN Regulations and NS Program and to provide consensus recommendations for their improvement. An independent facilitator and a Secretariat were contracted to design and implement the consultative process. Following discussions with several stakeholders, invitations to participate in the process (i.e., sit at the Table) were accepted by individuals representing Environment Canada (two seats), Health Canada (two seats) and Industry Canada (one seat), representatives of a broad range of industries affiliated with

the NS Program (seven seats in total) and PAG representatives (three from the Canadian Environmental Network, two from Labour, one from the Consumers Association of Canada and one from the Canadian Public Health Association). A listing of individual participants and their affiliations is provided in Appendix A.1. Several stakeholder groups declined a seat at the Table but requested that they be kept informed of the progress of the consultations (e.g., provinces, territories and Aboriginal associations).

The NSN Table held eight meetings and numerous subcommittee and other meetings between November 1999 and August 2001 to produce this report. At its first meeting, the Table agreed that the objective of this consultative process would be "to identify, discuss and develop consensus recommendations on ways to improve the NSN Regulations and the Program." The Table also agreed on a set of "procedural rules" to guide its deliberations (see Appendix A.2). One of the rules states that each participant has an obligation to strive to consensus; however, where consensus cannot be reached on a particular issue despite best efforts, the differing views relating to that issue will be clearly articulated. This report recognizes this agreement.

The NSN Table acknowledges that consensus recommendations pertaining to amendments of the current NSN Regulations cannot bind the Parliamentary process (Cabinet is responsible for, and accountable for, making Regulations). Nevertheless, all Table members have agreed to support the consensus recommendations as a package. Government representatives in particular have undertaken to do their best to ensure that consensus recommendations will be reflected in any ensuing changes to the NSN Regulations and NS Program. Where this may not occur, Environment Canada and Health Canada representatives will report back to all Table participants any deviations from the consensus and the reasons therefor.

During its deliberations, the NSN Table considered information available in the public domain as well as information provided or generated by Table members, consultants or experts invited to attend specific sessions. Key documents used by the Table are referenced in the Endnotes (see Section 4) and in Appendix A.3 of this report. A list of acronyms and definitions for technical and commercial terms used in this report are included in Appendix A.4. The remaining appendices are as follows: A.5 — Description of the "New Substances" Industry Sector in Canada; A.6 — Proposed Requirements for Non–Good Laboratory Practice (GLP) Studies; A.7 — Additional Information on the Assessment of Degradation Products; and A.8 — Test Criteria for the Sunrise Approach.

## 2.3 Guiding Principles of the NSN Table Deliberations

The NSN Table members agreed that there are certain fundamental principles that the NSN Regulations and NS Program must incorporate and that, consequently, must always be weighed by the Table in developing its recommendations. The expectation of the Table members is that the NSN Regulations and NS Program will:

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

The main focus of these consultations was on developing recommended amendments to the NSN Regulations and NS Program. However, it was necessary to set some boundaries on the scope of the consultations. These were discussed and agreed to at the first and second meetings. Table 2.1 describes the boundaries for the scope of the consultations on the NSN Regulations and NS Program set by the Table.

## Table 2.1: Boundaries for the Amendments to the NSN Regulations Consultation Process

| Issue | INCLUDED in Consultation Process | EXCLUDED from Consultation Process |
|---|---|---|
| **CEPA** | • Minor technical amendments may be possible<br>• Applications of principles in CEPA to the NSN Regulations | • CEPA and authorities in general |
| **Substance Types** | • Chemicals and biochemicals (inanimate)<br>• Polymers and biopolymers (inanimate) | • Animate products of biotechnology |
| **NSN Regulations** | Anything relevant to above substance types, including:<br>• information and administration requirements<br>• schedule and composition<br>• assessment periods<br>• volumes and triggers<br>• handling of polymers (high/low concern)<br>• transitional substances<br>• definitions | • Portions of the Regulations relating to animate products of biotechnology |
| **Policy** | • GLP and conducting tests<br>• Toxic Substances Management Policy (TSMP) relating to data requirements<br>• Endocrine disrupting chemicals relating to data requirements | • Precautionary principle<br>• TSMP in general<br>• Persistence, bioaccumulation and inherent toxicity: Inherent toxicity |
| **Assessment Methods** | • Quantitative structure–activity relationships (QSARs), surrogate data<br>• Guidance manual (transparency) | |
| **Program Efficiencies and Issues** | • Program processes and operations<br>• NDSL<br>• Publication of information<br>• Flagging DSL substances<br>• Minor organizational changes | • Major organizational changes<br>• Cost recovery |
| **Mutual Acceptance of Notifications (MAN)** | • MAN relating to Program efficiencies and CEPA authorities if related to NSN Regulations amendments | • Government policy on international initiatives (e.g., Organisation for Economic Co-operation and Development [OECD]) |

# 3. Themes and Issues

The focus of this report and the extensive deliberations of the NSN Table in developing recommendations for improving the NSN Regulations and the NS Program are captured in this section. The Table organized its deliberations into five themes with several related issues. The remainder of this section provides a brief description of each theme and associated issues and details the deliberations and recommendations of the Table with respect to those issues.

## 3.1 Improving the Environmental and Health Assessments for New Substances

### *3.1.1 Principles and Policies Affecting the Assessment and Management of New Substances*

The Table identified a number of principles and policies that could have a bearing on discussions about improving the environmental and human health assessments of new substances. These include the pollution prevention principle, the precautionary principle and the TSMP.[5]

#### (i) Pollution Prevention

Section 3 of CEPA defines pollution prevention as "the use of processes, practices, materials, products, substances or energy that avoid or minimize the creation of pollution and waste and reduce the overall risk to the environment or human health."

##### Table Deliberations

There was agreement that the purpose of the NS Program is to prevent pollution by assessing and responding to toxic substances very early in the substances' life cycles. As such, pollution prevention is a fundamental tenet of the NS Program. The intent is to ensure that no new substance is introduced into the Canadian marketplace before proponents provide an adequate set of data and an objective assessment of its potential environmental and human health risk is made. Substances suspected of being "toxic," as interpreted in CEPA (see section 84(1), "suspicion of toxic"), can be subject to controls authorized under the Act.

While this represents one view of pollution prevention in the context of CEPA, experience from the United States, which includes consideration of the comparative benefits of substances, provides a broader perspective of pollution prevention. The U.S. Environmental Protection Agency (EPA) has the option of considering whether a new substance presents a reduced risk compared with an existing chemical used in the same, or a similar, application. In the context of the NS Program and CEPA, currently there is no obligation to carry out such a review following notification. However, for substances where there is a "suspicion of toxic," there is adequate opportunity for notifiers to provide additional information about the substance to Health Canada and Environment Canada. The departments then use this information to develop appropriate controls for that substance.

Pollution prevention planning as authorized in Part 4 of CEPA was briefly discussed but was not considered directly relevant to the NS Program.

##### Table Recommendations

None.

#### (ii) The Precautionary Principle

CEPA has several references to the precautionary principle, including the preamble, which states the government's commitment to "implementing the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." In addition, the precautionary principle is referenced in the Administrative Duties section and in section 76(1), where assessments or reviews conducted in specific sections of Part V pertaining to existing substances (Control of Toxics) must apply the precautionary principle.

There is evidence that the principle is applied to a considerable extent within the NS Program. Environment Canada and Health Canada are empowered to make decisions to impose controls based on "suspicion of toxic" rather than on a determination of "toxic" as defined in section 64. For a discussion of additional

regulatory actions that may be taken upon establishing a "suspicion of toxicity," the reader should refer to Section 3.1.3. Acting on a "suspicion of toxic" reflects the reality that for new substances, the amount of evidence may be considerably less than that used to assess existing substances. This is particularly true with respect to exposure-related information, which, for the majority of new substances, is based on intended use and location, details of containment and waste processing, knowledge of existing and similar substances, generic scenarios and conservative assumptions of exposure. Professionals from both departments look for evidence of serious and irreversible damage among all the data reported with the notification, from in-house data sources, including other similar notifications, from predictive tools and from contacts with colleagues in other jurisdictions, where this may be warranted. Assessment methodologies take a conservative approach using predictive scenarios and uncertainty factors and reach a conclusion based on available evidence.

Where the evidence compiled during the assessment is reasonably suggestive of significant risk, CEPA provides the authority to act decisively with the notifying company (e.g., prohibition of or conditions on use, processing, handling). Where such action is taken, substances will not be added to the DSL, and, as a consequence, no other company can import or manufacture the substance without complying with the NSN Regulations. In the face of cost-effective controls, notifiers have the option of generating and providing additional information.

With its adoption at the 1992 Earth Summit in Rio de Janeiro, the precautionary principle has implications for all toxic substances programs, including new substances programs. A consequence of this is a mushrooming dialogue on the interpretation and application of the principle within the Canadian federal government (within and between departments) and other national governments and international organizations. Other stakeholders are also discussing and documenting their views.

### Table Deliberations

The Table acknowledges that the application of this important principle to new substances may be impacted by the broader discussions noted above.

The Table agrees that Environment Canada and Health Canada are often successful in applying the precautionary principle as described above; however, Table members remain concerned about the predictive capabilities of the current data set for certain types of assessments, e.g., when effects occur at very low levels. Endocrine disrupting substances (EDSs) were cited as an example and represent effects that are further complicated by the absence of adequate testing methodology for the foreseeable future (discussed in Section 3.1.4).

### Table Recommendations

None.

## (iii) Toxic Substances Management Policy (TSMP)

The TSMP is a policy of the federal government that "provides a framework for making science-based decisions on the effective management of toxic substances that are of concern because they are or may be used and released into the environment or because Canadians may be exposed to them through the environment."[6]

The policy has two key management objectives that distinguish between Track I substances, which are to be "virtually eliminated from the environment," and Track II substances, which are to be managed throughout their entire life cycles to prevent or minimize their release to the environment. The applicability of the policy to existing toxic substances is quite clear, and an implementation strategy has been made publicly available on Environment Canada's web site. The substantive content of the TSMP has been incorporated into CEPA, Part 5.

### Table Deliberations

Discussion of the Table indicated a need to clarify whether the TSMP applies to new substances where there is a suspicion of toxicity and, if so, how it ought to be applied. The following documentation was made available to the Table: *Toxic Substances Management Policy — Environment Canada Implementation Strategy for New Substances* (Draft, April 2001).[7]

There was general agreement that the TSMP addressed the management of new substances at the stage found in section 84 of CEPA (i.e., Action following Assessment). Decisions taken under the NS Program were considered supportive of the TSMP, since prohibitions constitute an equivalent to "virtual elimination" and imposing conditions constitutes an equivalent to "life cycle management." However, some Table members felt that further clarification was necessary about the meaning of virtual elimination and the impact it has on the selection of control actions.

Discussions about the four criteria used in the TSMP to distinguish Track I substances from Track II substances confirmed that all new substances meet the criterion for "predominantly anthropogenic." Also, for the most part, the criteria cut-offs for persistence and bioaccumulation are dictated by the TSMP and the Regulations and cannot be adjusted for new substances purposes.

The criterion causing the greatest difficulty for interpretation was "CEPA-toxic or equivalent," and the Table discussed various aspects of the issue in order to offer clarification. It was noted that the TSMP is silent on new substances but makes reference to substances that "may be used or released." This is inclusive text that suggests the TSMP should apply to new substances. CEPA is less clear. The Table noted that within the "Substances and Activities New to Canada" portion of the Act, section 84 authorizes the Ministers to take action, including prohibition, on the basis of a suspicion of toxic. A prohibition remains in force for up to two years to enable time to put a Regulation in place under section 93. On the other hand, to access section 93, an order has to be made by the Governor in Council adding the substance to the List of Toxic Substances. This triggers a process outside the new substances provisions that is aimed at confirming the recommendation of the Ministers to continue the prohibition and extend it to all companies. This potentially signifies a distinction between "toxic" and a "suspicion of toxic." The information-gathering authorities under sections 71 and 72 offer a similar distinction.

### Table Recommendation

1. Points of clarification should be summarized and included in the document *Toxic Substances Management Policy — Environment Canada Implementation Strategy for New Substances* (Draft, April 2001). This draft document should then be finalized and made public.

## *3.1.2 Adequacy of the Risk Assessment Methodology*

The Table addressed whether the assessment methodology and process employed by Environment Canada and Health Canada are adequate to protect the environment and human health.

Currently, Health Canada and Environment Canada use a semiquantitative risk assessment methodology that they have developed to estimate whether a new substance has the potential to cause harm to human health or the environment. The human health risk assessment of new substances is conducted by Health Canada. The environmental risk assessment is conducted by Environment Canada. As a generalization, the risk assessment process used by both departments attempts to predict the risk based on an examination of the available data and information on hazard or effects and estimates of exposure. Once the risk assessment is completed and a decision is made to intervene, risk management processes are then used. Quantitative risk assessment assumes that the risk of harm is a function of the hazard (conducted by Health Canada) or the effects (conducted by Environment Canada) potential of a substance and the estimated exposure of humans to the substance or its concentration in various environmental media. Both departments draw on the knowledge of many scientific disciplines, supplemented by professional judgement, in the process of estimating risk.

## Table Deliberations

Table members discussed several of the aspects of the current risk assessment methodologies in an attempt to arrive at some agreement relating to their adequacy for protecting human health and the environment. A primary focus of the discussions involved the accuracy/reliability of the information and data used to assess the hazard and the exposure potential of a new substance. Table members generally agree that the scientific disciplines that are brought to bear in characterizing risk are qualified by uncertainties due to theoretical and practical limitations in scientific knowledge, data collection and interpretation, modelling protocols, and the selection and interpretation of analytical methodologies. Many aspects of the risk assessment process require the exercise of judgement, upon which various segments of society can have equally legitimate but differing perspectives. Compounding assessment uncertainties are limitations in scientific understanding of interactions within and between ecosystems, levels of human and environmental exposure to specific chemicals, the potential for transgenerational impacts, and determining the extent and significance of interactions among substances that are released into the environment. For example, "intended use" and "volume" information is used by the regulators to predict the eventual concentrations of a new substance in the environment. There is a significant degree of uncertainty associated with this information. This is in part due to the fact that a "new substance" has not yet entered into the Canadian environment in significant quantities, thus necessitating that levels in the air, water, food or soil be predicted rather than monitored directly.

Currently, this uncertainty is dealt with, in part, by building "uncertainty factors" into the hazard assessment and conservative assumptions into the exposure assessment. The Table discussed several approaches to reduce the potential that an inaccurate exposure prediction would be of such magnitude as to cause the risk assessment to be erroneous. Discussions focused on "weighting" the information used in the risk assessment so that exposure information is given less weight than the more "fact-based" information relating to the hazard/effects assessment. One such alternative approach that was explored was based upon the former Accelerated Reduction/Elimination of Toxics (ARET) process.[8] ARET was established in the early 1990s as an approach to the selection of higher-priority substances for industry to reduce or eliminate their use in Canada without first going through a resource-intensive, comprehensive risk assessment process, as is done under CEPA with the Priority Substances List (PSL). In this ARET-based approach, criteria would be established to prioritize substances for reduction/elimination based on their toxicity, bioaccumulation/bioconcentration and persistence potential. Substances were categorized based on a scoring process for six criteria (acute lethality, chronic/subchronic toxicity [non-mammals], chronic/subchronic toxicity [plants], chronic/subchronic toxicity [mammals], teratogenicity and carcinogenicity). A highest score on any one toxicity element was used as a basis for inclusion in the ARET process, independent of other toxicological properties.

The Table members could not come to agreement on whether a "weighted" process could be used instead of the current semiquantitative risk assessment process to determine whether or not a new substance should be controlled prior to first import into or manufacture in Canada. The unresolved Table discussions relating to developing a proposed weighting scheme that would meet the needs of all Table members reflect broader philosophical differences among the Table members concerning the adequacy of the current risk assessment methodologies.

Table members agree that future use and exposure data requested in NSNs (see Section 3.1.6) should include information regarding alternative uses possible for the notified substance, as well as identification of any "old" substance(s) being replaced by the new substance. This information provides regulators with an improved opportunity to predict both future use patterns and potential future chemical use volumes of the new substance. Based on this discussion, a submission template inspired by that used by the U.S. EPA, but incorporating these additional data elements, has been developed and is being tested by some industry representatives.

## PAG Position on the Adequacy of Current Risk Assessment Methodologies

PAG representatives oppose the current techniques of quantitative risk assessment. In the view of the PAG representatives, most of the scientific disciplines that are brought to bear in characterizing risk are qualified by substantial uncertainties due to theoretical and practical limitations in scientific knowledge, data collection and interpretation, modelling protocols, and the selection and interpretation of analytical methodologies. They feel that many aspects of the risk assessment process require the exercise of subjective human value judgement, upon which various segments of society can have equally legitimate but differing perspectives. Compounding these uncertainties are difficulties in understanding the complex web of interactions within and among ecosystems, in determining levels of human and environmental exposure to specific chemicals, and in determining the significance of, and effective management options for, interactions among substances that are released into the environment. Formalized risk assessment too often skirts complex ethical issues surrounding transgenerational impacts for certain substances, the inability of many individuals to understand and voluntarily assume risks associated with exposures to certain substances, and the inequitable distribution of risks and benefits associated with the manufacture and use of a new substance. Contrary to what is described in Section 3.1.1(ii), the PAG believe that the current risk assessment approach fails to adopt a precautionary principle in cases where scientific evidence is inconclusive or incomplete.

PAG representatives proposed, as an alternative to the current risk assessment process, a "Sunrise" protocol, which is described in greater detail in Section 3.2.1 and Appendix A.8. One possible application of the Sunrise protocol could involve a scoring system (similar to that used by ARET) whereby each data element would be "weighted" by a certain number of points, the total of which, exceeding a threshold, would trigger regulatory action. In this way, an error in any one (or even a few) piece(s) of data would not be absolutely fatal to the decision-making, and hence the regulatory, process. The Sunrise protocol utilizes a precautionary and preventative approach and in so doing reflects the advances made in scientific understanding of environmental contaminants in a socially responsible manner. PAG representatives do not believe that sections 64 and 84(1) of CEPA'99 preclude the adoption of some version of the proposed weighting scheme, as it meets the requirements and definition of a formalized, quantitative risk assessment process.

## The Government and Industry Views on the Adequacy of Current Risk Assessment Methodologies

Government and industry representatives both support the continuing use of the current procedures utilized in the risk assessment of new substances. Government representatives interpreted that CEPA'99 legally mandates a formalized, quantitative risk assessment process that requires an analysis of prescribed information to assess both the potential hazard/effects and the exposure to a new substance. They believe that the methodology and premises utilized are generally consistent with those utilized by similar regulatory agencies in Canada and abroad. As described in Section 3.1.1, government and industry share the view that the precautionary principle is applied in the NS Program based on government's ability to take action on a suspicion of toxicity prior to obtaining scientific certainty.

Government and industry representatives recognize that scientific uncertainty is a significant, variable and ongoing reality in the risk assessment process, but prefer to focus on improving the reliability of the current assessment process rather than developing a different assessment scheme. Given that quantitative risk assessment processes are used by most jurisdictions around the world to assess risks associated with new and existing substances, a great deal of coordinated global scientific research is aimed at improving the underlying knowledge base and specific principles, policies and practices associated with risk assessment as a tool for evaluating chemical safety. The existing risk assessment process can be improved by developing improved modelling tools, as well as by requesting additional information to supplement the use/exposure information currently supplied for new substances.

### *3.1.3 Mechanism for Requiring Additional Information for the Risk Assessment*

#### Background/Context

In the new substances scheme laid out in CEPA'99, the normal means for identifying and requesting information from companies is through the NSN Regulations. The prescribed data requirements of these Regulations are intended to provide the information needed by government scientists to enable them to recommend scientifically sound decisions to their Ministers. Following assessment, CEPA'99 provides regulators with the authority, under section 84, to take a number of actions following the determination of a "suspicion of toxic," including requests for further information.

As predictable as this approach appears, the Table identified certain purposes for which it could be inadequate and inefficient. For example, PAG and industry representatives expressed the opinion that government regulators should have a clear authority upon which to base requests for additional data when a suspicion of toxicity arises and the available information is insufficient to adequately characterize the risk(s). The PAG members felt that this authority was important in the protection of human health and the environment; for instance, it would allow government to request, among other data, (sub)chronic tests not currently in the Regulations, but for which scientific justification could be made, since they bear on the department's ability to assess the long-term effects from a substance. Industry believed that this authority should be used as an alternative to prescribing, in the Regulations' schedules of information, those studies that have applicability to a narrower group of substances, thereby avoiding a costly, broad-brush approach being applied to all substances. Government expressed its preference for a system whereby a predictable set of data (i.e., including longer-term toxicity) would be obtained through the schedules, waivers could be used to "subtract" unnecessary information on a case-by-case basis and, in addition, regulators would have the ability to request additional data on a more select basis.

The Table was unable to identify any provisions outside of section 84(1)(c) that granted government the authority to require additional data of the type envisaged by the perspectives above. For that reason, the Table focused on this section and its legal interpretations to determine whether it represented a means of addressing their needs. Sections 84(1) and 84(2) are stated as follows:

84(1) Where the Ministers have assessed any information under section 83 and they suspect that a substance is toxic or capable of becoming toxic, the Minister may, before the expiry of the period for assessing the information,

(a) permit any person to manufacture or import the substance, subject to any conditions the Ministers may specify;

(b) prohibit any person from manufacturing or importing the substance; or

(c) request any person to provide any additional information or submit the results of any testing that the Ministers consider necessary for the purpose of assessing whether the substance is toxic or capable of becoming toxic.

84(2) Where the Minister requests additional information or test results under paragraph (1)(c), the person to whom the request is directed shall not manufacture or import the substance unless

(a) the person provides the additional information or submits the test results; and

(b) the period for assessing information under section 83 has expired or a period of 90 days after the additional information or test results were provided has expired, whichever is later.

Since its inception, the NS Program has used section 84(1)(c) to request additional testing on only one occasion, in part due to the fact that, in the face of a decision of "suspicion of toxic" and possible control / prohibition measures, notifiers typically request that the assessment period be paused while they obtain scientific information that could influence this outcome.

