

THE HEALTH-RELATED COMPONENTS OF CATEGORIZATION OF THE DOMESTIC SUBSTANCES LIST (DSL): APPROACH, RESULTS, AND NEXT STEPS

Background

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) provides the legislated framework for the identification and control of existing substances and management of those considered to pose a risk to human health and/or the environment.

CEPA 1999 required systematic consideration of approximately 22 400 existing substances within a prescribed (seven-year) time frame (by September 14, 2006) to set priorities for health risk assessment. This progressive mandate involved consideration of both exposure *and* hazard, was precedent setting internationally, and was technically demanding.

The priority-setting tools and assessment products that have been developed to meet this mandate set the stage for efficient health assessment for potential risk management of much greater numbers of existing substances than ever before, while maintaining scientific integrity and transparency.

These tools and products draw upon considerable prior program experience in the development of methodology for and completion of in-depth, detailed human health risk assessments on about 70 “Priority Substances,” most of which were published in the peer-reviewed scientific literature and/or served as the basis for international assessments.

Throughout the development of novel tools and assessment products to systematically set priorities for further work from among all existing substances, external experts were engaged in various stages of peer input, consultation, and review. The potential for conflict of interest was carefully considered and managed in such reviews.

Industrial stakeholders and representatives of the non-governmental environmental community were continuously informed during the development of tools and products for the health-related stream of categorization and screening. Formal written feedback was solicited through posting of proposals for public comment.

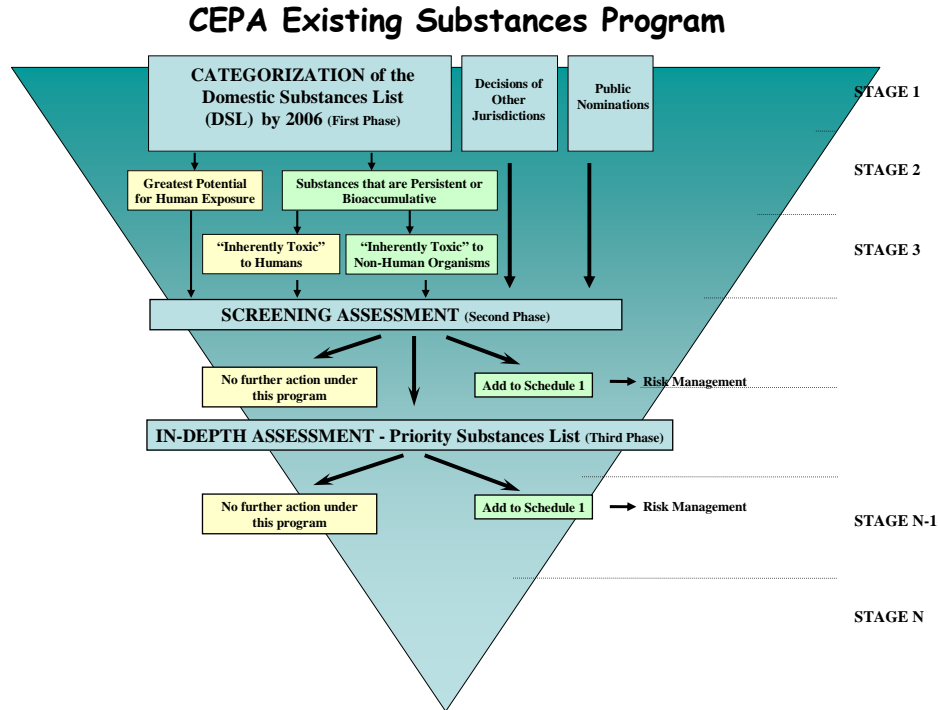
- Existing substances are those in an inventory known as the Domestic Substances List (DSL), published in 1994.
- The DSL is a compilation of about 22 400 substances used, imported, or manufactured in Canada for commercial purposes between January 1, 1984, and December 31, 1986, at a quantity of greater than 100 kg per year. It includes discrete organic compounds, inorganic substances, organometallic substances, polymers, and unknown or variable composition complex reaction products and biological materials (UVCBs).
- Substances that are not listed on the DSL are considered to be new to Canada. The DSL is periodically amended to add substances that have met the listing requirements under the New Substances Notification Regulations of CEPA 1999.