## Table Deliberations

When discussing section 84(1)(c) in the context of new substances provisions, Table members agreed that a threshold of "suspicion of toxic" has to be met in order to access this authority. However, it became apparent that there could be a range of interpretations about the knowledge needed to meet this threshold and the role that the requested information should play in decision-making. At one end of the spectrum, "suspicion of toxic" was viewed as a common threshold that would need to be met equally in order to access any one of the three authorities referenced in sections 84(1)(a), 84(1)(b) and 84(1)(c). In other words, the same degree of "suspicion" would be required in order to support decisions for each of a condition, prohibition and request for further information. Accordingly, section 84(1)(c) would be invoked only where there was already enough scientific evidence available to warrant that one or both of the other two measures (condition / prohibition) be taken. Some degree of toxicity would need to have already been established, and the assessment of further information would be meant to verify the degree of toxicity and therefore the degree of control that should be imposed.

At the other end of the spectrum, section 84(1)(c) was viewed as a mechanism that would be used when the available information was not considered sufficient to adequately characterize the risk(s) associated with the substance, but the information was sufficient to suggest that there may be a hazard and the possibility of exposure could not be ruled out. In these cases, there would be concern regarding the substance based on its inherent attributes (structure, physicochemical properties, toxicological effects), which, together with the possibility for exposure, could present a risk.

The application of section 84 being proposed by the Table more closely resembles the latter of these two interpretations, yet emphasizes precautionary measures to an even greater degree. According to this proposal, section 84 could be used, for example, to require tests additional to those found in the Regulations or to require that regulatory tests be conducted at lower-volume triggers. Examples of circumstances under which these actions may be warranted could be the presence of enough data to raise a suspicion of toxicity, but insufficient information to adequately characterize the substance, or the presence of structural features associated with adverse effects, combined with the possibility of exposure. It is important to note that, in keeping with this more liberal characterization of suspicion of toxicity in section 84, a substance may no longer be suspected to be toxic after the assessment of follow-up data.

It is acknowledged that section 84 was not designed for the purpose of routinely requiring information in cases where the Regulations do not sufficiently address the evaluators' general interests. Rather, it is a mechanism that needs to be operable when they have a suspicion of toxicity. In order to better address the Table's concerns and provide heightened legal clarity, the recommendation to amend CEPA to incorporate information-gathering authorities of the type discussed above is envisaged as the ultimate goal. However, recognizing the length of time required to attain this objective, Table members felt that broadening the interpretation of section 84(1)(c) would provide a workable alternative.

The Table is interested in ensuring that the proposed interpretation of "suspicion of toxicity" is consistently and predictably applied. Although it must allow evaluators the flexibility to selectively decide when additional tests are needed in connection with a suspicion of toxicity, the criteria upon which these decisions are based should be consistent and transparent. In other words, the interpretation of section 84(1)(c) should not be left to the discretion of each individual evaluator. It is not the intent of the Table to in any way erode or compromise the authority that is already exercised by government under section 84. In developing the new interpretation, government should satisfactorily address possible negative impacts that could be had upon the integrity of the threshold for "suspicion of toxic" findings that will continue to be used in support of decisions to impose conditions on or prohibit substances.

The Table emphasizes that the ability of Environment Canada and Health Canada to utilize section 84 in this manner will be crucial to the successful implementation of the main recommendations in this report. The development of a clear government guidance document that will facilitate this mechanism, therefore, must be given highest priority.

Table Recommendations

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.

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.

### *3.1.4 Endocrine Disrupting Substances (EDSs)*

#### Background

The endocrine system consists of the ovaries, testes, breasts, pancreas, hypothalamus and the pituitary, adrenal and thyroid glands. The endocrine organs and glands secrete hormones, such as estrogen, testosterone and thyroxin, that act as chemical messengers of instructions for neural development, growth, sexual differentiation, the development of the immune system, sperm production and ovulation and regulate most other components of metabolism and growth. Because distantly related groups like reptiles, insects, birds, humans and other mammals share some similar endocrine systems, including hormones, receptors and similar biological responses, effects observed in one species may convey important information with respect to potential impacts on another species.

Over the past few years, a growing body of scientific evidence has indicated that certain drugs, pesticides, industrial chemicals and natural compounds can alter the normal function of endocrine systems. Effects such as eggshell thinning in raptor birds, possibly mediated through disruption of normal endocrine function, have been observed in wildlife species due to exposure to certain organochlorine compounds. Data from laboratory experiments suggest that many substances may cause adverse biological effects at much lower levels than were previously considered to present minimal risk to the environment and humans. Examples of effects from low-level exposures include adverse effects on development and reproduction of aquatic life resulting from exposure to tributyltin, feminization of fish exposed to municipal effluents and depressed immune and thyroid function in fish-eating birds. Some epidemiological evidence suggests a potential for effects in humans from environmental exposure.

There is considerable scientific debate as to whether ambient environmental concentrations of certain substances are sufficiently high to exert adverse effects on the general population. There is disagreement over the occurrence of adverse effects resulting from low-level exposures to purported EDSs that may produce minor changes in hormone levels, receptor levels or both. In particular, scientific inquiry has been focused on:

- what classes of chemicals may affect the endocrine system;
- how much exposure to these chemicals it takes to produce adverse effects;
- how humans and wildlife are exposed;
- the combined effects of exposure to multiple EDSs; and
- the effects that are actually occurring among exposed humans and wildlife.

The Table viewed endocrine disruption as an important facet for assessment and decision-making about new substances because it identifies a chronic endpoint that is more sensitive than endpoints currently considered in the assessment process. It is recognized that endocrine disruption is a mechanism, not a single (toxicological) endpoint, and that attention should focus on development and growth during critical life stages rather than on mechanisms such as receptor-mediated responses.

At this time, there are no internationally accepted, validated screening methods that can be used consistently to test whether a new substance disrupts the endocrine system.

Although no OECD test methods are specifically designed to detect alterations in normal endocrine function, a substance with significant hormone-disrupting activity causing adverse effects may be manifested in certain existing mammalian tests. For example, the current OECD test guideline for the 28-day repeated-dose test (OECD Test Guideline 407 [9]) requires examination of organs associated with endocrine activity. Significant toxicity observed in these tissues may indicate alterations of normal hormone function. However, current experimental design is unlikely to detect subtle effects.

Enhancements to OECD Test Guideline 407, intended to increase the sensitivity of the test to endocrine disrupting activity, are undergoing international validation under the OECD Test Guideline Program. Enhancements may include an increase in the number of organ / tissue (e.g., prostate, ovaries, thyroid) weights measured, histopathology on an increased number of tissues (e.g., pituitary, ovaries and mammary gland), measurements of thyroid hormones and an examination of sperm morphology.

Currently, there are no ecotoxicity tests in the Regulations that address endocrine disrupting potential. While there is concern about endocrine disrupting potential and the need to flag potential EDSs in assessments, until scientific tools are validated and found applicable in regulatory programs, endocrine effects cannot be directly addressed. Environment Canada is examining the feasibility of collecting information on substances suspected of eliciting endocrine disruption effects and how information on such analogues can be incorporated into its regulatory programs. The applicability of structure–activity relationships (SARs) or analogues to identify substances will be investigated as they become available. These tools are not yet appropriate for application to regulatory programs for EDSs.

Section 44(4) of CEPA imposes a legal obligation on the Ministers of Health and Environment to "conduct research or studies relating to hormone disrupting substances, methods relating to their detection, methods to determine their actual or likely short-term or long-term effect on the environment and human health, and preventative, control and abatement measures to deal with those substances to protect the environment and human health." To this end, Canada is involved in the examination and validation of test methods currently being conducted by the U.S. EPA and OECD to address endocrine disrupting potential. In partnership with Health Canada, Environment Canada manages the Toxic Substances Research Initiative, which includes support for research on EDSs. Projects currently funded include analyzing EDSs in municipal sewage effluents, determining the effects of pesticides on terrestrial and aquatic wildlife and investigating effects of endocrine disruption on fish reproduction. In addition, Environment Canada has included research on EDSs in each of the major Regional Ecosystem Initiatives and has established a national multidisciplinary research program in collaboration with other government agencies, universities and industry. Similarly, multidisciplinary research into endocrine disrupting potential in Health Canada cuts across many branches of government. Staff of the NS Program actively keeps abreast of current research activities and is involved in the development of some research projects.

Environment Canada and Health Canada regulators are of the view that the scientific screens and tests proposed for assessing endocrine disrupting potential are not yet ready for legally mandated, routine use in regulatory programs. Substantial test development has been conducted; however, validation of appropriate tests continues. Many of the tests proposed for the screening program have been used in research, but have never been formally standardized or validated through interlaboratory comparisons for the purposes of screening for endocrine disrupting potential. Standardization and validation are necessary to establish the relevance, reliability and reproducibility of methods.

In February 2000, the Canadian Natural Resource Departments Endocrine Disrupting Substances (5-NR EDS) Working Group hosted a multistakeholder workshop to address the emerging issues associated with the scientific assessment of EDSs in the Canadian environment. The workshop identified knowledge gaps and research needs that are specific to meeting the needs of scientists and regulators.[10]

The development of screening and test methodology is recognized as an important research and policy area both within Canada and internationally. Substantial efforts are currently under way in other countries to develop and validate screening and testing methods for EDSs. For example:

- The U.S. EPA held a meeting in June 2000 to identify and set priorities for evaluating chemicals. Substances will be categorized based on such information as environmental release, receptor binding or the frequency with which a chemical is found in environmental media. In 2002, the U.S. EPA anticipates having mammalian tests validated and internationally accepted, with ecotoxicity tests following in 2005.
- The OECD, in which Canada is an active partner, has also initiated a program to harmonize testing and screening of EDSs. The OECD Task Force on Endocrine Disrupter Testing and Assessment (EDTA), which includes scientists from Health Canada and Environment Canada, is currently reviewing three screening tests for mammalian effects. These are the Hershberger Assay, the Uterotrophic Assay and the Repeated-Dose Oral Toxicity Test. A committee is also being created to address ecotoxicity tests.

The following table is an excerpt from the OECD Draft Workplan 2000–2001 and gives target dates for completion of development and validation of specific tests.

- In March 2000, a meeting of the OECD Expert Consultation on endocrine disrupter testing in fish took place in Tokyo. With respect to the assessment of endocrine disrupters in wildlife, the Task Force reviewed currently available screening and testing methods for non-mammalian species and identified areas for further research. It was generally recognized that the development of methods for the detection of endocrine disrupting effects on wildlife is in the preliminary stages (i.e., defining endpoints and test approaches) and that additional research into non-mammalian endocrinology is needed to assist in selecting the most appropriate endpoints for endocrine disruption in fish and other taxa.

Once valid test methods have been identified, it is likely that further research will need to be conducted to determine critical life stages of organisms.

### Table 3.0: Target Dates for Completion of Development and Validation of Specific Tests

(Excerpt from the OECD Draft Workplan 2000 - 2001)

| Project Title | Start Date | Expected Date of Submission to WNT* for Approval |
|---|---|---|
| Development and Validation of the Hershberger Assay | March 1998 | 2003 |
| Fish-Screening Test | 1998 | 2004–2005 |
| Development and Validation of Methods in Amphibians | Late 2000 | 2003–2004 |
| Development and Validation of the Uterotrophic Assay | March 1998 | 2002 |
| OECD Test Guideline 407 | Under validation | Not yet determined |

* National Coordinators for OECD Test Guidelines Program.

## Table Deliberations

The essence of the Table deliberations revolved around the extent to which screens and tests for assessing the endocrine disrupting potential of a new substance could be included in the NSN Regulations and NS Program and, if so, whether or not those current screens and tests should be regulatory requirements.

Table members agree and recommend that as soon as internationally accepted, validated screening and testing protocols become available, they should be incorporated into the NS Program by the most appropriate means (Regulations or Guidelines). The tests have to be suitable for a new substances regulatory system. Given the international cooperation on the development of the science in this area, these tests should be agreed to internationally as required for testing new substances (e.g., OECD). Under the present regulations, notifiers submitting substances identified as having endocrine disruptive potential can be requested to conduct additional testing deemed appropriate in alleviating any concerns, on a case-by-case basis.

The difficulty for the Table involved the extent to which the revised NSN Regulations and/or NS Program should deal with EDSs until validated screening methodologies have been accepted. Options the Table discussed included:

- screening new substances for endocrine disruptive potential through the application of the U.S. EPA Tier 1 and Tier 2 models;
- waiting until tests have been validated and internationally accepted (e.g., OECD). Such tests should be appropriate for use in a new substances context, including reasonable cost and time frame for completion. The rationale for this option is that if the tests are not validated, the results cannot be used by regulators in a reliable and predictable manner. It is inappropriate to conduct unvalidated studies for "routine" regulatory purposes. Moreover, there is the view that *in vitro* receptor-binding assays and SAR models currently under discussion in the scientific community to delineate endocrine-active effects are insufficient to determine adverse effects necessary for risk assessment; and
- not requiring testing for endocrine disrupting potential in the NSN Regulations but informing notifiers through the Guidelines that for notifications of certain classes of substance where there is reason to look for endocrine disrupting potential, notifiers may be asked to provide additional test data.

All Table members recognize that the views articulated above are legitimate and worthy of consideration by the regulators. However, members also recognize that the opposing views do not assist the regulators in moving this complex and sensitive issue forward. Therefore, in the spirit of the Table's mandate to develop consensus recommendations wherever possible, and following a great deal of debate, the Table agrees to and recommends the following process for dealing with screening and testing protocols to assess new substances for endocrine disrupting potential.

## Table Recommendations

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.

5. As internationally accepted, validated screening and testing protocols become available that are suitable for a new substances regulatory system, they should be incorporated into the NS Program by the most appropriate means (Regulations or Guidelines). It is noted that the initial availability of the current projected schedule of validated tests (2002–2005) is consistent with the timing for promulgating amendments to the NSN Regulations.

6. The NSN Guidelines Document[11] 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 SARs become accessible, they will be used appropriately in the assessment process. Furthermore, where this information leads to a suspicion of toxicity, appropriate control measures will be imposed, or requests for further test data under section 84(1)(c) of CEPA will be made as validated test procedures are determined. Lastly, the section on endocrine disruption will inform stakeholders of the intent to amend the NS Program (Regulations or Guidelines) to include data requirements for determining endocrine disrupting potential as they become available.

### *3.1.5 Occupational Exposure*

The Table addressed the question of whether the scope of the human health assessment should be expanded within the limits of the NSN Regulations to address worker health and, if not, whether the NS Program can do more to promote worker safety.

Under the NSN Regulations, the notifier must submit all available information, including exposure and hazard information, when this information is available. This includes information on adverse effects (i.e., hazards), or possible adverse effects, in persons exposed to the substance in the workplace. Health Canada uses this information as part of the risk assessment, but this risk assessment is done for the general population and is not specific to the workplace setting. Risk in the occupational environment would not trigger action under CEPA, since Health Canada does not have the authority under this Act to specify workplace controls.

Information on occupational hazards received by Health Canada under the NS Program is not automatically shared at this time, although attempts to establish mechanisms have occurred in the past. No mechanism to facilitate the transfer of this information is employed, even between federal departments.

There are jurisdictional concerns that have been voiced regarding the lack of appropriate coordination of federal/provincial/territorial efforts germane to this process. The management of hazardous substances is the jurisdictional responsibility of other authorities in many cases.

#### Table Deliberations

Several issues were identified that point to opportunities to improve the way in which occupational exposure information is managed within Health Canada and the way in which these data are transferred between departments or other agencies. The current process should be more proactive in ensuring that occupational health information is actively provided to those agencies that may need to act in order to ensure adequate protection of worker health.

#### Table Recommendations

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.
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.
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.

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.
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.)
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.
13. Health Canada should facilitate a multistakeholder consultation in relation to new substances in the occupational environment. Among other things, this consultation should identify ways in which:
    - new substances notified under the NSN Regulations will be assessed for risks associated with the occupational environment; and
    - a process for the identification of preventative and control measures can be implemented by the responsible agencies.

### *3.1.6 Data Requirements*

#### (i) Suite of Data Requirements for Chemicals and Polymers

**Background**

The NSN Regulations contain prescribed information elements for new chemical and polymeric substances submitted to the NS Program. Part of the mandate of the Table was to review the existing regulatory information elements and propose changes that will optimize the use of scientific information in the risk assessment carried out on substances new to Canada while maintaining or improving protection of the environment and human health.

To facilitate this discussion, the Table used the concept of a data "toolbox" to describe the entire suite of tests used to determine the identity, physical/chemical and toxicological data elements that are normally used in conducting risk assessments. To the extent possible, tests that are recommended for inclusion in the NSN Regulations should follow internationally accepted test protocols (e.g., OECD, American Society of Testing and Materials [ASTM]) and the Principles of GLP (see Section 3.1.6(iv)). Some tests described in the Guidelines to the NSN Regulations may not have internationally accepted protocols; therefore, acceptable protocols will need to be outlined in the Guidelines.

The Guidelines to the NSN Regulations will be used to describe test requirements in the "toolbox" that are not required in the Regulations, but may be requested by the Minister under certain circumstances. The Guidelines also provide guidance on when a notifier may want to submit a test or the circumstances under which an evaluator is likely to request a test. It became clear to Table members that the Guidelines play a critical role in enabling evaluators to request information that they feel is needed to make a thorough risk assessment, without requiring this information to be submitted in every circumstance.

Although the items in the "toolbox" are intended to cover the information needed to assess the vast majority of substances, the program would not be limited to these data, as CEPA allows the Ministers to request *any* additional data they consider necessary for assessing the substance following the finding of a "suspicion of toxic" (refer to sections 84(1)(c) and 84(2) of CEPA).

The information contained in the "toolbox" includes data relevant to assessing

- identity;
- environmental fate;

- persistence;
- bioaccumulation;
- intrinsic toxicity; and
- exposure.

The exposure assessment of a substance includes the evaluation of the overall environmental persistence of a substance and its degradation products. In the context of the NS Program, biodegradation and hydrolysis are key elements in determining the residence time of a substance in various environmental media (air, water, soil and sediment). However, depending upon the circumstances, other degradation / disposal processes may be considered, such as photodegradation, thermolysis and incineration.

The biodegradation / hydrolysis half-lives of a substance are evaluated using experimental, surrogate or predicted data. Substances with shorter half-lives and not released on a continuous basis may not reside in a medium for a sufficient period of time to allow for chronic exposure of organisms. However, biotic and hydrolytic degradation products are considered on an equal basis with the parent compound during the assessment, in order to determine the long-term potential toxicity of the breakdown products, as well as the potential toxicity of the parent compound. In general, these breakdown products tend to be less toxic, more water-soluble and, hence, more bioavailable to organisms; however, in some circumstances, degradation products possess greater toxicity than the parent compound.

In cases where data (ultraviolet / visible absorption spectrum) or the presence of certain functional groups (e.g., polycyclic aromatic hydrocarbons, nitroaromatics, aromatic amines, azo) suggests that photodegradation is occurring, the potential physical / chemical properties and ecotoxicity of the degradation product(s) will be examined further. In addition, depending on the type of substance (e.g., ethers, halogenated aromatics), volatilization during incineration may occur. Incinerators are subject to provincial / territorial regulations and have to follow regulatory requirements, including recommended emission limits (e.g., for dioxins) to ensure protection of public health and the environment. However, where a new substance is anticipated to form degradation products that are likely to lead to impacts not mitigated by emission standards, then the NS Program will respond with requests for additional information and / or impose restrictions. Additional information on the assessment of degradation products is available in Appendix A.7.

The current data requirements for polymers use OECD test methods applicable to discrete chemicals. The OECD test guidelines for these data elements may not be applicable to polymeric substances. Experience has shown that concepts such as water solubility and octanol / water partition coefficients ($K_{ow}$) as related to polymers are not always meaningful in the context of performing an environmental and human health risk assessment.

A technical subgroup investigated the issues of polymer behaviour in water and lipids. The group was asked to recommend methods that would generate more meaningful information for notifiers and evaluators.

## Table Deliberations

The Table discussed each individual information element in the context of why the data are needed, how the data would be used during an assessment and when it would be relevant to provide the data. The detailed technical information on the individual data elements referred to in the "toolbox" will be found in the document *Information Elements for Chemicals and Polymers Submitted to the NSN Program*. This document will include a description of each information element, whether it is in the current regulations or on the OECD Minimum Pre-Market Data Set (MPD),[12] and whether it is proposed for regulations or guidelines. It will also contain background information on how the data are used and a rationale for proposed changes. This document will be located on the NS Program web site: **www.ec.gc.ca/substances**.

The Table agreed that applying all information elements to all chemical and polymeric substances cannot be justified scientifically. Some information elements pertain to only a small subset of the substances. In other cases, the need for more information is based on the results of data from another test or the results of an evaluation of its environmental partitioning.

The Table recognized the important role of the NSN Guidelines. The ability of the NSN evaluators to request additional information when they do not have sufficient information to determine risk is vital to ensuring that necessary tests are done when they are warranted.

The Table discussed the application of section 84(1)(c) of CEPA to enable evaluators to request additional information (see Section 3.1.3).

### Table Recommendations

14. Only the information elements that have wide applicability in assessing substances and have internationally accepted test protocols should be included in the Regulations.

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 that these data are necessary for the assessment and the data are not forthcoming from the notifier, provision of the data could be required under sections 84(1)(c) and 84(2) of CEPA.

16. The NSN Guidelines should be referenced in the NSN Regulations. The revised Guidelines will be developed by government and industry representatives. All stakeholders should be given the opportunity to comment on the revised Guidelines.

17. The NSN Regulations should contain the information in Table 3.1 for chemicals and polymers.

## Table 3.1: Recommended Regulatory List of Data Elements for Chemicals and Polymers

| Chemicals | Polymers |
|---|---|
| chemical name | chemical name |
| trade names | trade names |
| Chemical Abstracts Service (CAS) # | CAS # |
| molecular formula | molecular formula |
| structural formula | structural formula |
| | reaction scheme[a] |
| gram molecular weight | number average molecular weight (Mn) and % below 500 and 1000 daltons |
| degree of purity | |
| impurities | polymer composition and additives |
| additives / stabilizers | |
| spectrum | |
| Material Safety Data Sheet (MSDS) | MSDS |
| melting point (-25°C – 300°C) | physical state of the polymer |
| boiling point (-50°C – 300°C) | |
| density | |
| vapour pressure | |
| | is the polymer formulated for dispersal in water? |
| water solubility | water availability[b] |
| octanol / water partition coefficient[c] | octanol / water partition coefficient |
| adsorption / desorption[d] | |
| hydrolysis as a function of pH[d] | hydrolysis as a function of pH[e] |
| ready biodegradation | ready biodegradation[f,g] |
| acute fish toxicity | acute fish or daphnid toxicity[f] |
| acute daphnid toxicity | |
| acute algal toxicity | acute algal toxicity[f] |
| acute mammalian toxicity study | acute mammalian oral toxicity study[h] |
| 2nd acute mammalian toxicity study[i] | |
| sufficient information to assess skin irritation | sufficient information to assess skin irritation[h] |
| skin sensitization study | skin sensitization study[h] |
| one *in vitro* gene mutation study | one *in vitro* gene mutation study[h] |
| *in vitro* chromosomal aberration study | *in vitro* chromosomal aberration study[h] |
| *in vivo* mutagenicity or micronucleus assay | *in vivo* mutagenicity or micronucleus assay[h] |
| 28-day repeated-dose mammalian toxicity study | 28-day repeated-dose mammalian toxicity study[h] |
| manufacture, use, disposal and exposure information | manufacture, use, disposal and exposure information |
| all other information and test data on hazard and exposure | all other information and test data on hazard and exposure |
| identification of other agencies notified and risk management actions taken | identification of other agencies notified and risk management actions taken |

**Note: Regulatory Exemption Criteria**

[a] Required for polymers of low concern (PLCs), except current Schedule X polymers.

[b] Amount of polymer available in solution (dissolved, dispersed, or as an emulsion). At pH 7 for anionic and neutral polymers, at pH 2 and 7 for cationic polymers and at pH 2, 7 and 9 for amphoteric polymers.

[c] Required only for chemicals having water solubility of less than or equal to 5 g/L.

[d] Required only for chemicals having water solubility of greater than or equal to 200 µg/L.

[e] Testing will be required at the pH where water availability was determined to be greater than 2%.

[f] Not required for polymers that have water availability at pH 7 less than or equal to 2%.

[g] Not required for branched silicone and siloxane polymers.

[h] Not required for polymers described in Table 3.3 (see Section 3.2 below).

[i] Not required for substances that boil below 0ºC and that have been tested for acute inhalation toxicity.

Table Recommendations

18. The data elements described in Table 3.2 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."

## Table 3.2: Examples of Data Elements to be included in the NSN Guidelines

| Data Element |
|---|
| global warming potential (GWP) |
| ozone depleting potential (ODP) |
| mitigation of toxicity to algae |
| mitigation of toxicity to fish by humic acid |
| suite of benthic tests |
| chronic aquatic toxicity tests |
| bioconcentration/bioaccumulation factor |
| particle size |
| other mammalian toxicity tests (including chronic tests) |
| tests to determine endocrine disruption potential |
| available information on occupational exposure and hazards |

Table Recommendations

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.

### (ii) Class Considerations

#### Background

As a result of the Program's experience in assessing new substances, a body of knowledge now exists on a number of classes of substances that can be applied to newly notified substances. The revised Guidelines will be used to identify those classes of substances that will usually require specific additional test information and those classes where prescribed test information is not needed and waiver requests will be granted. An example of a class of the latter is acid dyes, which are already well characterized and understood. Environment Canada and Health Canada have determined that generating certain physical/chemical (e.g., octanol/water partition coefficient, ready biodegradation, dissociation constant) data for highly water-soluble acid dyes will not provide additional insight into the substances' behaviour in the environment. Furthermore, some acid dyes have been shown to be of low concern in the aquatic environment; therefore, these would be eligible for waiver requests for all ecotoxicity tests and the acute oral/dermal toxicity test.

An example of a class of substances where additional information will likely be requested is those substances with a chemical structure indicating that the substance may have the potential to damage stratospheric ozone. Notifiers will be required to submit additional information on ozone depleting potential. Possible tests that may be asked for certain classes of substances are listed in Table 3.2.

Table Recommendations

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.

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.

### (iii) Good Laboratory Practice

#### Background

GLP principles are intended to promote the quality and validity of test data and to establish a basis for mutual acceptance of data (MAD). They cover the organizational processes and conditions under which studies are planned, performed, monitored, recorded and reported. The OECD has developed a series of decisions and guidelines relating to GLP.[13] Canada, as a member of the OECD, has made a commitment that test data submitted under federal regulations should comply with GLP.

The OECD Council Decision states that data generated in a Member country in accordance with OECD Test Guidelines and Principles of GLP shall be accepted in other Member countries for assessment purposes. This is the cornerstone of the OECD work on MAD. Should a company choose not to conduct physical or chemical tests in compliance with GLP, the data would not be covered by the OECD decision on MAD. This implies that the company recognizes that data generated without GLP may not be accepted by other OECD countries and that it understands the potential need to repeat these tests for other jurisdictions.

Although the primary intent of the OECD Principles of GLP was to define the way in which toxicity studies are undertaken and documented, the principles are not specific to any particular type of test or testing discipline. The OECD has recently made a distinction for short-term studies and has set out guidance to this effect. The guidance leaves it to regulatory bodies in Member countries to specify which tests should be conducted in accordance with GLP. All other studies must comply.

Environment Canada participates in accreditation programs such as those of the Canadian Standards Council (CSC)/Canadian Association of Environmental Analytical Laboratories (CAEAL) and the Ministère de l'Environnement du Québec. Accreditation provides for national and international recognition of laboratory results. Accreditation is a systematic approach that ensures minimum, agreed-to quality standards, but the client can require more stringent standards, such as GLP. An increasing number of Canadian laboratories are seeking accreditation.

The current NSN Regulations (section 31(2)) require that "The laboratory practices to be followed in developing test data…shall be consistent with the practices set out in the 'Principles of Good Laboratory Practice'…of the OECD *Guidelines for Testing of Chemicals*."

The recommended provisions allow Canada to comply with OECD Council Decisions on GLP, without putting Canadian notifiers at a disadvantage.

### Table Deliberations

Most toxicological tests are performed by independent laboratories capable of performing GLP-compliant studies, whereas many tests for physical or chemical properties are done in-house by the notifier, whose laboratories are not necessarily set up for GLP-compliant studies. The Table considered requiring full GLP compliance for all studies, including physical or chemical properties. A significant deterrent to this was the realization that data previously generated by industry would no longer meet regulatory standards and would need to be regenerated in a facility capable of performing GLP studies.

Industry representatives recognize that the use of GLP approaches for many toxicological and environmental fate studies is a long-established practice to assure regulators that studies reported are valid and can be adequately audited for validity. Industry, however, feels that the use of GLP approaches for physical or chemical tests is "an unnecessary and onerous imposition" in terms of administration and certification.

The PAG representatives are not averse to the suggestion that GLP is not necessary for physical or chemical tests so long as enough information is provided to Environment Canada and Health Canada to determine that the data on physical or chemical properties are reliable and established in a predictable and transparent manner.

The government representatives recognize the value in having tests for physical and chemical properties conducted by laboratories that are most familiar with, and capable of analyzing, a given substance. Table members agree that this will provide the most reliable and accurate data on the substance's physical and chemical properties.

### Table Recommendations

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, genotoxicity, skin irritation, skin sensitization, ecotoxicity and ready biodegradation.

23. Tests for, and reporting of, physical or chemical properties must either comply with 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). Full reports for non-GLP tests will be required in order to assess the quality of these studies and their results.

24. If the laboratory that is generating data submitted to the Program is accredited, the status of that accreditation must be stated and identified.

## (iv) Toxicity Testing Using Animals

### Background

A number of regulatory agencies have already recognized the necessity of considering the ethical issues surrounding animal testing, including the European Union (EU) and the Member countries of the OECD.

The Commission and Member States of the EU encourage research aimed at developing and testing other techniques able to provide the same level of information as that obtained by experiments carried out on animals, but that use fewer animals or less painful procedures.

Concerning the use of animals in regulatory toxicity tests, the OECD endorses the principles of the three Rs, as defined by Russell and Burch,[14] which include "replacement" of conscious living higher animals by insentient material; "reduction" of animals used to obtain information of given amount and precision; and "refinement" or decrease in the incidence or severity of inhumane procedures to those animals that still have to be used. Three test

methods (OECD Test Guidelines 420, 423 and 425[15]) have been recently adopted by the OECD to replace the traditional acute oral toxicity test (OECD Test Guideline 401[16]), as these new tests require fewer animals. OECD Test Guidelines 429,[17] 423 and 425 are currently being revised to achieve further reduction in the numbers of animals while improving their performance characteristics. The OECD emphasizes the importance of collecting as much information as possible about the substance to be tested prior to designing the toxicity study, in order to meet the intended objectives of testing using animals, while minimizing pain, distress and suffering.[18]

The NS Program supports the principles of the three Rs, as indicated in the current *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* (p. 52), which states that "the government supports the use of testing methods that reduce the number of animals used and that minimize animal suffering, when the quality of data generated is not affected. Consequently, the use of limit tests and validated *in vitro* test methods, where appropriate, is encouraged."

### Table Recommendations

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 that 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.

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 be added to 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. Pre-notification consultations are encouraged in such situations. In addition, the government commits to setting service standards to respond to this type of request.

## (v) Exposure Template

### Background

In conducting a risk assessment, the full life cycle of a new substance is examined, capturing environmental releases "from cradle to grave." Exposure from the intended use pattern supplied by the notifier and other potential uses is assessed.

The current Regulations address information elements germane to assessing exposure. However, these tend to be general in nature, resulting in a wide range of reporting, including many brief "one line" responses. This information has been identified as one of the main areas where evaluators find it necessary to go back to notifiers seeking additional information or clarification in order to complete the risk assessment.

The need for increased detail and standardization of release information for chemicals and polymers new to Canada has led to a review of the information needed. It has resulted in the consolidation of this information in a template, facilitating its use by notifiers and evaluators.

A draft of this template is currently undergoing testing by industry and government. The results of this testing will be used to refine the information requested and improve the utility of the template.

### Table Recommendations

28. The template for providing exposure information should be developed in a separate process from this consultation.

29. The obligatory exposure information required by the Regulations should be incorporated into a template.

30. A reduced list of exposure data and in formation should be required for PLCs and entry level chemicals.

### *3.1.7 Evaluation and Validation of Data Quality in the NS Program*

#### Background and Context

A number of methods are used in the NS Program to examine and validate data quality, including comparison of notified results with surrogate and modelled data, application of GLP in the laboratories conducting the tests and scrutiny by experienced evaluators. The possible deterrent effects of penalties for submission of false or misleading information (section 273 of CEPA) and product liability are other potential factors for consideration in this issue.

The Table identified three main questions relating to the quality and validity / credibility of data submitted as part of an NSN:

- Is the current NSN process dealing adequately with data quality and validity / credibility?
- What are the appropriate tools to validate data quality?
- How should GLP be addressed in the Program?

In addressing these issues, the Table looked closely at the following factors that influence the quality and validity / credibility of data submitted to the regulators:

- scrutiny by NS Program evaluators;
- verification of testing; and
- GLP (addressed in Section 3.1.6).

#### (i) Scrutiny by NS Program Evaluators

For study reports, evaluators scrutinize, among other things, the provided information to determine whether:

- the methodology is consistent with standard procedures (e.g., under OECD, ASTM, U.S. EPA *Toxic Substances Control Act* [TSCA] Protocols);
- the study is conducted in an adequate manner;
- the method is appropriate for the test material;
- there is an adequate level of reporting details; and
- the results are consistent within the study, between studies and with what is known about the class of substance.

When surrogate data (test results from a similar substance) are provided in a notification, evaluators scrutinize the rationale prepared by the notifier regarding the suitability of the surrogate substance and review the study report(s) as above. Professional judgement of the evaluator is used in determining the acceptability of the surrogate. Data on similar substances and modelled values can be useful in extrapolating data for the notified substance.

For QSAR estimates, evaluators assess the adequacy of the method and whether the estimate for that substance or class is considered reliable. Where possible, cross-validation (use of different methods) is carried out. For information on use(s), releases and potential exposure, the evaluator checks provided information against what is known for that type of substance (standard use / release scenarios, other notifications on same / similar substance).

In cases where the data are judged to be inadequate, the evaluator will first consult within and outside the Program, as appropriate, to confirm or alleviate concerns. If the data are still considered to be inadequate, the evaluator will contact the notifier to resolve the situation. When data are judged to be erroneous, not meaningful or not of sufficient quality to satisfy the evaluator, the notification is considered incomplete, and the assessment does not continue until the problems with the data are resolved.

All assessment reports are reviewed and approved internally by managers in the respective departments. At Environment Canada, for internal quality assurance purposes, officials of the National Water Research Institute (NWRI) have reviewed some assessments. It has been proposed that a biennial review by NWRI of selected assessments be conducted beginning spring 2002.

#### Table Deliberations

Confidence was expressed in the work done by evaluators in the NS Program at Environment Canada and Health Canada to assess the quality and validity of information.

It was noted that as the field of modelling data for assessment purposes develops better methods, evaluators will have more opportunities and tools to identify uncertain or equivocal data than is currently the situation and to justify further action by the notifier. This would require the acquisition or development of databases of information and predictive tools / software.

#### Table Recommendations

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.

### (ii) Government Verification of Test Results

Replicate testing by government (either in its own laboratories or through contract laboratories that are suitably qualified; see Section 3.1.6(iv)) of some of the data provided in notifications was suggested as a supplement to existing efforts to verify the validity of data used in decision-making.

#### Table Deliberations

Some members of the Table drew attention to the possibility that bias can creep into test data when the tests are conducted by or for a notifying company. In extreme cases, intentional misrepresentation of data, as typified by the Industrial Bio-Test scandal in the United States in the early 1980s, is also possible. These members encouraged discussion of other measures that may be warranted to achieve the goal of ensuring use of the most credible data in decision-making under the NSN Regulations. Government-funded repetition of some tests was identified as one such means that has been used successfully in food safety and other programs to spot-check the accuracy of data being submitted to governments. Implementing a validation testing component to the NS Program was viewed by these Table members as a critical component for increasing public confidence in Program decisions.

The Table discussed many aspects of this proposal, ranging from the strategy for selecting random samples to the costs of implementing such a program and the means for paying for these additional tests. It was clear from the discussion that there was a diversity of views about how such a program could be implemented and about the role that it would play alongside other measures already being implemented or proposed in relation to validation and public confidence. The absence of specific facts, expertise and analysis (e.g., options, costs) impeded resolution of the issue within the time frame of this consultation.

#### Table Recommendations

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.

## 3.2 The Regulatory Framework

### *3.2.1 General Discussions and Recommendations*

#### Background/Context

There is general consensus among the government, industry and PAG representatives that there is a need to reduce the complexity of the Regulations and improve the administrative efficiency of the Program. This simplification should aim at improving efficiencies and ease compliance without compromising the protection of human health and the environment.

The Table identified three major issues for discussion:

- whether there is an alternative approach to using volume-triggered tiered schedules;

- whether a tiered approach can be simplified, made more responsive and made easier to understand and implement; and
- whether the NDSL continues to play a role and, if so, what the test requirements should be.

### (i) Alternative Approach to a Tiered System

A fundamental discussion for the Table was on an alternative to the volume-triggered tiered approach. Currently, the Regulations provide a tiered approach to notification that links information requirements to factors such as quantity, special categories (e.g., research and development [R&D] substances, site-limited intermediates), intrinsic properties and substance classes (e.g., chemicals, polymers). The prescribed information depends on a combination of these factors and is specified in notification schedules.

#### Table Deliberations

Industry and government members share the view that the tiered system has proven to be successful in the past and have agreed to support its continuation, with greater attention being paid to those substances that are imported / manufactured in higher volumes, as increased volume can be correlated with increased exposure. Industry supports the current system because it allows for the level of testing to increase in step with increases in usage and commercial viability.

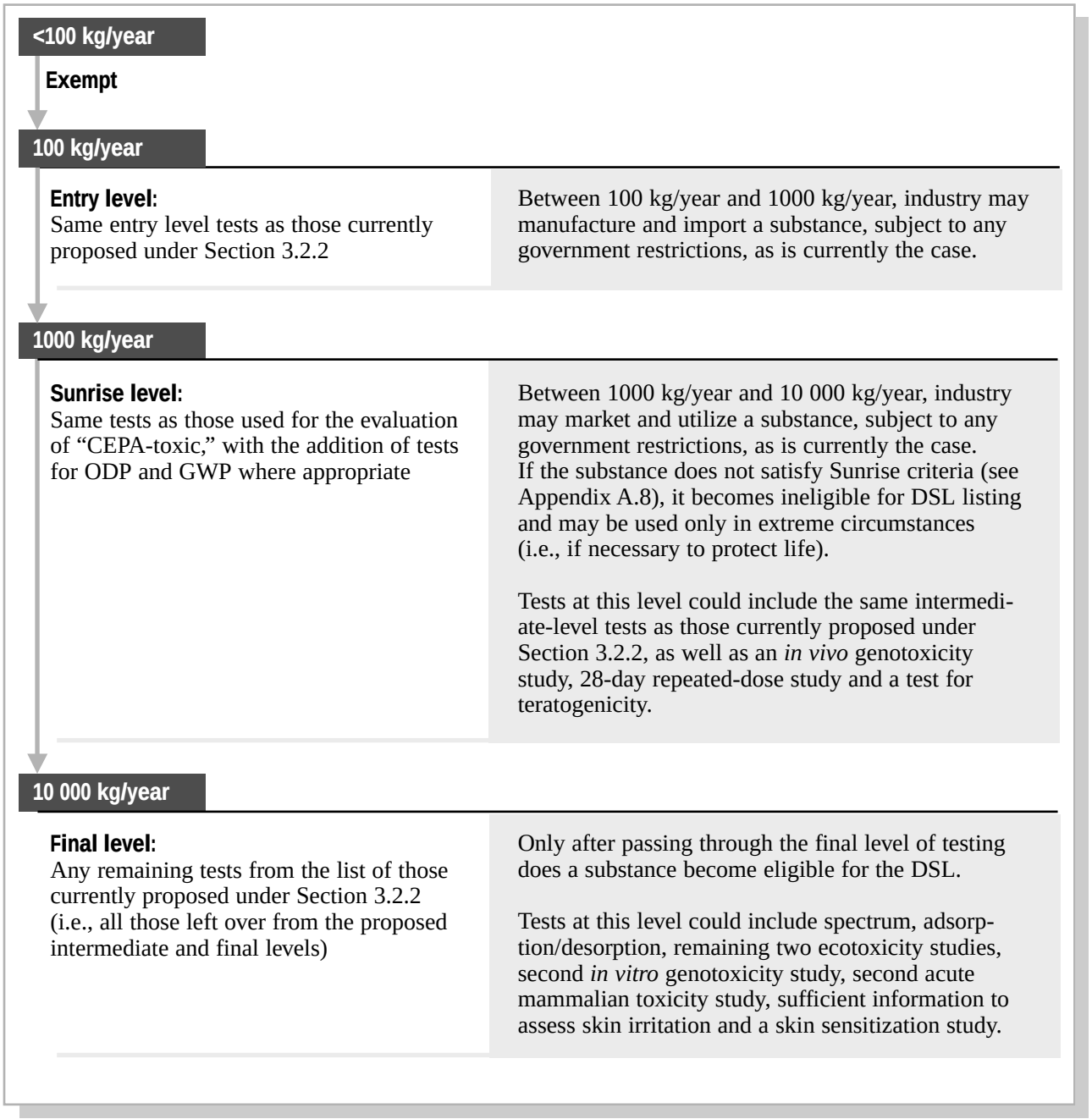
Some PAG members have consistently promoted an interpretation of toxic that is based on "hazard" assessment rather than "risk" assessment. This argument has been presented throughout the last decade, including the recent CEPA review discussions, and provided the basis for the PAG position during these NSN consultations as well. However, the revised CEPA did not adopt a hazard-based definition; rather, it interprets toxic in terms of both intrinsic properties and exposure potential. The existing NSN Regulations were also structured around a set of volume-triggered tiered testing requirements, thus incorporating the notion of exposure by requiring more extensive assessments for larger exposure potential.

Some of the PAG members take issue with volume triggers and an interpretation of toxic that includes exposure. First, they may allow pollution to accumulate through small, incremental releases. Second, they mean that substances may not be restricted until after some degree of damage has been done. The PAG propose a hazard-based system that they assert would be more preventative due to its emphasis on assessing and controlling substances from the onset. The assessment would be based solely on the intrinsic properties of the substances and would not allow harmful contaminants to be released into the environment even in small amounts. During these consultations, this system is referred to as the "Sunrise" approach.

While strict compliance with the Sunrise system would have required that full assessment of substances be conducted at the lowest possible volume, the PAG representatives have assented to an entry level trigger of 100 kg / year.

The PAG have come to a compromise and have suggested a revised approach to the notification system as illustrated in Figure 3.1.

## Figure 3.1: Notification Under the Modified Sunrise System



The difference between the government and industry proposal and the revised PAG position occurs at the 1000 kg/year trigger level. The issue at the heart of the two approaches is the evaluation of chronic toxicity. The PAG also have concerns about the lack of comprehensive genotoxicity testing and testing for teratogenicity and carcinogenicity at this 1000 kg/year trigger level. Government has suggested that section 84(1) of CEPA'99 provides one approach to request any additional information necessary to address concerns raised under the auspices of "suspicion of toxic." Section 3.1.3 provides additional context on the use of section 84(1).

Table Recommendation

33. An entry level trigger for non-NDSL chemical notifications should be established at 100 kg/year.

### (ii) Simplifying and Improving the Effectiveness of the Tiered Approach

The Table addressed both the complexity of the tiered approach and the user friendliness of the schedules themselves. The complexity of the current approach is a major concern for all stakeholders. There was consensus by the Table that the current tiered approach could be simplified. As a first step, the volume triggers could be simplified for non-NDSL substances.