How has Health Canada completed this mandate?

Categorization of the DSL under Section 73 of CEPA 1999 required Health Canada to identify substances that should be considered further for the screening assessment of risks to human health and the environment, on the basis that:

- they present to individuals in Canada “greatest potential for exposure” (GPE); or
- they are “inherently toxic to humans” (IThuman) for a subset of DSL substances considered to be either persistent (P) or bioaccumulative (B)¹ — that is, to identify DSL substances that are PBIThuman (Figure 1).

¹ P and B were determined by Environment Canada.



A simple exposure tool (SimET) was developed to identify substances on the DSL considered to represent GPE. This approach was based on *three* lines of evidence: 1) quantity in commerce in Canada; 2) number of companies involved in commercial activities in Canada; and 3) the consideration by experts of the potential for human exposure based on various use codes. The proposed approach was released for public comment in November 2003 and also enabled designation of substances as presenting an Intermediate (IPE) or Lowest Potential for Exposure (LPE), based on criteria for quantity and nature of use.

A series of simple (SimHaz) and complex hazard tools (ComHaz) as well as a complex exposure tool (ComET) were also developed (Figure 2), to be implemented within an integrated framework for the health-related components of DSL categorization.

Tools for Health-Related Components of DSL Categorization

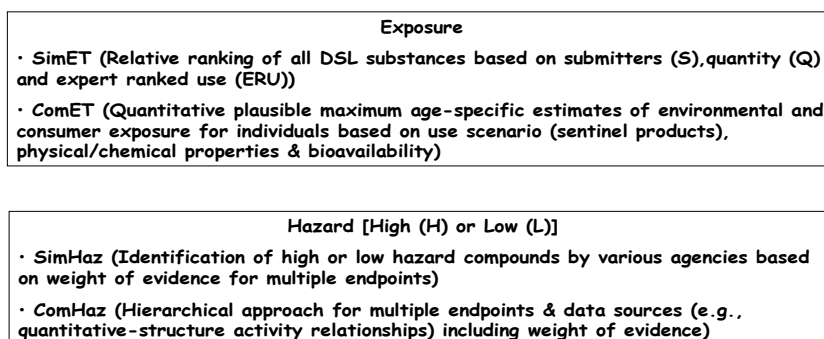


Figure 2

This approach, which took into consideration both exposure and hazard, resulted in the identification of substances that represented the highest priorities for action from a human health perspective. It also offered a number of advantages and exceeded the requirements of categorization, by:

- drawing maximally on work completed in other jurisdictions while avoiding continued focus on data-rich compounds;
- not only identifying substances for screening assessment on the basis of exposure, hazard, and/or risk, but also *prioritizing* them on the basis of potential exposure, hazard, and/or risk to human health;
- identifying true priorities for both assessment and data generation, since exposure and complex hazard components of the framework were unbiased in relation to data availability; and
- identifying not only those substances that were IThuman for a subset of substances, but all of the approximately 22 400 existing substances based on criteria for weight of evidence of hazard consistent with those for Priority Substances or screening health assessment.

Implementation of this framework and associated tools has application well beyond simply identifying substances for assessment. These tools enable the efficient prioritization and subsequent screening health assessment of *any substance* considered by the program. Health priorities from categorization have been prioritized by group, based on whether they are exposure, hazard, or risk based, and within groups, based on consideration of their relative potential for exposure. Continued application of the complex tools following the release of the results of categorization will contribute to screening assessment for prioritized compounds.