There are currently three different types of volume triggers: annual, cumulative and "in possession." In total, nine volume triggers are associated with the current regulatory framework. It is proposed that triggers based on annual import/manufacture volume be continued and that cumulative and "in-possession" triggers be eliminated.

The elimination of cumulative triggers means that Environment Canada and Health Canada will no longer be able to identify those intermediate-volume chemicals that have significant long-term activity in Canada. However, Environment Canada and Health Canada believe that the assessment process would be better served by addressing issues of long-term environmental and human health risks at lower tiers, rather than by delaying receipt of information until quantities accumulate over many years. This has meant that as data requirements were considered for the schedules, care was taken to ensure that data elements that address persistence, bioaccumulation and toxicity are included in lower-level schedules.

In determining which tests are required at each tier (populating the schedules), industry representatives made the case that testing is expensive in terms of dollars, time and animals, whereas the tiered approach permits the phasing-in of test requirements and associated costs in a way that allows notifiers to absorb the costs. Government representatives used their experience with past notifications to help them to determine what information they need to be able to make sound risk assessments. The framework of "populated" schedules that is proposed by government and industry in Section 3.2.2 was reached after lengthy discussion and analysis of past notifications. For the reasons described in Section 3.2.1(i), the PAG do not support the proposed framework. Rather, they recommend including chronic toxicity, teratogenicity, genotoxicity and carcinogenicity testing at the 1000 kg/year level in the Regulations so that those substances exhibiting a range of toxic effects may be identified early in the assessment process and prevented from accumulating in the environment.

In order to make the tiered approach easier to use for PLC notifications, the Table discussed the development of a computer software-based "smart system" to help notifiers through the process (Section 3.2.2(iii)). The Table also addressed the schedules for special categories in the current Regulations and has proposed recommendations for simplifying their application in Section 3.2.3.

Table Recommendations

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.

### (iii) Administration of the NDSL

The NDSL specifies substances that are not on the DSL but are in international commerce. It originates from the obligation of the Minister of the Environment, under section 25(2) of CEPA, 1988 (section 66(2) of CEPA'99), to compile a list of substances not on the DSL but

believed to be in international commerce. As a basis for this list, Environment Canada chose the U.S. TSCA Inventory of 1985. The NDSL was first published on January 26, 1991, and consisted of the 1985 version of the TSCA list minus the substances on the Canadian DSL. Substances on the NDSL require less detailed notification packages for assessment under the current NSN Regulations than substances that are new to both the Canadian marketplace and world commerce.

Beginning in 1995, the NDSL has undergone annual revisions that add or delete all substances incorporated into, or removed from, the TSCA Inventory five or more years before the date of the NDSL revision. The 2001 NDSL update was, therefore, based on the TSCA Inventory of 1996.

Notification experience suggests that there are cases where there is a need to obtain additional data to better understand or validate concerns that are raised during the assessment of these substances. This may be due in part to the differences in the Canadian and U.S. systems used to evaluate new substances and the way in which the data are requested. Based on the Program experience until October 1999, covering 1877 NDSL substances, 21 substances were controlled in Canada but not controlled in the United States. Three of these substances were assessed in the United States, but their assessment did not result in known controls on their manufacture or use. The remaining 18 substances had not been assessed in the United States.

#### Table Deliberations

The administration of the NDSL was established with annual updates based on the version of the TSCA Inventory that existed five years earlier. The five-year lag was adopted to allow for adequate experience in use, with the presumption that any concerns would become apparent during the lag period. In practice, this has not been proven to be a factor. Rather, the five-year lag has caused a degree of complexity in the management of the necessary records to effect accurate updates.

The experience of NS Program reviewers since the inception of the NSN Regulations in 1994 has shown that there are instances in which more data are required for NSNs covering NDSL substances. These particular needs have been addressed, as explained in subsequent sections (see Sections 3.2.2(ii) and 3.2.2(v)), by a proposed restructuring of the schedules that would apply to NDSL substances.

In consideration of the past seven years of experience and the proposed changes to the schedules, the government has suggested that it would be appropriate to alter the annual NDSL update to incorporate a one-year lag in relation to the TSCA Inventory.

#### Table Recommendation

35. The NDSL should be updated annually, based on the U.S. TSCA Inventory of the previous year.

### *3.2.2 Proposed Framework for the New Regulations*

New substances fall into five categories that are considered here for the purpose of assigning test requirements to schedules: non-NDSL chemicals; NDSL chemicals; PLCs; non-NDSL polymers; and NDSL polymers. Additionally, there are special categories that include substances intended for R&D, for product development, for export only or for use as site-limited intermediates.

Although all three stakeholder groups started from different positions, industry and government were able to reach agreement on proposed frameworks for all five categories of new substances and the special categories. During these discussions, specific concerns of the PAG were taken into consideration, but overall the PAG still favour the Sunrise approach. However, in light of the fact that the two proposed “NDSL” schedules (Sections 3.2.2(ii) and 3.2.2(v)) represent significant improvements over the status quo, the PAG are prepared to agree with them as outlined below.

Furthermore, it is recognized that, in all categories, additional data can be requested of the notifier at each stage in the process to satisfy a concern relative to a “suspicion of toxicity” under section 84(1)(c). As well, notifiers may request waivers for data elements if they can satisfy certain criteria.

### (i) Proposed Framework for Non-NDSL Chemicals

Three schedules are proposed by industry and government, as outlined below. The PAG favour the adoption of the Sunrise approach as described in Section 3.2.1, due to concerns regarding the absence of regulatory requirements for chronic (and other) toxicity data early in the assessment process.

- ***Entry Level:*** It is proposed that the annual trigger for these substances be raised from 20 kg / year to 100 kg / year. This volume is not likely to pose a risk to human health or the Canadian environment. The trigger is low enough that an "inventory" of substances in commerce in the country can be maintained and effectively captures the "cradle" in cradle to grave management of substances.
- ***Intermediate Level:*** The volume trigger for this level is proposed to remain at 1000 kg / year.
- ***Final Level:*** This schedule is to be required prior to reaching 10 000 kg / year and must be completed prior to DSL listing. The cumulative volume trigger of 50 000 kg no longer applies.

#### Information in Schedules

**Entry Level for Non-NDSL Chemicals (100 kg/year)**

- chemical name
- trade names
- CAS #
- MSDS
- a summary of all other information and test data on hazard and exposure (that are in the person's possession)
- exposure data and information
- identification of other agencies notified and risk management actions taken

**Intermediate Level for Non-NDSL Chemicals (1000 kg/year)**

- entry level information
- molecular formula
- structural formula
- gram molecular weight
- degree of purity
- impurities
- additives / stabilizers
- melting point
- boiling point
- density
- vapour pressure
- water solubility
- octanol / water partition coefficient
- one acute mammalian study
- one *in vitro* gene mutation study
- one acute fish, daphnid or algae study
- ready biodegradation
- manufacture, use, disposal and exposure information
- a summary of all other information and test data on hazard and exposure (to which the person ought reasonably have access)

**Final Level for Non-NDSL Chemicals (10 000 kg/year, DSL eligible)**

- intermediate-level information
- spectrum
- adsorption / desorption
- hydrolysis
- remaining two ecotoxicity studies
- second *in vitro* genotoxicity study
- *in vivo* genotoxicity study
- second acute mammalian toxicity study
- sufficient information to assess skin irritation
- skin sensitization study
- 28-day repeated-dose study

### (ii) Proposed Framework for NDSL Chemicals

Three schedules are proposed by the Table:

- ***Entry Level:*** The proposed entry level trigger volume remains unchanged at 1000 kg / year.
- ***Intermediate/Final "A" Level:*** The proposed intermediate / final trigger volume is 10 000 kg / year.
- ***Final "B" Level:*** The proposed final-level trigger volume is 50 000 kg / year.

### Information in Schedules

The proposed entry level data requirements are identical to those for non-NDSL chemicals. The proposed intermediate/final data requirements match the intermediate non-NDSL chemical proposal. The proposed final-level schedule will apply only to certain NDSL chemicals that meet specific criteria that are indicative of significant human exposure.

**Entry Level for NDSL Chemicals (1000 kg/year)**

- chemical name
- trade names
- CAS #
- MSDS
- a summary of all other information and test data on hazard and exposure (that are in the person's possession)
- exposure data and information as specified in an exposure template in the Guidelines
- identification of other agencies notified and risk management actions taken

**Intermediate/Final Level "A"* for NDSL Chemicals (10 000 kg/year, some chemicals DSL eligible)**

- entry level information
- molecular formula
- structural formula
- gram molecular weight
- degree of purity
- impurities
- additives/stabilizers
- melting point
- boiling point
- density
- vapour pressure
- water solubility
- octanol/water partition coefficient
- one acute mammalian study
- one *in vitro* gene mutation study
- one acute fish, daphnid or algae study
- ready biodegradation
- manufacture, use, disposal and exposure information
- a summary of all other information and test data on hazard and exposure (to which the person ought reasonably have access)

**Final "B" Level for NDSL Chemicals (50 000 kg/year, DSL eligible)**

*For those chemicals likely to have a release to the environment after wastewater treatment of >3 kg/day per site averaged over a month, including envisioned future uses by multiple users and/or a variety of applications:*

- adsorption/desorption
- hydrolysis
- 28-day repeated-dose mammalian toxicity study

*For those chemicals considered likely to be present in consumer products where significant exposures are likely:*

- 28-day repeated-dose mammalian toxicity study
- an *in vitro* study for chromosomal aberrations; if an *in vivo* study is already available, it will be considered as alternative data

### (iii) Proposed Framework for Polymers of Low Concern

This proposal retains the distinction between PLCs and other polymers.

There are several issues related to PLCs:

- the ability of industry to properly identify PLCs (it has been the experience of regulators that approximately 20% of polymers submitted as "low concern" do not meet the criteria);

*NDSL chemicals that are not anticipated to be used in consumer products or released to the environment in excess of an average (on a monthly basis) of 3 kg/day per site, after wastewater treatment, will be candidates for addition to the DSL at this point, provided their assessment does not lead to "suspicion of toxic." All other NDSL chemicals will be subject to the requirements of the "Final 'B' Level," below, prior to attaining a volume of 50 000 kg/year (see Figure 3.2 at the end of Section 3.2).

- the amount of effort and time required for their notification and assessment; and
- what is done with the information.

In an effort to address the first issue, Environment Canada is exploring the development of a computer software-based "smart system" to assist notifiers in the identification of PLCs.

A contractor is being sought to develop a "query" system, where the user is prompted to respond to a series of questions. When sufficient information has been gathered to determine whether a substance meets the "low concern" criteria or not, the questioning stops. The Table supports this approach.

PLCs are notified solely in the entry level schedule of the polymer notification framework. The assessment period associated with PLCs is discussed as part of Section 3.2.4.

The government expressed concern that PLCs eligible for listing on the DSL could subsequently be manufactured/imported in variations with characteristics outside the low concern boundaries. The risk assessments conducted for PLCs are based on the low concern criteria and use reduced data requirements, compared with the data prescribed for the other categories of polymers. Polymers introduced subsequently that do not meet the PLC criteria could have significantly different properties from the PLCs assessed and would, therefore, present a different risk profile from the low concern version. This concern was generally accepted by all members of the Table.

Table members agreed that PLCs (excluding certain polyesters)* be listed on the DSL via a mechanism to be developed (e.g., flagging) to indicate that they have been assessed based on the low concern criteria. Import or manufacture of these substances would be unrestricted as long as they continued to meet the low concern criteria set out in the Regulations. Prior to the import or manufacture of a designated PLC that does not meet the low concern criteria, a higher-level notification would be required.

*Polyesters manufactured from monomers and reactants defined in Schedule 10 of the current NSN Regulations.

### Information in Schedule (see Figures 3.3 and 3.4 at the end of Section 3.2)

**Entry Level (1000 kg/year)**

- chemical name
- trade names
- CAS #
- molecular formula
- structural formula
- reaction scheme
- polymer composition and additives
- MSDS
- number average molecular weight and % below 500 and 1000 daltons
- reduced manufacture, use, disposal and exposure information
- a summary of all other information and test data on hazard and exposure (that are in the person's possession)
- identification of other agencies notified and risk management actions taken

## (iv) Proposed Framework for Non-NDSL Polymers — Excluding Low concern Polymers and Those with All Monomers Listed on the DSL/NDSL (see Government and Industry Perspectives below)

Two schedules are proposed by industry and government. The PAG favour the adoption of the Sunrise approach (as described in Section 3.2.1 and in Section 3.2.2, Table Deliberations) due to concerns regarding the absence of regulatory requirements for chronic (and other) toxicity data early in the assessment process. The PAG also recommend that the regulatory status of monomers *not* affect the notification scheme, and that notifiers may utilize waivers where appropriate to reduce the requirements for this category of substance.

- ***Entry Level:*** This entry level schedule is currently required at 1000 kg/year. It is proposed that this be maintained.
- ***Final Level:*** Under the present notification system, final polymer notification occurs at 10 000 kg/year. It is proposed that this trigger be maintained.

## Information in Schedules

The proposed entry level data requirements are identical to those proposed for PLCs, whereas the proposed final-level data requirements are based on a combination of data requirements from the current (1994 Regulations) Schedule VII and VIII notifications. This proposal simplifies the Regulations by reducing the number of schedules for non-NDSL polymers from 3 to 2.

**Entry Level (1000 kg/year)**

same as for PLCs above

**Final Level (10 000 kg/year, DSL eligible)**

- entry level information
- physical state of the polymer
- is the polymer formulated for dispersal in water?
- water availability
- octanol/water partition coefficient
- hydrolysis as a function of pH
- ready biodegradation
- two acute toxicity tests for the most sensitive species (defaults are acute algae toxicity and acute fish or daphnid toxicity)
- acute mammalian oral toxicity study*
- sufficient information to assess skin irritation*
- skin sensitization*
- 28-day repeated-dose mammalian toxicity study*
- one *in vitro* gene mutation study*
- *in vitro* chromosomal aberration study*
- *in vivo* chromosomal aberration or gene mutation or other indicator of genotoxicity*
- remaining manufacture, use, disposal and exposure information
- a summary of all other information and test data on hazard and exposure (to which the person ought reasonably have access)

*Exemptions for specified polymer classes will be allowed when the notifier demonstrates that certain criteria have been met. See Tables 3.3 and 3.4 for the list of these polymer classes and guidance on possible waiver conditions.

## Table 3.3: Exemptions for Health Hazard Toxicity Data

The following polymer classes are exempt from all health toxicity tests (OECD 401 to OECD 476). This list is subject to change as more information becomes available.

| Polymer Class | Definition |
|---|---|
| Low Concern | As defined in the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*. |
| Cationic | Polymers that do not meet the low concern criteria solely due to the presence of the following cationic or potentially cationic groups: primary, secondary, tertiary or quaternary amine groups, carbodiimides and sulphoniums. Although the following cationic groups are not included — hindered amines, isocyanates (free and blocked) and phosphoniums — waivers may be considered on a case-by-case basis.<br><br>Exception to the exemption: cationic polymers with Mn > 10 000 daltons whose intended or expected use was likely to result in direct inhalation exposure of the general population would not qualify for the exemption. |
| Aldehyde | Polymers that do not meet the low concern criteria *solely* due to the presence of aldehydes that exceed the functional group equivalent weight of 1 in 1000. |
| Vinyl Ether | Polymers that do not meet the low concern criteria *solely* due to the presence of vinyl ethers that exceed the functional group equivalent weight of 1 in 5000. |
| Sulphonic Acid | Polymers that do not meet the low concern criteria *solely* due to the presence of sulphonic acids that exceed the functional group equivalent weight of 1 in 5000. |

## Table 3.4: Waivers for Health Hazard Toxicity Data for Polymers with No Molecular Weight Species Below 1000 Daltons (i.e., <0.1%)

| Conditions for which Waivers for Health Toxicity Tests Can Be Requested | Conditions for which Waivers for Health Toxicity Tests Cannot Be Requested |
|---|---|
| If information on hydrolysis, biodegradation potential or toxicity supports the rationale that the polymer will not be broken down and will not be biologically absorbed.<br><br>Requests to waive the acute toxicity test should be accompanied by information that supports the rationale that the polymer is not biologically absorbed. | If information on hydrolysis, biodegradation potential or toxicity does not support the rationale that the polymer will not be broken down and will not be biologically absorbed. |

### (v) Proposed Framework for NDSL Polymers and Non-NDSL Polymers with All Monomers Listed on DSL/NDSL — Excluding Low concern Polymers

Three schedules are proposed by the Table:

- ***Entry Level:*** The proposed entry level trigger volume is identical to those proposed for PLCs and non-NDSL polymers, 1000 kg / year.
- ***Intermediate/Final "A" Level:*** The proposed intermediate / final trigger volume is identical to the final trigger level proposed for non-NDSL polymers, 10 000 kg / year.
- ***Final "B" Level:*** The proposed final-level trigger volume is identical to the final trigger level proposed for NDSL chemicals, 50 000 kg / year.

#### Information in Schedules

The proposed entry level data requirements are identical to those for PLCs and the proposed non-NDSL polymers. The proposed intermediate / final data requirements will be reduced relative to the final non-NDSL polymer proposal. The proposed final-level schedule will be similar to that for chemicals, in that it will apply only to certain polymers that meet specific exposure criteria.

**Entry Level (1000 kg/year)**

identical to non-NDSL polymers above

**Intermediate/Final "A" Level (10 000 kg/year, some polymers DSL eligible)**

- entry level information
- physical state of the polymer
- is the polymer formulated for dispersal in water?
- water availability
- octanol / water partition coefficient
- hydrolysis as a function of pH
- one aquatic toxicity test for the most sensitive species (fish, daphnia, algae); default acute algae toxicity
- acute mammalian oral toxicity study*
- remaining manufacture, use, disposal and exposure information
- a summary of all other information and test data on hazard and exposure (to which the person ought reasonably have access)

**NOTE:** Polymers in this section that are not anticipated to be used in consumer products or released to the environment in excess of an average (on a monthly basis) of 3 kg / day per site, after wastewater treatment, will be candidates for addition to the DSL at this point, provided their assessment does not lead to "suspicion of toxic." All other polymers of this section will be subject to the requirements of the "Final Level," below, prior to attaining a volume of 50 000 kg / year.

**Final "B" Level (50 000 kg/year, DSL eligible)**

*For those polymers likely to have a release to the environment after wastewater treatment of >3 kg/day per site, averaged over a month, including envisioned future uses by multiple users and/or a variety of applications:*

- 28-day repeated-dose mammalian toxicity study*
- one *in vitro* study, either gene mutation or chromosomal aberration*

*For those polymers considered likely to be present in consumer products where significant exposures are likely:*

- 28-day repeated-dose mammalian toxicity study*
- one *in vitro* gene mutation study*
- one *in vitro* chromosomal aberration study* (if an *in vivo* study is already available, it will be considered as alternative data)

## Table Deliberations

### Government Perspectives

**NDSL Framework**

The Environment Canada and Health Canada representatives feel that the proposed data requirements for NDSL substances represent an improvement over the existing data requirements for these substances.

*Exemptions for specified polymer classes will be allowed, or waivers may be possible, when the notifier demonstrates that certain criteria have been met. See Tables 3.3 and 3.4.

The proposed changes include a 28-day repeated-dose toxicity study that would be required prior to the substance exceeding a trigger volume of 50 000 kg / year, where the average daily release (after waste treatment) is estimated to be 3 kg / day per site or where significant consumer exposure is expected. In addition, in situations where significant consumer exposure to the chemical is expected, two *in vitro* tests for examining mutagenicity or chromosomal aberration (or equivalent testing) will be required prior to exceeding the above trigger volume. Further elaboration of the criteria for "significant consumer exposure" is necessary and will be carried out and published in the revised Guidelines.

The 3 kg / day release value was derived based on outcomes of standard quantitative risk assessment procedures using conservative assumptions that are routinely utilized by the NS Program for assessing "suspicion of toxic."

The 28-day repeated-dose mammalian toxicity study is capable of identifying adverse effects following multiple exposure to the notified substance and serves to provide significantly more information on the various systemic toxic effects that cannot be detected reliably in an acute study. The repeated-dose study, in conjunction with other studies, is expected to identify indications of toxicity that could lead to "suspicion of toxic," and further testing to characterize intrinsic toxicity or specific health hazards may be necessary. Its inclusion represents a significant improvement over the current data requirements for assessing substances that are on the NDSL.

The inclusion of the genotoxicity tests in situations where widespread or significant consumer exposure is anticipated improves the scope and robustness of the data package for assessing potential health risks such as cancer and developmental defects in the general population resulting from exposure to the new substances.

It is notable that many of the NDSL notifications submitted to the Program in the past have included several genotoxicity studies; the current proposal would subject all substances that meet the criteria outlined above (listed on NDSL; prior to exceeding 50 000 kg / year; >3 kg / day per site; significant consumer exposure) to more complete testing than is currently required.

From an environmental perspective, the proposed changes for NDSL polymers include the provision of one acute toxicity test (regardless of charge) for the most sensitive species (acute algal toxicity by default) and hydrolysis as a function of pH. For NDSL chemicals, the proposed changes include the addition of one acute fish, daphnid or algae study and a ready biodegradation test. The proposed changes will provide a better characterization of the toxicity of the notified substance by reducing uncertainty in the assessments. Furthermore, data on hydrolysis and ready biodegradation will reveal whether the notified substances can be degraded and, if so, identify environmental degradation products.

Overall, the Environment Canada and Health Canada representatives believe that the proposed data requirements for NDSL substances will provide for a more robust assessment of human health and the environment.

**Monomer Status**

Initially, it was the view of Environment Canada and Health Canada that there is no scientific justification for the current system of modifying data requirements based on whether or not monomers are listed on the DSL or NDSL. Further, accounting for monomer status would add complexity to the polymer framework.

A review of impacts by Environment Canada and Health Canada determined that environmental and human health will remain protected even if the current provisions remain in place, since data are likely to be provided at a later date, if warranted. Environment Canada and Health Canada recognize that there is an industry sector that is dependent upon creating new polymers with existing monomers, and that a niche for this activity has been created by existing provisions in the current NSN Regulations. Environment Canada and Health Canada agree, therefore, with industry's proposal to maintain the regulatory status of monomers for polymers that do not fall into the PLC category.

## Industry Perspectives

### NDSL Framework

Industry initially proposed that the treatment of the NDSL should be strengthened within the context of MAN. The original premise was that the NDSL was based on the U.S. TSCA Inventory and that the history of NDSL notifications did not suggest that there were overarching concerns with the reduced data requirements imposed on these substances. From this knowledge base, industry originally proposed that the notification requirements for NDSL substances were adequate and additional relaxation of data requirements could be considered.

Industry had further proposed that the scope of the NDSL should be enhanced by recognizing other international inventories, like the European Inventory of Existing Chemical Substances (EINECS) and European List of New Chemical Substances (ELINCS), thus continuing to promote MAN. Inclusion of a broader inventory base would provide considerable opportunities to make reviews more efficient and timely without any loss of protection of human health and the environment. The expansion of the NDSL beyond the TSCA Inventory would allow greater access to the Canadian market while still providing the departments the opportunity to assess these newer substances.

Based on evidence provided by Health Canada, demonstrating that chronic toxicity endpoints were not adequately addressed in some cases, industry has acceded to the government proposal to provide certain data elements based on considerations for significant consumer exposure or release to the aquatic environment. This compromise was agreed to in view of the rationale provided by government that for specific release scenarios, additional health endpoints should be examined.

Consistent with the above points, industry continues to strongly advocate that opportunities to improve international cooperation on the assessment of new substances should be pursued, as outlined in Section 3.4 of the Table report.

### Monomer Status

Industry believes that NSN Regulations of CEPA treat polymers more severely than warranted, based on the low intrinsic toxicity associated with these substances and in comparison with other jurisdictions. The current regulatory framework recognizes the inventory status of monomers in determining the test program. Furthermore, Canadian industry has established ongoing commercial activities in the polymer field based on the inventory status of the monomers. Additionally, a segment of industry has already been negatively impacted by the current data requirements, since these businesses are based on European sources where polymer notifications are not required as long as all monomers are listed. An appreciable increase in the data requirements would destroy the commercial viability of this type of polymer.

The revised proposal continues to recognize the important role that inventory status plays within the regulatory framework, while providing government with additional human health endpoints where warranted. This represents a clear increase in the data available for assessment where the use pattern may lead to significant consumer exposure or release to the aquatic environment.

## PAG Perspectives

### NDSL Framework

The PAG acknowledge that the NDSL chemical and NDSL polymer proposals represent significant improvements over the status quo and are thus willing to compromise on their initial "Sunrise" position in order to reach consensus on these two schedules.

However, the PAG still have numerous concerns with the proposals as outlined. They feel that the decision to accept reduced data requirements for NDSL substances is not scientifically based and may therefore result in heightened health risks. In particular, the PAG are concerned that chronic health concerns are not adequately addressed by this proposal. The only longer-term toxicity test being proposed is the 28-day repeated-dose mammalian test, and even this is only selectively required at the 50 000 kg/year level for those substances meeting certain exposure/consumer criteria. By government's own

admission, systemic toxicity is not well predicted by toxicity tests with a time frame less than 28 days or by QSAR models. Additionally, since the U.S. EPA does not automatically review this or subchronic/chronic toxicity tests for all substances placed on its inventory, there can be no heightened confidence in the safety of NDSL substances in this area. Accordingly, the PAG argue that NDSL substances should be subject to the same testing requirements as non-NDSL substances, particularly with respect to systemic health effects.

The PAG also take issue, for numerous reasons, with the exposure cut-off that has been introduced as a decision point prior to final schedule testing. First, the reliance on exposure at this critical juncture runs directly counter to the PAG's Sunrise philosophy and its emphasis on hazard-based judgements. Rather, the exposure-based proposal gives no consideration to the relative potencies of substances; for example, substance A may exhibit twice the chronic toxicity of substance B, and yet both would need to meet the same exposure criteria in order to warrant the 28-day test. Second, little thought has been given to the implementation and enforcement of the 3 kg/day per site cut-off limit. The very real possibility exists that, once a low-exposure substance has been placed on the DSL, its cumulative releases will rise due to new-found uses, a surge of multiple users or simply an increase in use by the original notifier. It is unclear how these changes will be monitored and regulated for DSL substances. The use of the Significant New Activities (SNAcs) provisions in CEPA'99 (see sections 80 and 81) has been proposed as a means of addressing these concerns; however, the implementation of this proposal may be problematic due to the fact that SNAcs have been neither designed nor previously utilized for this purpose. Third, the exposure measurement itself is of questionable accuracy, since it is often based on projections rather than direct measurements. As a result of these concerns, the PAG feel that it is highly inappropriate to use exposure as a criterion for requiring final-level health tests.

**Monomer Status**

The PAG do not accept the non-NDSL polymer framework and the accompanying reduction in test requirements that has been proposed for those polymers with all monomers listed on the DSL or NDSL. First, the PAG feel that this recommendation by industry and government is not scientifically based and allows for potentially harmful polymers to gain access to the DSL without receiving complete assessments. Second, the complexity of the polymer framework is further heightened by the requirement that an additional regulatory procedure be introduced for this class of polymers. Third, government workload will necessarily increase due to the fact that, in cases where suspicions of toxicity exist, regulators will need to specifically request all of the data elements that would otherwise have been routinely provided under a regular polymer notification. Fourth, this has the added disadvantage of reducing transparency. Due to these disadvantages with the government/industry proposal, the PAG instead recommend that the regulatory status of monomers not affect the notification scheme, and that notifiers may utilize waivers where appropriate to reduce the requirements for this category of substance.

## Table Recommendations

The Table did not reach complete consensus on a proposed framework for data schedules. The perspectives of each sector are articulated above.

36. The framework as outlined in the proposed framework for NDSL Chemicals (Section 3.2.2(ii)) and the proposed framework for NDSL polymers and non-NDSL polymers with all monomers listed on the DSL/NDSL (Section 3.2.2(v)) should replace the current requirements for the relevant categories of substances.

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.

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.

39. A more streamlined method should be pursued as an alternative to SNAcs.

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.

41. A "smart system" to simplify the notification of PLCs should be developed and implemented.

### *3.2.3 Special Categories*

Currently, there are five special schedules: three for polymers (Export-only / Site-limited Intermediate, R&D and Product Development) and two for chemicals (Export-only / Site-limited Intermediate and Product Development).

The use of the schedules for these special categories has been limited, representing less than 2% of the total number of new notifications. Schedule IV, for product development chemicals, has been used 13 times (0.3% of all notifications). Schedule V, for site-limited intermediate chemicals and export-only chemicals, has been used 39 times (1% of all notifications).

#### (i) Research and Development and Product Development Substances

The current regulations contain separate definitions for R&D and product development substances, with specific schedules for each. The Table proposes that these definitions be amalgamated, resulting in a single R&D category.

Under the amalgamated definition for R&D and product development, there is a need to be able to recognize that the activity concerning a substance truly qualifies for the R&D special category. This determination is rather easy to make during the early stages of the R&D process. It becomes more complex, however, as the substance moves into the product development mode, especially when volumes are increased in order to conduct efficacy trials in the facilities of potential customers. Test marketing, however, is accepted as a boundary condition, which clearly denotes when the special provisions of the R&D category have been relinquished.

*Polyesters manufactured from monomers and reactants defined in Schedule X of the current NSN Regulations.

#### Table Deliberations

The current definition of "test marketing," as contained in the NSN Regulations ("the exploration of the market capability of a product in a competitive situation where the creation or improvement of the product is not the primary objective"), adequately describes the movement of a substance into a commercial mode and is proposed to be left intact.

A parallel program exists for R&D in the United States under the TSCA. The parameters governing the R&D exemption under the TSCA have been well described over the more than 20 years that this legislation has been in effect, through various information bulletins and other less formal communications. Due to the significant level of experience and the close similarity of the TSCA provisions to those proposed for the revised NSN Regulations, it is proposed that the TSCA guidance be used as a reference in developing the CEPA R&D guidance (see the EPA New Chemical Information Bulletin[19]).

The recommended requirements for R&D substances provide an equivalent level of environmental and human health protection as currently available and also recognize the nature of R&D substances. They allow for the deferral of test data, yet simplify the Regulations by eliminating separate categories for R&D and product development substances.

In summary, the manufacture and import of R&D substances would be subject to the proposed intermediate and final notifications, with no requirement to submit test data until the substance is commercialized (i.e., when the substance no longer meets the definition of R&D). If the substance is not commercialized,

there would not be any ongoing notification responsibilities.

The PAG acknowledge that this proposal is not consistent with the "Sunrise" protocol but are prepared to agree with it as outlined.

Table Recommendations

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.

43. The current schedules for special categories should be replaced within the framework outlined in Section 3.2.2 with the following:

### a) R&D — Chemicals

Table Recommendations

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.

45. Prior to exceeding 1000 kg / year, the following data will be required:

    • chemical name
    • trade names
    • CAS #
    • MSDS
    • molecular formula
    • structural formula
    • gram molecular weight
    • degree of purity
    • impurities
    • additives / stabilizers
    • a summary of all other information and test data on hazard and exposure
    • identification of other agencies notified and risk management actions taken
    • (manufacture, use, disposal and exposure information)

    These data elements are equivalent to the proposed intermediate schedule (Section 3.2.2(i)), but with no requirement to notify test data.

46. The notification of the "final" schedule (as outlined in Section 3.2.2(i)) will be required prior to exceeding 10 000 kg / year. This will inform Environment Canada and Health Canada of the increased volume of the R&D substance and provide an opportunity for the notifier to update information supplied in the first notification. There would be no additional infor-mation requirements at that time beyond the "correction of information" provision of CEPA (section 81(11)).

### b) R&D Polymers

Table Recommendations

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 is 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)), but with no requirement to develop test data.

### (ii) Site-limited Intermediate Substances and Export-only Substances

#### Background

By definition, site-limited intermediates and export-only substances will not be distributed within Canada. Site-limited intermediate and export-only substances are not eligible for listing on the DSL. Changes to the original notice (e.g., changes in the site or release conditions) must be submitted to the Minister, so that the information may be reviewed to see if the assessment outcome still applies (section 81(11)). To become eligible for the DSL, renotification using the normal notification process would be necessary. As a consequence, risk assessment will focus on exposure from manufacturing, processing and transit facilities. Because there may be limited opportunity for release and exposure, Table members believe that the regulations for site-limited intermediate and export-only substances can be simplified if "sufficient containment" can be demonstrated and other issues raised can be addressed appropriately.

In considering export-only substances, it is important to recognize that Environment Canada is currently developing regulations to implement the requirements of the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. This Convention requires, among other things, that receiving countries of a given chemical be notified if a final regulatory action prohibiting or severely restricting the use of this chemical has been taken. This includes chemicals that have been refused approval for use in the domestic market as a human health or environmental protection measure. The notice sent to the receiving country must indicate the assessment outcome and the regulatory action taken. Operationalizing the PIC provisions within the context of the assessment of new substances becomes an integral element in Canada's ability to fulfil its obligations internationally. There are other requirements relevant to new substance evaluations. For instance, if a substance is banned or severely restricted as a result of these evaluations, Canada must notify the PIC Secretariat of this action.

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

#### Table Deliberations

As a means to eliminate special categories for the management of these types of substances, an attempt was made during these consultations to identify the use of waiver requests under section 81(8)(b) as a way of handling the associated data requirements. Based on legal opinion, it was determined that there is no practical mechanism to use these waiver requests to simplify the structure of the Regulations for all site-limited intermediates and export-only substances. Section 81(8) indicates that waiver of information requirements can be granted as follows:

> On the request of any person to whom subsection (1), (2), (3) or (4) applies, the Ministers may waive any of the requirements to provide information under that subsection if
>
> (a) in the opinion of the Ministers, the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;
>
> (b) the substance is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the person requesting the waiver is able to contain the substance so as to satisfactorily protect the environment and human health; or

(c) it is not, in the opinion of the Ministers, practicable or feasible to obtain the test data necessary to generate the information.

The "Manufactured at a Location …" portion of section 81(8)(b) is applicable only to substances manufactured in Canada and cannot be applied to imported substances. It may be applied to all substances manufactured in Canada, including export-only and site-limited intermediate substances. The "Prescribed Purpose" portion of section 81(8)(b) relates specifically to the type of use to which the substance will be subject. Environment Canada's legal services have interpreted this to simply mean the "use" of the substance (see French version for clarity). The "Prescribed Purpose" provision is applicable to both imported and manufactured substances. Based on the conflicting waiver requirements under this section, export-only or site-limited intermediate substances could not be captured uniformly by a "Prescribed Purpose" regulation as required in section 89(1)(f) of CEPA. Government proposed that further discussions be pursued to identify the potential to apply the "Prescribed Purpose" portion of section 81(1)(b) of CEPA to special categories (see also Section 3.2.5 of this report).

## Proposed Definitions for Site-limited Intermediate and Export-only Substances

The proposed definitions for chemicals and polymers that would qualify for the site-limited intermediate and export-only provisions are:

*"Contained Site-limited Intermediate Substance"* means a substance that is not an animate product of biotechnology and that, in the Ministers' opinion, is contained so as to satisfactorily protect the environment and human health in Canada and is:

(a) manufactured and consumed at the site of manufacture;

(b) involved in two sites by being manufactured at one site, transported to the second site, and consumed; or

(c) imported, transported directly to the site of consumption, and consumed.

*"Contained Export-only Substance"* means a substance that is not an animate biotechnology product and is manufactured or imported for export only and that, in the Ministers' opinion, is contained so as to satisfactorily protect the environment and human health.

The Table agreed to a cut-off for "sufficient containment" of an absolute release limit of 1 kg/day per site to the aquatic environment. The type of information that would be required should sufficiently characterize the total quantity released, waste treatment methods being employed, the media to which the substance is discharged and the dilution factors that apply. The stewardship practices associated with handling, cleaning and disposing of packaging associated with the substance must also be addressed. All processes involving the notified substance must be addressed.

## Management of Site-limited Intermediate Substances

The proposed framework for notifying site-limited intermediates would be identical to that for the R&D substances (Section 3.2.3(i)).

The structure proposed by government includes a requirement to demonstrate "sufficient containment" and the elimination of data requirements (hydrolysis as a function of pH, ready biodegradation, acute mammalian toxicity). The overall notification scheme follows that laid out for R&D substances, including data requirements and structure (see Section 3.2.3(ii)). Government has stated that the "sufficient containment" criteria provide better overall protection of human health and the environment in a Canadian context.

## Management of Export-only Substances

During these consultations, the treatment of export-only substances demonstrated that there were both policy and regulatory framework issues that require careful consideration. These concerns were summarized by the PAG.

The PAG has expressed concern about the ethics of the proposal to reduce data requirements for export-only substances. More specifically, the PAG questions the justification for eliminating any requirements for test data from the final notification schedule of

export-only substances. The PAG believes that this move may weaken the scientific information available for the substances' assessments, as well as send a symbolic message that Canada is subscribing to the "not in my back yard" philosophy.

It has been noted that the government's authority extends only as far as those substances within Canada's borders; however, the government's jurisdiction would not be breached if the existing level of testing requirements were simply maintained. That is, since these minimal requirements for test data were acceptable under the original NSN Regulations, then they are still within the government's scope today.

Additionally, the Table has agreed that there currently exists no mechanism for sharing data with receiving jurisdictions unless controls have been imposed. However, maintaining the current level of rigour and testing of export-only substances is consistent with the stated objective of developing international information-sharing agreements.

The PAG recognize that it is desirable to have export-only substances manufactured in a country such as Canada where a new chemical assessment scheme exists. However, the PAG feel that it would be counterproductive to weaken the effectiveness of that system in the process of attracting manufacturers. Another concern raised by the PAG was that inadequate consideration had been given to workplace safety issues.

The structure proposed by government includes a requirement to demonstrate "sufficient containment" and the elimination of data requirements (hydrolysis as a function of pH, ready biodegradation, acute mammalian toxicity). The overall notification scheme follows that laid out for R&D substances, including data requirements and structure (see Section 3.2.3(ii)). Government has stated that the "sufficient containment" criteria provide better overall protection of human health and the environment in a Canadian context. The revised government proposal continues to allow for scrutiny of an export-only substance, unlike the new substance assessment systems currently employed by other countries. There is concern that if the Canadian system for assessing export-only substances is too onerous, there will be a greater incentive for manufacturing these materials elsewhere.

Consensus was not reached on the issue of export-only substances.

#### Table Recommendations

48. The framework for the notification of "Contained Site-limited Intermediate Substances" should be identical to that for R&D substances.

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.

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.

51. The definitions for "site-limited intermediate" and "export-only" substances that the Table has agreed to (see above) should be accepted and used in the revised NSN Regulations.

### *3.2.4 Assessment Periods*

Assessment periods for each schedule are written into the Regulations. A balance must therefore be sought between providing the NS Program staff with sufficient time to carry out an evaluation and not delaying the notifier's ability to carry on with business. Assessment periods are counted in calendar days and allowances are made for weekends and statutory holidays.

#### Table Deliberations

The government representatives indicated that the actual assessment periods are short. With the current rate of notifications, assessment periods pose a significant challenge for managing program resources.

Government is proposing a new scheme for assessment periods based on notification contents and trigger quantities in the proposed

structure of NSN schedules. Proposed changes to the assessment periods reflect more accurately the length of time required to process and evaluate NSNs under the new framework. Generally, the greater the volume or the closer a notification is to the final tier, the more attention and therefore the more time that are required.

Government has consulted with NSN evaluators on the adequacy of the current and proposed assessment periods. Environment Canada and Health Canada believe that changes to the assessment periods for the proposed levels of chemicals and polymers will provide specific benefits for various proposed levels and an overall benefit of simplifying the NSN process.

Industry representatives felt that the proposed assessment periods for entry level notifications and PLCs are too long. They urged Environment Canada and Health Canada to review their internal procedures so that when assessments are completed before the end of the assessment period, notifiers are informed immediately, and the periods are terminated.

### Table Recommendations

52. The assessment periods as described in Table 3.5 should be established.

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.

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.

## Table 3.5: Proposed Assessment Periods for New Substance Notifications

| | Proposed Level | Proposed Period (days) | Non-NDSL Triggers (kg/year) | NDSL Triggers (kg/year) |
|---|---|---|---|---|
| **Chemicals** | Entry | 30 (NDSL) / 5 (non-NDSL) | 100 | 1 000 |
| | Intermediate | 60 | 1 000 | 10 000 |
| | Final | 75 | 10 000 | 50 000 |
| **Polymers** | Entry (non-low concern), low concern | 30 | 1 000 | 1 000 |
| | Final (non-NDSL) | 60 | 10 000 | 10 000 |
| | Final (NDSL only, low exposure) | 60 | | [50 000] |
| **Special Categories*** | All | 30 | All | |

* Special Categories include R&D, site-limited intermediates and export-only substances.

### *3.2.5 Facilitation of Waivers for Substances Used for a Prescribed Purpose*

It is recognized in CEPA that it may not be necessary to provide all of the information set out in schedules in every case. Information can be waived under section 81(8)(b) of CEPA if the notified substance is to be used for a prescribed purpose. In order to utilize this provision, regulations need to be in place that set out the purpose for which a substance must be used so as to permit the waiver of information (section 89(1)(f)).

The concept in this CEPA provision is that a risk assessment can be carried out in the absence of some information that would normally be required, on the basis of the inherent use of the substance. Information that could be waived may be associated with the assessment of exposure or of hazard (or effect).

If the information that is requested to be waived is related to the assessment of exposure, then the prescribed use must be well characterized with regard to all types of exposure associated with this use.

If the information to be waived is related to the assessment of hazard or effect, this would require the exposure to be sufficiently low so that the risk associated with the substance would be negligible, making it unnecessary to characterize the hazard or effect further.

#### Table Recommendations

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.

### *3.2.6 Record-keeping and Enforcement*

A working group was established within Environment Canada (separate from this consultation) to address issues that had been identified concerning the enforceability of the NSN Regulations over the past number of years. There was one particular issue that the working group felt should be referenced in this report. It is the need for better clarity as to the type of information that a notifier will maintain so that it will be readily available for an enforcement officer to review.

When the matter was presented to the Table, it became apparent that a relatively short addition to the NSN Regulations would be sufficient to accommodate the need. It was agreed that the more detailed explanations would best be dealt with in the Guidelines document. This approach will be necessary in order to address the various types of notifiers, including Canadian agents for foreign suppliers, as well as the wide range of record-keeping systems in use. Industry expressed the importance, from its standpoint, of obtaining clarification as to the type of records necessary, as well as the length of time that they need to be maintained.

The type of wording that the working group recommends for inclusion in the NSN Regulations is: “The company or agent shall maintain all appropriate records or other documents on-site in Canada for at least five years following the end of the calendar year in which they are made.” What is meant by the words “appropriate” and “on-site” would be explained in the Guidelines.

The Table is in general agreement with the inclusion of such a recommendation.