The simple exposure and hazard tools were applied to the entire DSL (see Figure 3), leading to the draft “maximal list” of health priorities (Figure 4). The potential for persistence or bioaccumulation to additionally contribute to exposure for certain subsets of substances — namely, those that are organic — was also taken into account.

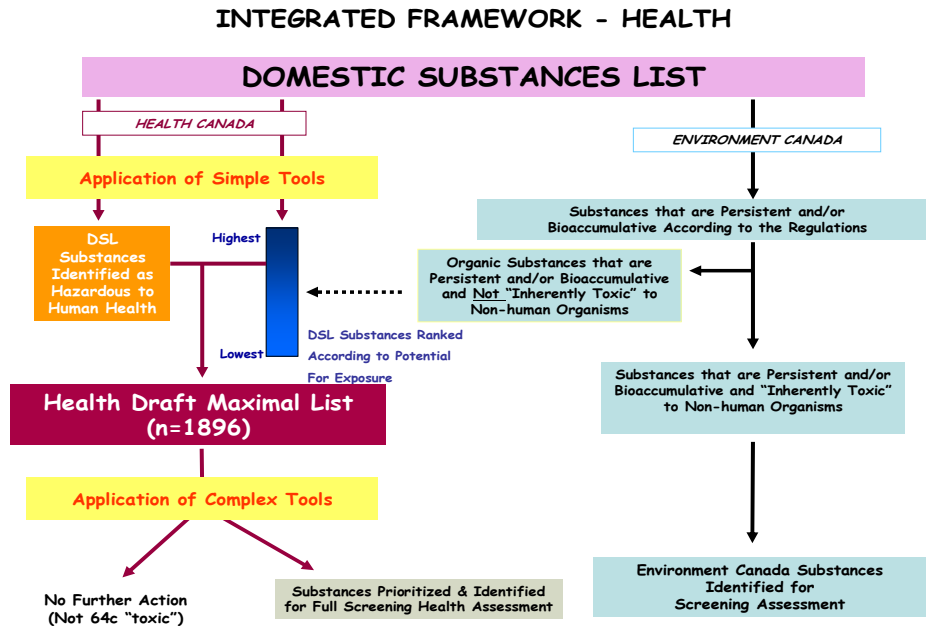


Figure 3

Health Draft Maximal List

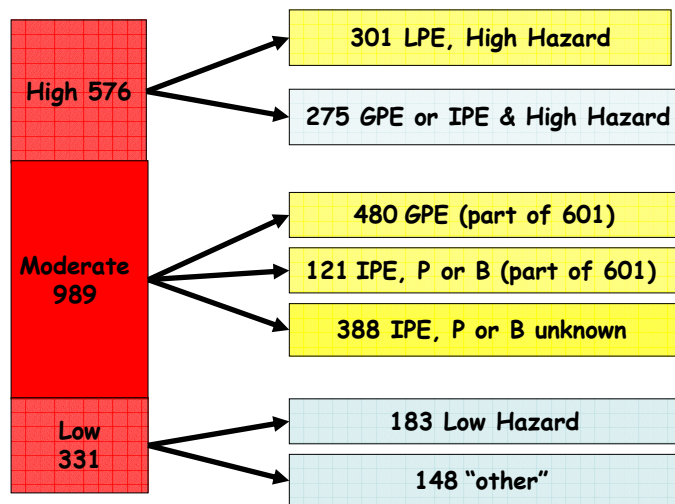


Figure 4

This health draft maximal list, released in October 2004, was composed of approximately 1900 substances grouped according to their high, moderate, or low likelihood of being considered further in DSL categorization and screening assessment. This list identified the maximum numbers and names of substances for inclusion on the list of substances requiring further assessment in 2006 in a close to final form.

This list was released at that time in an effort to reduce uncertainty for stakeholders regarding the likelihood of substances to remain on the list in September 2006 and to permit sufficient time and opportunity for interested parties to submit specified data in focused areas for consideration in subsequent refinement of the list.