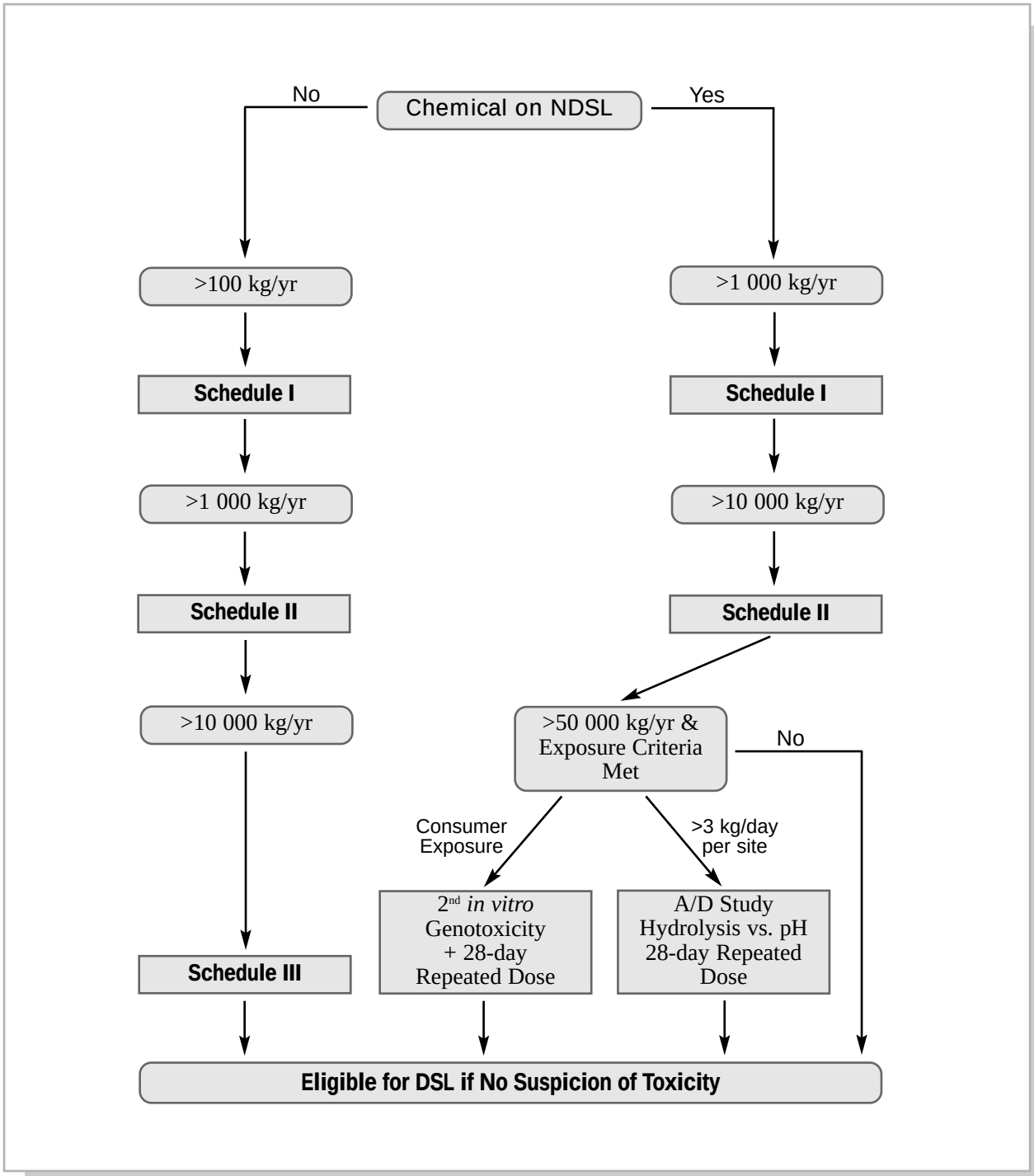
#### Table Recommendations

56. The revised NSN Regulations should include wording, such as that above, which states the obligation of the notifier / agent to maintain in Canada, for at least five years, appropriate records that are available for inspection.

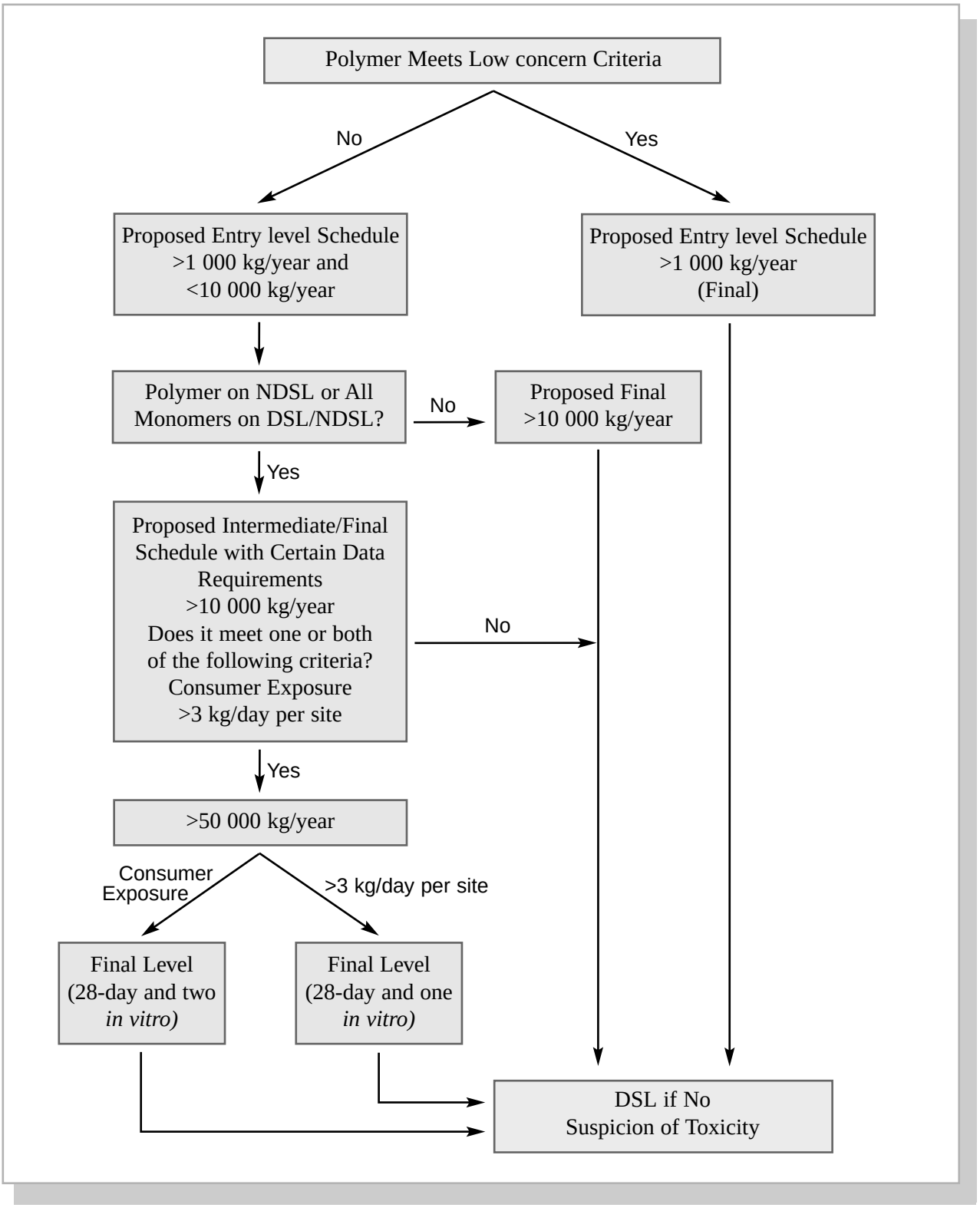
57. The revised NSN Guidelines should clarify the type of information the notifier must maintain.

The following three figures summarize, from Section 3.2, the proposed chemical and polymer regulatory frameworks.

## Figure 3.2: Proposed Chemical Framework

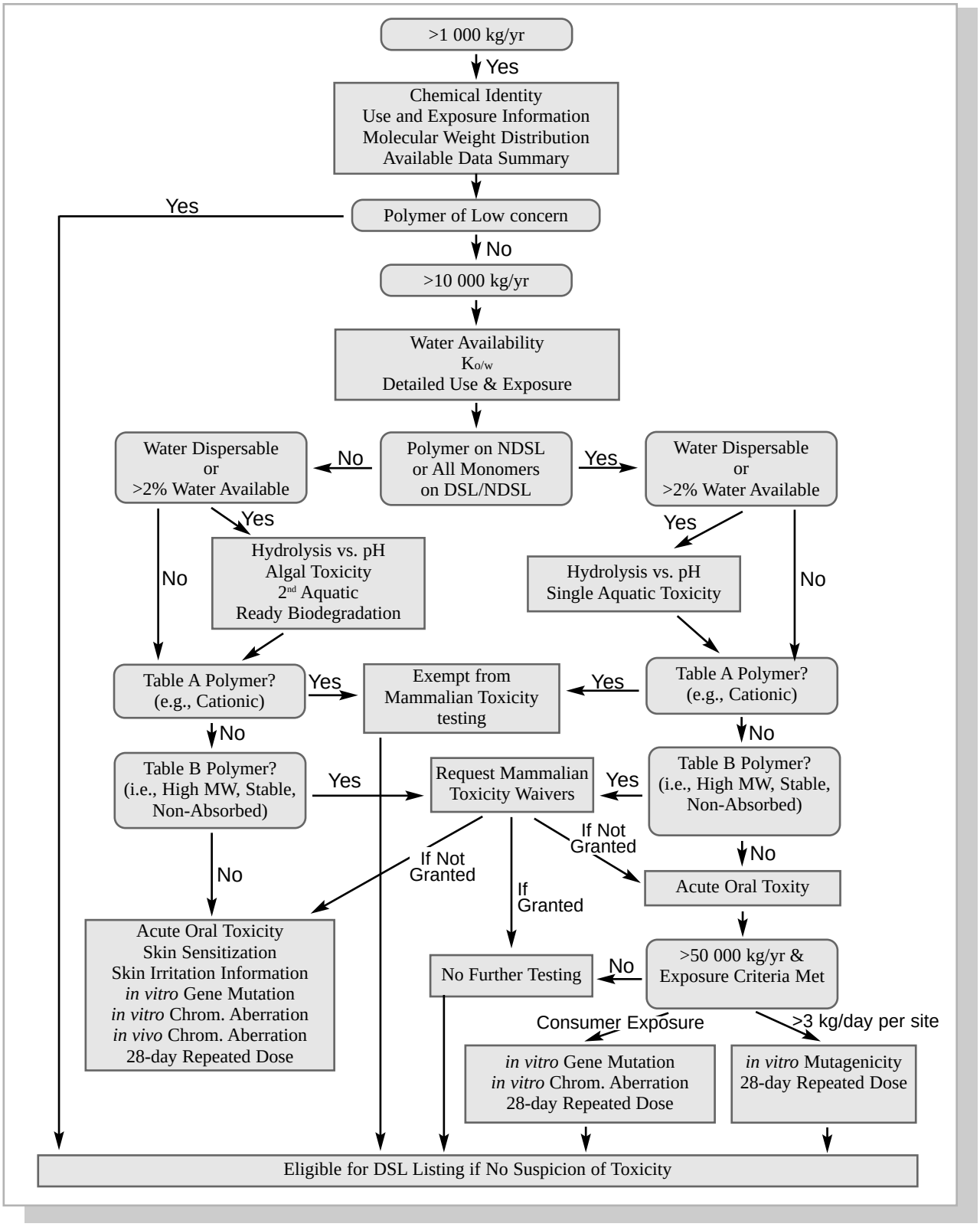


## Figure 3.3: Proposed Polymer Framework



## Figure 3.4: Proposed Polymer Framework Including Data Requirements

This figure provides a more comprehensive presentation of the framework shown in Figure 3.3, incorporating details as to the data required at each decision point.



## 3.3 Transparency of the NSN Regulatory Process

### Background

Transparency refers to the "state of openness" of a particular system. As a generalization, an open or transparent system is one that:

- provides relatively easy access to policies, practices, procedures and decisions;
- ensures that all documents are comprehensive and written in plain language;
- provides appropriate opportunities for stakeholders to participate fairly, in a timely manner and at a reasonable cost in the development, implementation and monitoring of the laws, policies, practices, procedures and decisions;
- provides interested parties with access to justifications for the decisions taken that impact on their well-being (e.g., legal, economic, environmental, health, social); and
- allows for appropriate cost-effective review / appeal mechanisms.

Principles of transparency require a delicate balancing of economic, environmental and social interests. For example, PAG consider access to information a fundamental prerequisite to full and effective participation in environmental law and policy development. Industry representatives argue that access to confidential information must be considered in light of the potential harm / economic loss that a company may sustain if information of this type became freely available to competitors. Industry considers proprietary data an extremely valuable commodity representing a long-term investment in research, manufacturing experience, marketing strategy and business development. Industry perspectives on the extent of openness as it relates to access to proprietary data will undoubtedly differ from PAG perspectives on that same issue.

The Table discussed opportunities to improve transparency by examining (i) NSN information relating to regulations, guidelines and policy documents; (ii) confidential business information and publication of risk assessments; and (iii) mechanisms for challenging assessment decisions.

### (i) NSN Information — Regulations, Guidelines and Policy Documents

#### Background

CEPA includes provisions that address various aspects of transparency, including information on the NSN Regulations and NS Program, information access, CBI, information disclosure and masking the name of certain substances being listed on the DSL. Most of the information that is available can be accessed through the CEPA Environmental Registry web site (**www.ec.gc.ca/CEPARegistry**) and the NS Program web site (**www.ec.gc.ca/substances/**). There are also draft policy documents related to the NS Program that are as yet unpublished.

It is not currently possible to obtain the risk assessment reports on which decisions are based, except through the federal *Access to Information Act*.[20]

#### Table Deliberations

Implementing transparency principles requires human and financial resource commitments. The more transparent the system, the more human and financial resources and time that are required for its administration. Resource considerations are particularly acute in the current NS Program because Program managers must allocate resources to address transparency needs while meeting legally mandated timelines for making NSN decisions. The Table attempted to balance these legitimate considerations in providing recommendations on how to improve transparency within the NS Program.

Table members agree that the current NS Program lacks an appropriate level of transparency. The Table agrees that reducing the complexities of the current NSN Regulations and improving administrative efficiencies are essential tools for promoting transparency in the NS Program. Both of these concerns are discussed elsewhere in this report, particularly in Section 3.2.

### Table Recommendations on 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 substances 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.

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.

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, PSLs) that apply to a particular substance in one easy search operation.

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 through partnerships with stakeholders.

### Table Recommendations on Improving Transparency of NSN Policy Documents

62. Several policy documents/statements should be developed in order to comprehensively describe and explain how the NS Program operates. These include:

- a comprehensive, understandable policy statement describing the environmental and health risk assessment methodologies used by Environment Canada and Health Canada for the NSN assessment phase;
- examples of exposure scenarios used for assessing potential human exposure and potential exposure in the environment;
- how the NS Program operationalizes the precautionary principle and pollution prevention principles;
- how the NS Program interprets "toxicity" and "suspicion of toxic" in making its risk assessments;
- the policy employed by Environment Canada and Health Canada in treating confidential information, including CBI, 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) below);
- 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[21] [USA], exchanges with the National Industrial Chemicals Notification and Assessment Scheme[22] [Australia]).

### (ii) Confidential Business Information and Access to Risk Assessments

#### Background

The current NSN Regulations require notifiers to submit certain types of data as part of their notification package. Some of the information submitted can be claimed as CBI by the notifier. Items that can be claimed as CBI include substance identity, company name, whether the substance is manufactured and/or imported and in what quantity. Information related to health and environmental protection cannot be claimed as CBI. There are provisions in the Masked Name Regulations to protect the chemical name and corresponding CAS Number. To have a substance listed on the DSL with a masked name, the claimant must provide written justification and an appropriate name, to meet the requirements of the Masked Name Regulations. Environment Canada will not accept a claim for a masked name if the substance name has been disclosed anywhere in the public domain (e.g., inventories of other countries).

#### Table Deliberations

Industry is extremely sensitive about disclosure of CBI because disclosure to competitors could easily mean the loss of a competitive edge gained by substantial investments in R&D. The PAG argue that opportunities for public participation are meaningless without full and fair opportunity to access information needed to participate effectively. The Table agrees that the existing requirements outlined in the Masked Name Regulations for handling masked name entries to the DSL are appropriate. Similarly, the ability to claim substance volume, company name and manufacture/import information as confidential is seen as acceptable.

The publication of assessments would inform interested parties that new substances are being introduced to Canadian commerce. The Table explored creative ways of disclosure of assessment information while still protecting CBI, including the publication of assessment reports after confidential information has been removed. However, in order to remove CBI, regulators and notifiers would need to work closely together. This alliance would be poorly perceived by the public. This approach would also be resource-intensive for both parties. The Table did not pursue this approach further.

The Table considered the option that Environment Canada and Health Canada prepare summaries of the assessment report with a listing of information or studies submitted. While resource implications are recognized, this is the preferred option of the Table. In the published assessment, the substance would be identified either by name and CAS Number or, in the case of substances claimed confidential, by masked name and accession number and would focus on health and environmental information. The CAS Number or accession number could be used as a reference by anyone wanting to challenge the assessment by submitting new information under section 70 of CEPA. Health Canada or Environment Canada could then reassess the substance, considering the new information, and change the assessment outcome as necessary.

Summary assessment reports could be produced on some or all of the notifications received. The Table discussed which notifications should be summarized and made available, cognizant of the resource implications involved. Summarizing and publishing all assessment reports would require too many resources, and many of the reports would not provide significant information. Publication of reports being listed on the DSL would provide information on those substances that are being commercialized. Reports on substances subject to controls would also be published regardless of the level of notification. To save resources, PLCs could be either listed simply as PLCs without an assessment or alternatively not published at all.

#### Table Recommendations

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 CBI received from another source.

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.

### (iii) Mechanisms for Challenging Assessment Decisions

#### Background and Table Deliberations

Currently, CEPA does not have a formal appeal mechanism for challenging a regulatory decision relating to the assessment of a new substance. A section 70 submission by a person engaged in the commerce of new substances could trigger a reassessment of the substance if the new information submitted were found to be relevant. The option is always open to challenge an assessment via an application for judicial review in the federal courts.

The Table did consider the merits of recommending a formal appeal mechanism but recognizes that changes to CEPA would likely be required to implement this process. The Table recognizes that substantive amendments to CEPA such as a new substances assessment appeal mechanism are not likely to happen prior to the statutory review of CEPA in 2005. PAG representatives strongly believe that a formal appeal mechanism is vital to ensuring the credibility and transparency of the assessment process.

Table Recommendation

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.

## 3.4 Improving Responsiveness of the NSN Regulations and NS Program in the Global Context

#### Background

There are currently at least eight countries/legal jurisdictions that have instituted a unique domestic chemical inventory and a process for the notification and assessment of new substances. In all cases, these have been driven by the objectives of protection of human health and the environment. Although they have similar goals, the methods of accomplishing them vary considerably. The proliferation and variation of chemical control systems sometimes lead to unnecessary duplication of efforts. Many companies now market their products globally, giving rise to multiple notifications of the same substance. Significant effort is expended by both the notifying company in preparing a notification dossier and the government authority in reviewing it.

Canada has long been party to international cooperation on chemicals, including agreements on MAD and the principles of GLP. More recently, new international initiatives are emerging that are advancing concepts such as MAN in the interest of achieving improved efficiencies while maintaining or improving human and environmental health protection within participating countries. Examples of the initiatives in which Canada is involved include:

- an OECD Task Force on New Industrial Chemicals that is undertaking a number of initiatives, ranging from information and work-sharing, through bilateral/multilateral arrangements, to management of CBI;
- the “Four Corners Agreement” (4CA) between Canada and the United States that provides a formal mechanism for sharing data and assessments to allow for reductions in the data required for their notification in either country; and
- a Canada–Australia Bi-lateral Arrangement that is currently being set up for purposes similar to the 4CA and that acknowledges similarities in notification systems and market conditions.

Most sectors of Canadian industry depend on imports for access to current novel and less harmful chemical technologies in order to innovate and compete in world markets. While chemical production in Canada is considerable, the variety of chemicals produced is limited. Furthermore, Canada is a relatively small market in comparison with its major trading partners. The majority of chemical imports originate in the United States or the European Community, where notification and assessment will have taken place.

## Table Deliberations

Table members agreed on the desirability of pursuing harmonization among national notification and assessment schemes. The potential benefits for Canada are many, including gaining access to sound science for decision-making, minimizing duplicative effort, greater efficiency and effectiveness, and greater ability of Canadian industry to compete with producers of chemicals and manufactured products in world markets. Members acknowledged the significant challenges that harmonization represents for Canada. It requires the cooperation and commitment of other countries. In addition, there are significant technical and scientific challenges that need to be addressed, including differences in data sets used in assessments, risk assessment methodology, exclusions and exemptions from notification, and protection of CBI. Table members also noted the significant policy challenges that harmonization poses for all countries. Harmonization must lead to a raising of health and environmental protection standards and not drop to the "lowest common denominator" in terms of science-based decision-making. An alternative perspective was that harmonization provides an opportunity for Canada to advocate higher standards that ensure that all new substances in international use receive the same rigour in assessments. It was felt that this could be accomplished while retaining Canada's legislative authority to make decisions that are most appropriate for protection of Canadian health and environment.

The Table reviewed international efforts in which Canada is participating. The Table observed that these efforts are proceeding without having formally shared with stakeholders a clear vision of harmonization relating to NSN or a strategic plan that describes near- and long-term goals, priorities and the means to achieve them. Table members noted that this was a significant limitation to cooperation with stakeholders.

The Table noted that a strategic plan must be flexible and responsive to current and future international initiatives (including those in the EU[23]). Furthermore, based on experiences with harmonization of efforts for existing substances, the Table suggested that an initial objective for new substances should be the pursuit of international harmonization of hazard assessments rather than risk assessments that require a means for handling differences in exposure characterization. In the longer term, the strategic plan should clarify Canada's interests regarding the potential for broader harmonization.

In the context of notifications and assessments taking place in other jurisdictions, the Table noted the opportunity for Canada to be one of the largest beneficiaries from the advancements in information and work-sharing, standardization of notifications and assessment reports, and related initiatives. Gaining access to and utilizing assessments from other countries are anticipated to result in validation of processes, strengthened assessment capacity, cost savings and improved efficiencies.

In order to realize the potential benefits from cooperation with other countries, Canada will be required to make significant investments and commitments to ensure it can play a meaningful and influential role. This would involve the types of science investments described in Section 3.5(iii) below.

The Table agrees that the current revisions to the NSN Regulations and Guidelines should, wherever appropriate, encourage the attainment of international harmonization.

## Table Recommendations

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 NSN 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.

## 3.5 Service Delivery

### Background

Table members recognize that service delivery for the NS Program operates within a legislative framework (CEPA and the NSN Regulations), and, as such, compliance is mandatory. Compliance with the legislation is achieved through compliance promotion initiatives and enforcement. A notifier who chooses to import a new substance into, or manufacture a new substance in, Canada is obliged to provide prescribed information. Health Canada and Environment Canada are required to perform assessments, make decisions to protect human health and the environment and ensure compliance with the law. Within this framework, those charged with the administration and enforcement of the NS Program deliver a service to a wide range of stakeholder groups with significantly different needs. This section deals with how the regulations are delivered, not the content of the regulations or their enforcement (see Environment Canada's CEPA Enforcement and Compliance Policy,[24] currently being revised).

The Table agreed that a "quality service" approach may both enhance the effectiveness of the Regulations to protect human health and the environment and reduce the negative perception that the Regulations are a barrier to investment and innovation (see the New Substances Notification Impact Working Group Report and the Cost Recovery Report[25]) when balanced with improved enforcement of the Regulations. While outside the scope of these consultations, the enforcement function is recognized by the Table as an integral part of a quality service approach to achieving the CEPA objectives for new substances.

The Table recognized that current service delivery efforts are generally satisfactory and noted that Environment Canada and Health Canada have undertaken a number of initiatives aimed at improving service delivery. Nevertheless, all Table members agree that various aspects of service delivery can be improved. This section of the report provides recommendations on how this may be done without impairing the effectiveness of the NSN Regulations in protecting health and the environment, taking into consideration the needs of all stakeholders, and at acceptable cost to the Program and its stakeholders. It addresses the way in which advances in leadership, the management of service delivery, information technology and innovation might be used to meet service delivery targets.

### Table Deliberations

#### (i) Quality Service

Quality service management practices to define and meet the needs of each stakeholder group need to be developed across the Program. For example, while industry representatives reported excellent technical feedback, service delivery is not uniform across the Program. The Program has established confidence in its ability to meet legislated timelines; however, measurable service / performance indicators and a complaints resolution mechanism would be value-added components. These service / performance indicators for health and the environment must recognize the legislated mandate and the Program's responsibility to the Canadian public by also addressing their concerns about the effectiveness of the regulatory system. A quality service framework should provide for a better, cheaper and safer system.

In reviewing quality service issues, the Table referred to the Auditor General of Canada's April 2000 Report on Service Quality[26] and "Achieving Citizen / Client-Focused Service Delivery: A Framework for Effective Public Service Organizations,"[27] developed by the Treasury Board Secretariat and the National Quality Institute.

Measurable service / performance indicators should be employed to help identify opportunities for continuous improvement. These indicators are critical for ensuring the effectiveness of the Program in protecting the health and

environment of Canadians and for improving the internal efficiency and administration of the Program. These indicators must be selected and implemented in an open, transparent and accountable manner. They must also be periodically reviewed against international service delivery initiatives (e.g., within OECD).

While timelines are important to some stakeholders, there are other measures of service quality. The Table recognizes that a single window may not be feasible in a program where two ministers share responsibility. The fact that there are two departments with structural and organizational differences has sometimes been a source of frustration. Access to the data required for transparency of the Program could be handled better with a service quality standard that addresses this.

The Table agrees that the NS Program is not uniformly understood by all stakeholders. Confidence in the Program could be improved by dedicating increased resources to education, training and information provision. Different levels of education, training and information will be needed for different stakeholder groups, and all these needs should be recognized and addressed through the various media available to the Program. Education and training should be used not only to increase confidence in the Program, but also to promote compliance with the Regulations. Better education and training for industry should help raise awareness of the need to comply with the NS Program and create a more level playing field. A simple process, preferably electronic, for feedback that is user-friendly, accessible, used constructively and well publicized would also improve service delivery.

Partnerships with various stakeholder groups should be employed to increase the effectiveness of training and information dissemination; however, there must be dedicated resources for this activity. Secondments between the Program and industry and PAG could create benefits for all, such as the exchange of valuable expertise and raising stakeholder confidence in the Program. Regulators should work with stakeholders to explore ways in which such secondments could be facilitated without having a negative impact on the confidentiality of competitive business information supplied for notifications.

Table Recommendations

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.

68. Service / performance indicators should be developed and reviewed periodically against international service delivery initiatives (e.g., within OECD).

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.

### (ii) Leadership for Cultural Change

A key concept of a quality-based approach to service delivery is organizational development and the understanding of its current “culture.” This enables the strengths and challenges of the organization to be identified and the pathways and opportunities for change to be planned.

The Table recognized that NSN staff deal with technical, scientific and administrative issues under challenging legislated deadlines. While stakeholders report incidents of exemplary service, the delivery is not always uniform. A commitment to “service culture” in the processing of applications that emphasizes the importance of quality service principles can positively contribute to maximizing human health and environmental protection.

Some industry stakeholders continue to perceive the NSN Regulations as a barrier to innovation, foreign direct investment and trade. A cultural shift that focuses on, and consistently promotes, quality service delivery should reduce these negative perceptions while maintaining or improving health and environmental protection.

A cultural shift will also improve the commitment to openness, transparency and accountability. While the issue of transparency is addressed elsewhere in this report (see Section 3.3), it is identified here as a third area that may benefit from cultural change. Recent improvements to the NSN Regulations web site have increased the Program's transparency, and implementation of the Table recommendations detailed in Section 3.3, including annual statistical reporting, will provide further needed improvement. The Table agrees that the Program should report annually, in addition to statistical data, on its progress in establishing and meeting service standards, continuous improvement goals, measurable service / performance indicators, education and training activities, and its impact on sustainability. These measures are cost- and resource-intensive and must be appropriately funded.

Cultural change requires senior management visibility, participation in communicating the values to all stakeholders, commitment and accountability.

### Table Recommendations

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.

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 NSN staff together as an option to improving service delivery should be considered.

## (iii) Innovation

This section addresses three areas of innovation: information technology, science and the use of novel strategic approaches to achieving the goals of the NSN Regulations.

The Canadian government outlined its commitment in the 1999 Speech from the Throne[28] to becoming a "model user of information technology and the Internet," with government services available online by 2004. The Table reviewed several innovative ways of improving the effectiveness and efficiency of service delivery. It sought ways to:

- fully exploit the potential of the growth in information technologies;
- reduce the direct costs to comply with the NSN Regulations; and
- encourage broader compliance.

The NSN Regulations delivery service was designed as a paper process. Information technologies have been added, but it remains a paper process facilitated by electronics. Greater use of new technologies could allow the government and stakeholders to realize significant service quality improvements and efficiencies.

Most of the information supplied by applicants is increasingly available in electronic format. Industry wants the option to file applications electronically with CBI fully protected, track the application's progress and respond to questions electronically. The feasibility of redesigning the whole process to one centred on electronic communication should be examined and implemented if found to be beneficial. This would enable industry and government to realize considerable cost and time savings. Information sharing between Program staff would be simplified, scheduling and tracking would be more efficient, and it should be possible to extract data for transparency and performance accountability automatically.

Furthermore, a "smart" system (an interactive, intuitive and responsive computer system) could facilitate electronic filings and simplify the perceived complexities of schedules that are currently part of the NSN Regulations by taking a more intuitive and interactive approach. It should also minimize errors and omissions, reduce the need for training and reduce the perception that complexity is a barrier to compliance.

Noting that secure electronic filing and a "smart" system will require the development of extensive new software, the acquisition of

hardware components and their integration with current systems, the Table recognizes the prudence of a phased approach, such as filing by disk until other more expensive improvements are in place. Environment Canada and Health Canada are encouraged to pursue their efforts for obtaining funding to assist them in implementing the above-mentioned measures.

Another way of reducing the direct costs to applicants is by facilitating the opportunity to share data among applicants. International cooperation agreements allow notifiers to have access to data packages filed for the same or similar substances in other countries. Development of the existing elective information-sharing agreements using a "smart" system that encourages the use of common data packages should be explored. A barrier to increased data sharing is concern for the protection of CBI. A "smart" system providing a "brokerage" between the current and an earlier applicant should be explored.

With regard to scientific innovation, the March 2001 Report of the National Round Table on the Environment and the Economy entitled *Managing Potentially Toxic Substances in Canada*[29] recommends significant increases in science expenditures, improved coordination among involved institutions and increased scientific staffing to better understand and judge the scientific information government receives, advances in scientific knowledge and the increasingly complex assessment issues.

The Table agrees that the scientific issues are becoming more complex and that additional funding and better coordination among government agencies may be required for government to keep up with the changes and discoveries and fulfil its obligation to protect the health and environment of Canadians. At the same time, the Table agrees that some fundamental changes are needed to avoid a situation where the number and complexity of tests requested by the regulators (in the evaluation of new chemicals) increases with the growth in science to the point where it becomes unnecessarily cumbersome. Governments also have an obligation to their citizens to develop and validate current assessment methods with a view to making them more effective, as exemplified by the Commission of the European Communities White Paper, *Strategy for a Future Chemicals Policy*.[30]

The Table believes that the NS Program must seek the resources to strengthen its scientific capacity to meet its obligations:

- to develop and validate test methods, screening procedures and modelling techniques;
- to assess the adverse effects of chemicals (e.g., low-level, long-term and interactive);
- to improve existing and develop new toxicological methods that better predict a chemical's hazard and do so more quickly and more cheaply than current procedures; and
- to continually simplify, improve and validate the effectiveness and efficiency of the risk assessment process itself.

The Table recognizes that similar efforts are already well established or proposed elsewhere in the world, so one way to achieve the new and improved methods is through work sharing with other nations with high environmental and human health standards and participation in international efforts. These issues are detailed in Section 3.4 of this report. For Canada to play a role in this process, it must both gain far more knowledge about the various ways in which our trading partners assess hazards and also increase the international profile of our procedures.

### Table Recommendations

72. The feasibility of redesigning the program delivery to permit secure electronic filing with access simplified by a "smart" system should be examined.

73. Information sharing should be facilitated and international cooperation continued and possibly expanded.

74. Opportunities for secondments among government and stakeholders should be explored and pursued where mutually beneficial.

75. Government should work with stakeholders to examine innovative measures for ensuring compliance with the NSN Regulations.

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.

# 4. Endnotes

[1] Government of Canada, *Canadian Environmental Protection Act (CEPA) Part 2 — Toxic Substances: Substances New to Canada* (1999); available at: **www.ec.gc.ca/substances/nsb/eng/reg_e.htm**

[2] Government of Canada, *New Substances Notification Regulations* (July 1994); available at: **www.ec.gc.ca/substances/nsb/eng/reg_e.htm**

[3] Environment Canada, *New Substances web site*: **www.ec.gc.ca/substances/nsb/eng/biag_e.htm**

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[5] Environment Canada, *Toxic Substances Management Policy* (June 1995); available at: **www.ec.gc.ca/toxics/en/index.cfm**

[6] Environment Canada, *Toxic Substances Management Policy* (June 1995).

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[8] Environment Canada, *ARET (Accelerated Reduction/Elimination of Toxics), "Voluntary Action on Toxic Substances"*; available at: **www.ec.gc.ca/aret/homee.html**

[9] Organisation for Economic Co-operation and Development (OECD), *OECD Test Guideline 407, Repeated Dose 28-day Oral Toxicity Study in Rodents* (Updated Guideline, adopted July 27, 1995).

[10] Environment Canada, *Establishing a National Agenda on the Scientific Assessment of Endocrine Disrupting Substances 5NR Workshop Report* (February 2000); available at: **www.ec.gc.ca/eds/fact/index.htm**

[11] Government of Canada, *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* (1993); available at **www.ec.gc.ca/substances/nsb/eng/gui_e.htm**

[12] Organisation for Economic Co-operation and Development, Environment Directorate, Environmental Health and Safety Division, *OECD Minimum Pre-Market Data Set*; available at: **www.oecd.org/EN/home/0,,EN-home-0-nodirectorate-no-no-no-0--no-,00.html**

[13] Organisation for Economic Co-operation and Development (OECD), Environment Directorate, Environmental Health and Safety Division, *Guidelines for Testing of Chemicals*; available at: **www.oecd.org/EN/document/0,,EN-document-524-14-no-15-24345-524--no-00,00.html**

[14] W.M.S. Russell and R.L. Burch, *The Principles of Humane Experimental Technique* (London, UK: Methuen, 1959).

[15] Organisation for Economic Co-operation and Development (OECD), *OECD Test Guideline 420, Acute Oral Toxicity — Fixed Dose Method* (Original Guideline, adopted July 17, 1992); *OECD Test Guideline 423, Acute Oral Toxicity — Acute Toxic Class Method* (Original Guideline, adopted March 22, 1996); *OECD Test Guideline 425, Acute Oral Toxicity: Up-and-Down Procedure* (Original Guideline, adopted September 21, 1998).

[16] Organisation for Economic Co-operation and Development (OECD), *OECD Test Guideline 401, Acute Oral Toxicity* (Updated Guideline, adopted February 24, 1987).

[17] Organisation for Economic Co-operation and Development (OECD), *OECD Test Guideline 429, Skin Sensitisation: Local Lymph Node Assay* (Draft New Guideline, November 2000).

[18] Organisation for Economic Co-operation and Development, Environment Directorate, Environmental Health and Safety Division, *Guidance Document on the Recognition, Assessment, and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation* (OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 19) (June 2000); available at: **www.oecd.org/EN/home/0,,EN-home-0-nodirectorate-no-no-no-0--no-,00.html**

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[20] Government of Canada, *Access to Information Act* (1985); available at: **laws.justice.gc.ca/en/A-1/index.html**

[21] Environment Canada and Health Canada, *New Substances Notification Advisory Note 01-99, Renewal of the Agreement for Sharing of Information Between the U.S. Environmental Protection Agency (USEPA), and Environment Canada (EC) and Health Canada (HC) (Four Corners Agreement)* (1999); available at **www.ec.gc.ca/substances/nsb/eng/advisory_e.htm**

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[25] Environment Canada, *Discussion Paper: Cost Recovery for the CEPA New Substances Notification Program (Chemicals and Polymers)* (1998); available at: **www.ec.gc.ca/substances/nsb/eng/rec_e.htm**

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[30] Commission of the European Communities, *Strategy for a Future Chemicals Policy, Commission of the European Communities White Paper* (February 2001).

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[32] Environment Canada, *Environmental Leaders 2: Accelerated Reduction/Elimination of Toxics (ARET)* (1997), p. 36.

[33] Environment Canada, *Environmental Leaders 2: Accelerated Reduction/Elimination of Toxics (ARET)* (1997), p. 36.

[34] Environment Canada, *Environmental Leaders 2: Accelerated Reduction/Elimination of Toxics (ARET)* (1997), p. 36.

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[38] M. Swanson and A. Socha, *Chemical Ranking and Scoring: Guidelines for Relative Assessments of Chemicals* (1997), p. 120.

# APPENDICES

## A.1: Table Members

### Federal Government

**Andy Atkinson (alternate for Environment Canada)**
New Substances Branch
Environment Canada

**Ranjan Bose (alternate for Health Canada)**
Chemicals 2 Section
New Substances Assessment and Control Bureau
Product Safety Programme
Healthy Environments and Consumer Safety Branch
Health Canada

**Irene Caldwell**
New Substances Branch
Environment Canada

**Dave McBain**
New Substances Branch
Environment Canada

**Gary McGee (alternate for Industry Canada)**
Manufacturing Industries Branch
Industry Canada

**Shaunalea Savard**
Chemicals 3 Section
New Substances Assessment and Control Bureau
Product Safety Programme
Healthy Environments and Consumer Safety Branch
Health Canada

**Jackie Sitwell**
New Substances Assessment and Control Bureau
Product Safety Programme
Healthy Environments and Consumer Safety Branch
Health Canada

**Tony Stone**
Manufacturing Industries Branch
Industry Canada

### Industry

**Ilse Bacchus**
PPG Canada Inc.

**Ernie Henderson**
BASF Canada

**Allan Jones**
Industry Co-ordinating Group for CEPA

**Peter Marr**
Dominion Colour Corporation

**David Sheppard**
3M Canada Inc.

**Jack Soule**
Dupont Canada Inc.

**Don Wilke**
Procter & Gamble Inc.

### Public Advocacy Groups

**Dave Bennett**
Canadian Labour Congress

**Stephane Gingras**
Great Lakes United

**Jessica Ginsburg**
Canadian Environmental Defence Fund

**Jenny Hillard**
Consumers Association of Canada

**Brian Kohler**
Communications, Energy and Paperworkers' Union of Canada

**Burkhard Mausberg**
Canadian Environmental Defence Fund

**Fred Ruf**
Canadian Public Health Association

## Observer

**Yves Bourassa**
Regulatory and Economic Assessment Branch
Environment Canada

## Secretariat

**Linda Jones**

**Sheila McCrindle**

**Hajo Versteeg**

## A.2: Procedural Guidelines Adopted by the Table Members

During its first meeting, Table members agreed on the following set of "Guiding Principles" to help direct the consultative process:

- Multistakeholder Consultation (MSC) members have the right to help shape the substantive issues to be addressed at all MSC meetings, and the process for addressing them.
- MSC members have a right to be heard and an obligation to listen. Members do not have a right to dominate discussions or to promote their own particular agenda to the detriment of the MSC mandate.
- MSC members must be prepared to present their views in a constructive manner that fosters mutual problem solving.
- MSC members must agree to build on common ground and remain flexible in order to seek consensus in developing recommendations.
- MSC members must recognize and respect the legitimacy of views that differ from theirs.
- MSC members must strive to develop recommendations that can be realistically implemented.
- MSC members must have timely and equal access to a common information base.
- By definition, a consensus-driven exercise is not a "majority rules" exercise. When, despite best efforts, general agreement / consensus is not achieved on a particular issue / recommendation, the differing views pertaining to that issue / recommendation will be clearly and fairly recorded in the public record. For this to occur, individual members have an obligation to articulate their views clearly and concisely at MSC meetings. In this way, the Ministers of Environment and Health, who are ultimately responsible for acting on the recommendations of the MSC, can make fully informed decisions.
- Where consensus is achieved, MSC members have an obligation to support that consensus in its entirety. It is *not* appropriate for members to promote only those parts of the consensus that meet their own particular agenda.

**Table Members** are appointed by organizations that have been invited to participate in the consultations. Each invited organization was asked to nominate one or a number of delegates. Each organization has undertaken its own selection process and has put mechanisms in place to keep other interested parties informed on the progress of the consultations. MSC Members are expected to abide by the consultation principles outlined above.

The Environment and Health Canada representatives (the **Co-chairs** of this MSC) are ultimately responsible for delivering the results / outputs of this MSC to their senior management for full and fair consideration in amending the NSN Regulations. Where consensus is reached, the Co-chairs are responsible for vigorously promoting that consensus in its entirety to their senior management. Where consensus recommendations are not incorporated into the amended Regulations, the Co-chairs have a responsibility to fully explain to the MSC members the reasons for the deviation(s). The Co-chairs are responsible for ensuring that the MSC process has adequate resources to complete its task.

The **Secretariat** will undertake to:

- arrange all meeting logistics, including subcommittee meetings;
- provide secretarial services, including services at meetings;
- manage financial arrangements, including contracts with group members;
- contract out or conduct research if, and as, requested by the MSC;
- prepare briefing binders, including draft proposals if, and as, requested by the MSC;
- prepare draft Records of Decision / Action Items from meetings, which, initially, will consist of **brief** decision points, action items and follow-up activities, including assigned responsibilities (subject to the approval of the MSC, detailed meeting minutes are not necessary);
- provide information to any interested party (i.e., stakeholders not at the table, including federal and provincial / territorial agencies and members of the general public); and

- act as the clearinghouse to receive, distribute and manage information. A web site will be established to provide participants with electronic access to all relevant documents, meeting information and records of meetings. The web site will also house an area that will be accessible only by password, to allow members to share restricted information and to facilitate the drafting of MSC reports.

**The entire MSC Table will approve subcommittees and their membership.** Subject to direction from the Table, subcommittees will discuss in detail individual substantive issues and will draft reports / recommendations for discussion / approval by the MSC. The subcommittees will be supported by the Secretariat.

Each member (or group of members) should select an **alternate** to act as a replacement if necessary. *To ensure continuity, alternates will be used only as a last resort.* Alternates must be able to speak for the member / organization represented. Decisions reached by the Table are not to be revisited at subsequent meetings by individual members who missed a previous meeting, whether or not their alternate was present. The Secretariat will ensure that alternates are provided with all information given to the members, including meeting information, draft minutes and reports. Alternates are expected to maintain the confidentiality of the Table and must abide by the principles detailed in this document. Participatory funding will be paid to the alternate (if needed) as outlined in the funding policy when the alternate is replacing a member entitled to funding at the meeting.

Eligible participants will be compensated for their travel and accommodation expenses to attend meetings and for meals not provided during meetings. Original receipts must be provided with expense claims, which are to be submitted to Environment Canada (the Secretariat has all relevant information). **Eligibility for funding** is subject to Environment Canada's guidelines for participatory funding, which are contained in the document *Our Commitment to Effective Consultation*, May 1996. This document can be found on Environment Canada's web site at **www.ec.gc.ca/consult/policy%5Fe.html**. The facilitator will, in close consultation with the Co-chairs, be responsible for participatory funding decisions. Subject to overriding Environment Canada and Health Canada policy, the criteria for granting funding are based on demonstrable need, value for money and accountability. All aspects of the funding policy, including actual amounts granted to particular MSC members and accountability reports, must be completely open to public scrutiny (including the media). In the end, participatory funding decisions are subject to the principles of fairness, reasonableness, overall budget constraints, government policy and respect for public monies.

All **information**, except information that has historically been considered confidential (draft minutes, draft reports, etc.) will be made available to the public, including the media, if requested.

Subject to the agreement of the group, **observers** may sit in on meetings. Observers may provide input at meetings, *but* only if requested by the facilitator or the group (as opposed to individual members). Observers must respect all confidences of the process. The number of observers should be kept to a minimum, and observers cannot be seen to be disrupting the flow of the meetings. The most likely type of observer will be a technical expert who is approved by the Table as a member of a subcommittee. It may be useful for these individuals to attend some or all of certain Table meetings. Any member contemplating inviting an observer must first discuss the idea with the group or, at least, with the facilitator. Observers should not necessarily expect to attend meetings if they arrive without prior approval from the Table. Observers are not eligible for participatory funding.

Flexibility, understanding, respect and compassion are keys to the success of the MSC.