The proposed integrated framework for the health-related components of DSL categorization was released for public comment in June 2005.

Following release of the health draft maximal list, a number of activities were undertaken, aimed at:

- refining and prioritizing the list of substances to be considered for further action;
- clearly articulating the basis for any further consideration, or not, at this time; and
- accounting for all substances on the health draft maximal list, whether or not further action was contemplated.

A summary of the key milestones associated with the health-related components of DSL categorization is presented in Figure 5.

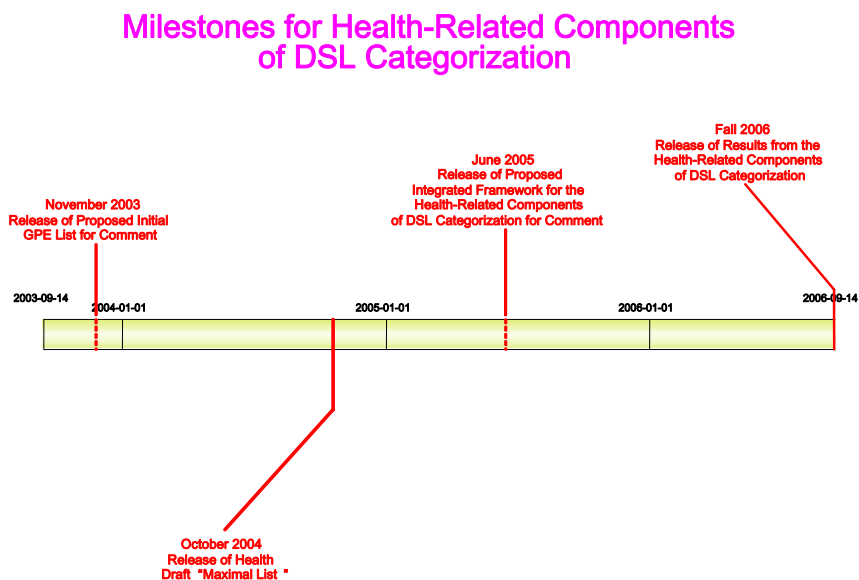


Figure 5

Outcomes of the health-related components of DSL categorization

A schematic outlining the principal results of the health-related components of DSL categorization is presented in Figure 6. These results are presented in an accompanying document (see *Results of the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999*).

Approximately 1150 substances from the draft maximal list of health priorities are now being considered as either high or moderate health priorities for further action. Substances have been prioritized for further action on the basis of potential risk (exposure and effect), hazard, and exposure considerations.

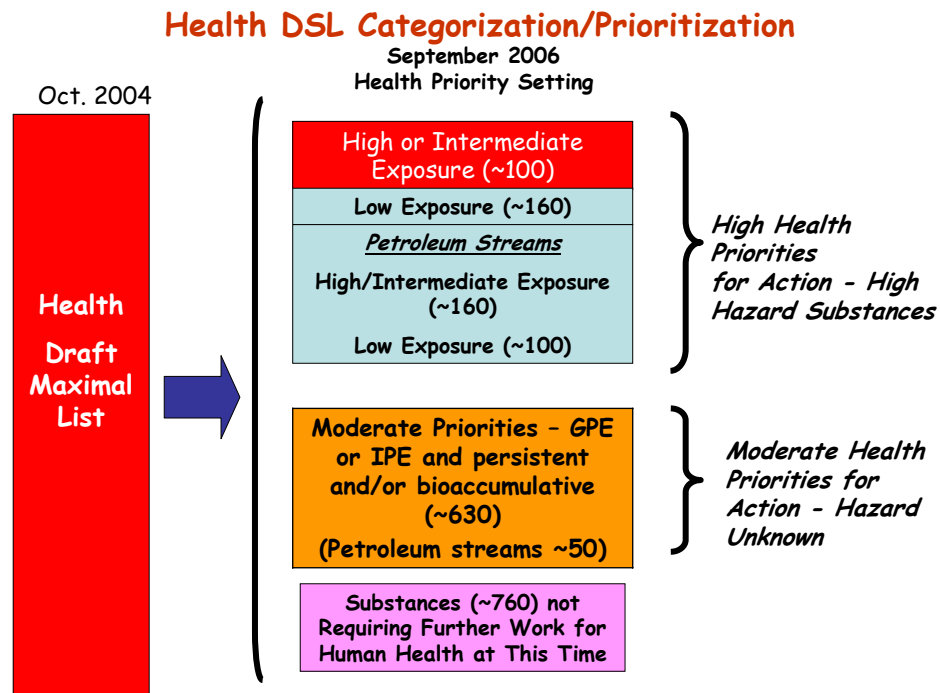


Figure 6

The **high health priorities for action** group² is composed of all substances on the DSL identified as posing a high health hazard, based on a weight of evidence determination by the simple hazard tool (SimHaz). Within this group, there are:

² See table entitled “High Health Priorities for Action” in *Results of the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999*.

- approximately 100 substances that present greatest or intermediate potential for exposure³ (i.e., substances that are included on the basis of risk — having high health hazard and GPE or IPE);
- approximately 160 substances that present lowest potential for exposure (i.e., substances that are included on the basis of hazard — having high health hazard but LPE); and
- approximately 260 high health hazard petroleum streams of high, moderate, or low potential for exposure.

- The health-related categorization of the DSL, while risk based and believed to identify true health-based priorities, is ***not synonymous*** with human health risk assessments conducted under CEPA 1999.
- The substances in the high health priorities for action group have ***not yet been critically assessed*** in regards to any potential risks to human health. Rather, they have been ***prioritized for further action*** (i.e., assessment) on the basis of the risk-based considerations of exposure and hazard. Assessment enables additional quantification of risk from more fully characterized sources.
- All of the substances in the high health priorities for action group were identified as representing a ***high health hazard*** on the basis of potential to induce cancer and/or adversely affect reproduction and development, two critical determinants of the health of Canadians of all ages.

The **moderate health priorities for action** group⁴ is composed of substances (n = ~630)⁵ included on the basis of exposure considerations — that is, substances that are either GPE or IPE and persistent or bioaccumulative.

- The substances in the moderate health priorities for action group have been identified ***only on the basis of their exposure potential for humans***.
- Following release of the results of categorization, complex tools will continue to be applied to substances in the moderate health priorities for action group. On this basis, it is highly likely that many will not be found to present a risk to human health at exposures typically experienced by the general population of Canada.

Substances included in the high and moderate health priorities for action groups have also been delineated according to whether:

³ About 20 of these are *Food and Drugs Act* substances in commerce between 1984 and 1986, which were added to the DSL and identified on the basis of hazard only.

⁴ See table entitled “Moderate Health Priorities for Action” in *Results of the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999*.

⁵ About 50 of these are petroleum streams.

- they meet the health-related categorization criteria specified within Section 73 of CEPA 1999 — that is, they are:
 - GPE; or
 - persistent and/or bioaccumulative and “inherently toxic” to humans (PBITHuman);
- they are considered to represent other high priorities for assessment for human health, on the basis that they are:
 - high hazard substances but not persistent or bioaccumulative or presenting greatest potential for human exposure; or
 - either persistent or bioaccumulative, and also presenting an intermediate potential for human exposure (IPE).

About 40% of the substances on the draft maximal list of health priorities (n = ~760) are considered to no longer require further work for human health at this time.⁶ This group of substances includes:

- those having been assessed and/or managed under CEPA (i.e., listed on the first or second Priority Substances List (PSL1 or PSL2) or CEPA Schedule 1 or 3). This was based on careful consideration of the specific substances assessed and/or managed from a health perspective;
- low hazard compounds (determined by application of low hazard components of simple (SimHaz) and complex (ComHaz) hazard tools) and low concern polymers; and
- “deprioritized” substances reflecting changes to their designation as PBITeco (persistent, bioaccumulative, and inherently toxic to non-human organisms) as well as changes in SimHaz criteria.