## A.3: Background and Supporting Documents

This appendix does not duplicate the documents referenced in Section 4 of the report, "Endnotes."

1. *Report of the New Substances Notification Impact Working Group*
   Environment Canada, 1999
   Available at:
   **www.ec.gc.ca/substances/nsb/eng/rec_e.htm**

2. *Discussion Document on Amendments to the CEPA New Substances Notification Regulations (Chemicals and Polymers)*
   Environment Canada and Health Canada, August 1999

3. *Importation and Manufacture of Chemicals and Polymers in Canada: Are You Required to Notify?*
   Environment Canada and Health Canada, April 1998
   Available at:
   **www.ec.gc.ca/substances/nsb/eng/notify_e.htm**

4. *Our Commitment to Effective Consultation*
   Environment Canada, 1996
   Available at:
   **www.ec.gc.ca/consult/policy_e.html**

5. *Study to Assess the Socio-economic Impact of the Proposed Regulations Respecting Notification of Substances New to Canada*
   Environment Canada, 1993
   Available from the New Substances Branch, Environment Canada

6. *New Substances Notification Program Regulatory Impact Analysis Statement*
   Environment Canada, 1994
   Available at:
   **www.ec.gc.ca/substances/nsb/eng/reg_e.htm**

7. *Toxic Substances Management Policy: Persistence and Bioaccumulation Criteria*
   Environment Canada, June 1995

8. *Toxic Substances Management Policy: Report on Public Consultations*
   Environment Canada, June 1995

# A.4: List of Acronyms and Definitions

## Glossary of Terms and Abbreviations

| | |
|---|---|
| ARET | Accelerated Reduction / Elimination of Toxics |
| ASTM | American Society of Testing and Materials |
| 4CA | Four Corners Agreement (Canada / U.S.) |
| CAEAL | Canadian Association of Environmental Analytical Laboratories |
| CAS | Chemical Abstracts Service |
| CBI | Confidential Business Information |
| CEPA | *Canadian Environmental Protection Act* |
| CFC | Chlorofluorocarbon |
| CSC | Canadian Standards Council |
| DSL | Domestic Substances List (Canada) |
| EDS | Endocrine Disrupting Substance |
| EDTA | Endocrine Disrupter Testing and Assessment |
| EINECS | European Inventory of Existing Chemical Substances |
| ELINCS | European List of New Chemical Substances |
| EPA | Environmental Protection Agency (U.S.) |
| EU | European Union |
| GLP | Good Laboratory Practice |
| GWP | Global Warming Potential |
| ICG | Industry Co-ordinating Group |
| $K_{ow}$ | Octanol / Water Partition Coefficient |
| MAD | Mutual Acceptance of Data |
| MAN | Mutual Acceptance of Notifications |
| Mn | Number Average Molecular Weight |
| MPD | Minimum Pre-market Data Set |
| MSC | Multistakeholder Consultations |
| MSDS | Material Safety Data Sheet |
| MW | Molecular Weight |
| NDSL | Non-Domestic Substances List (Canada) |
| 5-NR EDS | Canadian Natural Resource Departments Endocrine Disrupting Substances Working Group |
| NS | New Substances |
| NSN | New Substances Notification |
| NWRI | National Water Research Institute |
| ODP | Ozone Depleting Potential |
| OECD | Organisation for Economic Co-operation and Development |
| PAG | Public Advocacy Groups |
| PIC | Prior Informed Consent |
| PLC | Polymers of Low Concern |
| PSL | Priority Substances List |
| QSAR | Quantitative Structure–Activity Relationship |
| R&D | Research and Development |
| SAR | Structure–Activity Relationship |
| SNAc | Significant New Activity |
| TSCA | *Toxic Substances Control Act* (U.S.) |
| TSMP | Toxic Substances Management Policy |

## Definitions

### *Domestic Substances List (DSL)*

The DSL is an inventory of 24 017 (in August 2001) existing substances in Canada. The original list was composed of substances that were in commerce in Canada between January 1, 1984, and December 31, 1986. Substances are added to the list by meeting the requirements of the NSN Regulations (CEPA, sections 66 and 87). The List allows for a distinction to be made between existing substances and those that are new to Canada.

### *Environmental Contaminants Act Amendments Consultative Committee (ECAACC)*

The ECAACC was a multistakeholder committee established in 1985 by the federal Ministers of Environment and Health to review proposals for a number of improvements to the 1976 *Environmental Contaminants Act*. The objectives

of the Committee were to identify proposals for amendments where consensus agreement exists. The ECAACC submitted its final report in 1986.

### *European Inventory of Existing Chemical Substances (EINECS)*

The list of chemical substances in commerce in Europe. In August 2001, EINECS contained 100 192 substances.

### *National Industrial Chemicals Notification and Assessment Scheme*

In Australia, the National Industrial Chemicals Notification and Assessment Scheme came into effect in 1990. It is administered by the National Occupational Health and Safety Commission (Worksafe Australia), managed by the Director of Chemicals Notification and Assessment and overseen by the Minister for Industrial Relations. As with other countries, the regulation of new chemicals is based on a distinction between established domestic substances and new substances. The Australian Inventory of Chemical Substances consists of over 40 000 substances and is an "open" inventory to which new substances are added five years after they have been assessed. (From Discussion Paper: Cost Recovery for the CEPA New Substances Notification Program (Chemicals and Polymers), Environment Canada, 1998)

### *New Substances Program*

The statutory powers for the development of notification regulations within CEPA allowed Environment Canada and Health Canada to establish a new assessment program recommended by the Environmental Contaminants Act Amendments Consultative Committee consultation process. The main regulatory features of the program are establishment of classes of substances (schedules); identification of administrative and information requirements; timing of notification prior to import or manufacture; requirements for the departments to assess information within a set time; and specification of conditions, test procedures and laboratory practices to be followed when developing test data.

### *Non-Domestic Substances List (NDSL)*

The NDSL specifies substances that are not on the DSL but are believed to be in international commerce. The NDSL is based on the U.S. *Toxic Substances Control Act* Inventory of Substances. Substances listed on the NDSL require less detailed notification packages for assessment than substances that are new to both the Canadian marketplace and world commerce (section 66 of CEPA).

### *Priority Substances List*

The *Canadian Environmental Protection Act* (CEPA) instructs the federal Ministers of Environment and Health to develop a list of substances that should be given priority for assessment to determine whether they are "toxic" as defined under the Act. The Ministers may recommend controls for those substances that are found to be "CEPA-toxic." Management strategies for such substances are developed through a Strategic Options Process in consultation with stakeholders. (From Executive Summary of the Report of the Ministers' Expert Advisory Panel on the Second Priority Substances List (October 1995))

### *Schedule 1 of CEPA*

The list of substances that are determined to be toxic by the Governor in Council.

### *Toxic*

Under section 64 of CEPA, a substance is defined as toxic as follows:

> A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that
>
> (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
>
> (b) constitute or may constitute a danger to the environment on which life depends; or
>
> (c) constitute or may constitute a danger in Canada to human life or health.

### *Toxic Substances Control Act (TSCA) Inventory (U.S.A.)*

"From a regulatory standpoint, the Inventory lists chemical substances that are 'existing' in U.S. commerce for purposes of implementing TSCA."* In August of 2001, the TSCA Inventory contained 82 000 substances.

*Toxic Substances Control Act Chemical Substance Inventory, "1990 Supplement to the 1985 Edition of the TSCA Inventory." U.S. Environmental Protection Agency. June 1990 (EPA560/7-90-003).

## A.5: Description of the "New Substances" Industry Sector in Canada

The industry sectors most immediately affected by the NSN Regulations include those that manufacture, import or depend on access to substances not on the DSL. This is primarily the specialty chemicals industry and their industrial customers, especially that segment in which product technology is rapidly changing. This category includes dyestuffs, paints and coatings, adhesives, sealants, specialty organics, photographics and printing, ingredients of plastics, etc. The NSN Regulations also affect a broad range of customers of the chemical specialty industry, from the producers of soaps and detergents to the manufacturers of furniture or the formulators of crankcase oils. The Industry Co-ordinating Group (ICG) is an umbrella group composed of representatives of many industry sectors that are affected by CEPA and its Regulations. The ICG acted as a coordinating body for the consultations on the revised NSN Regulations for its member associations and other interested industry groups. (See a list of member associations below.)

Compared with larger industrial nations, Canada can be characterized as a significant exporter of commodity chemicals generally produced in large volumes and an importer of specialty chemicals generally produced in small volumes. In the area of specialties, Canada is not a leader in the synthesis of new substances; however, it is very innovative in the application of new substances, e.g., new coating formulations, adhesives, formulated plastics, etc. Access to new substances is essential to allow the specialty chemicals industry to continue to be active participants in Canadian commerce and to provide gainful employment.

Access to new product technology from the specialty chemicals industry is also essential for the continued health of manufacturing industries, such as automobiles, trucks, textiles, formulated plastics, paper products, etc. In many cases, the Canadian supplier of custom products to these industries plays an important role in their continued success. In other cases, Canadian customers can obtain from foreign suppliers finished products or articles manufactured using new technology.

Using Standard Industrial Classifications representing those chemical substances subject to the NSN Regulations (SIC 3711-12-31-99, inorganic chemicals, organic chemicals, plastics, resins and specialty chemicals), Statistics Canada data for 1996 suggest a total domestic market for primary chemicals and polymers of $19.8 billion (1996 $).

### List of ICG Member Associations

Canadian Association of Chemical Distributors

Canadian Chemical Producers' Association

Canadian Electricity Association

Canadian Fragrance Materials Association

Canadian Importers Association

Canadian Manufacturers and Exporters

Canadian Manufacturers of Chemical Specialties Association

Canadian Paint and Coatings Association

Canadian Petroleum Products Institute

Canadian Plastics Industry Association

Canadian Textiles Institute

Crop Protection Institute of Canada

Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers

Forest Products Association of Canada

Mining Association of Canada

Soaps and Detergents Association

# A.6: Proposed Requirements for Non-GLP Studies

## Introduction

It has been proposed by the Table (see Section 3.1.6(iii)) that requirements pertaining to GLP for tests for physical/chemical properties be separated into two provisions, one of which must be met. The first, that tests for physical/chemical properties "comply with OECD GLP for 'short-term' tests or equivalent GLP regulations," is self-explanatory, and the second, that such tests "provide enough information to demonstrate the reliability and adequacy of the data," will be elaborated upon below.

## What Constitutes "Enough Information"

During the course of an evaluation, information pertaining to how the test was conducted, deviations from standard protocols, handling of data, etc. is necessary for an evaluator to determine the reliability and adequacy of data received.

The type of information needed (most of which was extracted from reporting requirements of GLP) should include, where relevant for the test method:

- identification of the test guideline and methodology used;
- identification of the test substance and its purity;
- reference methods, standards and controls employed;
- name and address of the test facility, and person responsible for the data;
- dates on which the study was initiated and completed;
- raw data;
- deviations from standard protocols;
- analytical details, including sample preparation, instrument settings and calibration standards and methods; and
- a detailed presentation of results, calculations and statistical methods.

Revised guidelines will articulate the type of information required to demonstrate the reliability and adequacy of test data. It is intended that this would alert notifiers to the potential need for submitting these data. Notifiers will be advised to contact the program for a pre-notification consultation to discuss any potential issues.

As is current practice, in cases where the information submitted is deemed by an evaluator(s) not to be sufficient, notifiers will be advised to request that the assessment time clock be stopped (i.e., the assessment is suspended) until the information is supplied. If the information is not forthcoming from the notifier, the notification package will be considered incomplete and sent back to the notifier.

# A.7: Additional Information on the Assessment of Degradation Products

The exposure assessment of a substance includes the evaluation of the overall environmental persistence of a substance and its degradation products. In the context of the NS Program, biodegradation and hydrolysis are key elements in determining the half-life of a substance in various environmental media (air, water, soil and sediment). However, depending upon the circumstances, other degradation / disposal processes may be considered, such as photodegradation, thermolysis and incineration.

The biodegradation / hydrolysis half-lives of a substance are evaluated using experimental, surrogate or predicted data. Substances with shorter half-lives and not released on a continuous basis may not reside in a medium for a sufficient period of time to allow for chronic exposure of organisms. Also, biotic and hydrolytic degradation products are considered on an equal basis with the parent compound during the assessment, in order to determine the long-term potential toxicity of the breakdown products, as well as the potential toxicity of the parent compound. In general, these breakdown products tend to be less toxic, more water-soluble and, hence, more bioavailable to organisms; however, in some circumstances, degradation products possess greater toxicity than the parent compound.

This appendix examines four cases of previously notified polymers and chemicals and summarizes Environment Canada's concerns with degradation products. It also draws attention to the type of additional information that was requested by the department to ensure a comprehensive risk assessment of the notified substance and its degradation product(s) and the respective evaluation decisions.

## Case Studies

1. A polymer was notified and assessed by the departments. The substance was initially notified as a low concern polymer, but has subsequently been reclassified as not low concern, based on the fact that it is expected to degrade or decompose. It was determined that microbial degradation of the polymer in anaerobic sediments would lead to release of a potentially toxic degradation product. To address these concerns, the notifier was contacted to conduct an anaerobic degradation test to ascertain the substance's stability under anaerobic conditions. To date, the information has not been received. A Schedule VIII notification will be required, including hydrolysis and ready biodegradation data.

2. In another example, a polymer and its degradation products were of moderate (bordering high) toxicity in the aquatic environment. Information supplied in the notification package indicated that acid treatment (i.e., hydrolysis under acidic conditions) of the polymer alleviated environmental concerns by preventing aqueous discharge of the oil layer containing the hydrophobic (toxic) degradation product. The notifier was requested to provide additional information with respect to the effectiveness of the sewage treatment plant to degrade the notified polymer. The environmental risk assessment focused on the toxicity, release and fate of the parent compound, as well as of the toxic degradation product. The substance was subject to a Ministerial condition; restrictions included that the substance be hydrolyzed prior to disposal, with the requirement that hydrolysis efficiency remove at least 90% of the substance from the aqueous discharge. The above actions ensured that the substance would not be released at levels resulting in a risk to humans or the environment.

3. For an alkyltin notification, the impurities and degradation products were determined to be more inherently toxic than the parent compound. The toxicity of the notified substance and its degradation products was investigated using toxicity data for shorter alkyl chain structural analogues (i.e., the expected worst-case degradation product of the notified alkyltin), as well as available data from the scientific literature. The environmental risk assessment focused on the potential release of the substance to the environment. Additional information was obtained from the notifier with respect to handling, processing and use of the substance. Toxicity concerns were alleviated by

imposing a condition on the import and manufacture of the substance, including a restriction on the substance being released into the environment, and a condition requiring that handling, processing and use of the substance occur only in a fully contained process; any unreacted substance would have to be recovered and reprocessed.

4. A brominated flame retardant was notified and assessed by the departments. Three potential routes of degradation were identified, using experimental data and available data in the scientific literature for structural analogues. These were as follows: 1) degradation of the linear carbon chain; 2) dehalogenation in water and sediment; and 3) hydrolysis, although the latter was determined to be limited and not of concern due to the substance's lack of appreciable water solubility. Sediment species were exposed to degradation products; once transformation occurred in the sediment, the more soluble degraded substances could be transported back into the water column from interstitial waters. Ecotoxicity of the notified substance and degradation products was examined in the 1) water column for the parent compound, 2) sediment for degradation products and 3) water column for reflux of degradation products. Sediment toxicity data were available in the literature for a surrogate degradation product. A suspicion of toxic was determined on the basis of release of the substance in liquid form, resulting in a risk to the aquatic environment, and on the basis of highly toxic degradation products. A condition was imposed by Environment Canada, limiting importation of the substance to instances where it is encapsulated in plastic pellets or flakes.

In the above cases, the notifier was contacted for additional information, and/or supporting documentation/surrogate data were available to the evaluator to assess the potential risk of the notified substance and its degradation product(s).

It is recommended that examples of the type of additional information requests with respect to degradation products be provided in the Guidelines rather than in the Regulations, since the information described above would be required only on a case-by-case basis. The NS Program will continue to address toxicity of degradation products in the risk assessment, without compromising risk to the environment and human health. The Program will respond with requests for additional information and/or impose conditions, when warranted.

# A.8: Test Criteria for the Sunrise Approach — from the Public Advocacy Group Representatives Discussion Paper, August 2000

The various tests necessary for adequately measuring the various characteristics of concern are outlined below. Some of these tests are already required on the highest schedules for chemicals and polymers; others have been proposed to a subcommittee to the NSN consultation process.

### *Toxicity*

Acute toxicity: tests for mammalian, fish, daphnia and algal toxicity.
Chronic toxicity: determination of an effective concentration to 50% for growth, total mass or photosynthesis rate inhibition in higher plants, 90-day mammalian, and indicators of chronic toxicity, such as a lowest-observed-adverse-effect level (LOAEL), a no-observed-adverse-effect level (NOAEL) and the maximum allowable toxicant concentration (MATC) in aquatic assays.[31]

### *Persistence*

Those tests relating to persistence already required by the highest schedule (such as hydrolysis and ready biodegradability), although the criteria cut-off of substances' half-lives in the media of air, water, sediment and soil may need to be lowered from that provided by the Toxic Substances Management Policy (TSMP).

### *Bioaccumulation*

Those tests relating to bioaccumulation and the octanol/water partition coefficient ($K_{ow}$) already required by the highest schedule (such as water solubility, fat solubility, dissociation constant), although the criteria cut-off for log $K_{ow}$ may need to be lowered from that provided by the TSMP.

### *Ozone Depleting Potential (ODP)*

Tests for 20, 100 and 500 ODP, as well as the atmospheric lifetime for those classes of substances to which these measurements apply.

### *Global Warming Potential (GWP)*

Tests for 20, 100 and 500 GWP, as well as the atmospheric lifetime for those classes of substances to which these measurements apply.

### *Endocrine Disrupting Substances (EDSs)*

Screening new substances for endocrine disrupting potential is possible and can add value in the NSN assessment. The U.S. Environmental Protection Agency Tier 1 and Tier 2 model is proposed here:

### *Tier 1 Screening*

*In vitro* assays include:

- an estrogen receptor binding or reporter gene assay;
- an androgen receptor binding or reporter gene assay; and
- a steroidogenesis assay with minced testis.

*In vivo* assays include:

- a rodent 3-day uterotrophic assay;
- a rodent 20-day pubertal female assay with enhanced thyroid endpoints;
- a rodent 5- to 7-day Hershberger assay;
- a frog metamorphosis assay; and
- a fish reproductive screening assay.

The assessment can evaluate the Tier 1 data and other scientifically relevant information (e.g., high through put screenings, quantitative structure–activity relationships, referred to as "QSARs," or literature data) to decide if the chemical can be moved to a "hold category (needs no further analysis at this time)" or needs to undergo Tier 2 Testing. Tier 2 testing will determine whether it may have an effect in humans that is similar to the effect produced by a naturally occurring hormone.

The Tier 1 assays have the necessary breadth and depth to detect all currently known chemicals that may affect the endocrine, androgen and thyroid systems. Therefore, after having gone through the Tier 1 screening battery, a chemical will be designated as having either the potential for estrogen, androgen or thyroid activity, which will require further analysis in Tier 2 tests to verify and evaluate that potential; or low or no potential for estrogen, androgen or thyroid activity, which will allow the chemical to be put on "hold."

### *Tier 2 Testing*

The Tier 2 tests are longer-term studies designed to encompass critical life stages and processes, a broad range of doses and administration by a relevant route of exposure. Effects associated with endocrine disruption may be latent and not manifested until later in life or may not appear until the reproductive period is reached. Therefore, Tier 2 tests will usually encompass two generations and will include effects on fertility and mating, embryonic development, sensitive neonatal growth and development, and transformation from the juvenile life stage to sexual maturity.

Tier 2 tests include:

- a two-generation mammalian reproductive toxicity study or a less comprehensive alternative;
- a mammalian reproductive toxicity test;
- an avian reproduction toxicity test;
- a fish life cycle toxicity test;
- an opossum shrimp (Mysidacea) or other invertebrate life cycle toxicity test; and
- an amphibian development and reproduction test.

Environment Canada and Health Canada may decide to require less testing based on scientifically relevant information showing that effects can be adequately characterized in a one-generation assay.

### *Evaluation Methods*

The Sunrise clause could take the form of either an absolute threshold limit for each criterion or a scoring system wherein a substance could not exceed a certain cumulative score for all categories combined. An example of the latter approach, as applied to select indicators, is illustrated below:

Before applying such a system, careful thought would have to be given to what numeric test results would be associated with each score and the relationship that ranks achieved in each category would have to one another. For instance, it could be decided that a substance would be DSL-bound if it did not exceed x number of "poor" scores throughout the entire assessment process. Alternatively, the tests could be divided into smaller subsets according to nature of the effect, location of the effect, etc., and allocated a given number of allowable "poor" scores for each subset.

## Table A.1: Sunrise Clause Scoring System for Select Indicators

| Score* | Good | Moderate | Poor |
|---|---|---|---|
| Acute Aquatic Lethality ($LC_{50}$ or $EC_{50}$, mg/L)[32] | >100 | 100–1 | <1 |
| Chronic Aquatic Toxicity (NOAEC, mg/L)[33] | >0.02 | 0.02–0.0002 | <0.0002 |
| Acute Oral Lethality ($LD_{50}$, mg/kg)[34] | >500 | 500–5 | <5 |
| Persistence (half-life in aquatic environment, days)[35] | <50 | 50–180 | >180 |
| Bioaccumulation (Bioaccumulation Factor [BAF], where log BAF = 1.07 log $K_{ow}$ – 0.21)[36] | <500 | 500–1 000 | >1 000 |
| Ozone Depleting Potential (ODP, relative to CFC-11 and CFC-12)[37] | <0.01 | 0.01–0.70 | >0.70 |
| Global Warming Potential (GWP, equal mass relative to $CO_2$ over 100 years)[38] | <1 | 1–500 | >500 |

* $LC_{50}$ = median lethal concentration; $ED_{50}$ = median effective dose; $LD_{50}$ = median lethal dose; NOAEC = no-observed-adverse-effect concentration; CFC = chlorofluorocarbon.