Substances in subsets of this third group will be tracked for any new information that might warrant subsequent action (e.g., assessment).

- Many of the substances identified by the health-related categorization of the DSL as priorities for action *may be managed through, for example, industry initiatives to reduce exposure. This will be additionally considered in subsequent stages.*
- This list also provides useful information on a number of substances considered to represent a **low concern** with respect to any potential adverse impact upon human health.

⁶ See table entitled “Substances Not Requiring Further Work for Human Health at This Time” in *Results of the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999*.

Following development of the maximal list, some additional substances⁷ were prioritized for consideration on the basis of updates to weight-of-evidence hazard determinations in the simple hazard tool (SimHaz) or as a result of changes to determinations of persistence and/or bioaccumulation. Next steps for these substances will be considered post–September 2006.

These groups of substances account fully for all of the substances on the draft maximal list of health priorities.

In addition to these lists of substances representing the health-related results of DSL categorization, in September 2006, the finalized integrated framework on the health-related components of DSL categorization will also be released. A summary table of comments received in response to the call for public comment on the integrated framework and the Health Canada response to these comments, as well as lists of questions and answers related to the health-related categorization of the DSL, will also be issued.

The health-related categorization of the DSL will not necessarily cease on September 14, 2006. It is envisaged that the DSL will be reviewed on an annual basis to determine if any additions to the list should be considered as priorities for further screening health assessment, based on the simple and complex exposure and hazard tools.

Next steps for the high and moderate health priorities for action groups

An action plan has been developed to deal with the substances in the high and moderate health priorities for action groups (see Figure 7).

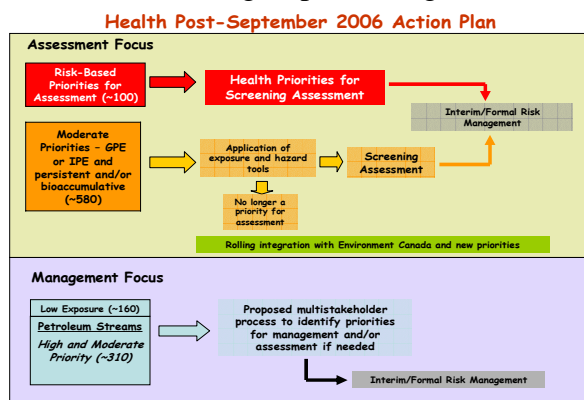


Figure 7

Depending upon the group, the focus of the initial efforts will be on assessment and/or management:

⁷ See table entitled "Additional Substances for Consideration Post–September 2006" in *Results of the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999*.

- The **high (risk-based) priorities for assessment** group will undergo screening assessment as part of early joint work planning with the priorities identified by Environment Canada. Envisaged interim products to increase efficiency in assessment are being “mapped” and prototypes developed. Use and hazard profiles are in preparation for these substances, and they are being scoped for their likely complexity and resulting impact on scheduling for completion.

- Of the approximately 22 400 substances on the DSL, these 100 discrete substances have been identified as the ***top health priority*** for further action on the basis that they pose greatest or intermediate potential for exposure and present a hazard to human health. The extent to which these substances are risk managed outside of CEPA 1999 has not yet been considered.

- It is anticipated that, not long after screening health assessment work on the **high (risk-based) priorities for assessment** group is under way, the Department will begin evaluation of the **moderate health priorities** group, by first applying the relevant exposure and hazard tools developed for DSL categorization. Envisaged process and products for the various subsets of substances within the moderate health priorities group are in development and will be shared with stakeholders when available. Substances in this group will also be part of joint work planning with priorities identified by Environment Canada.
- For all (high and moderate priority for action) **petroleum streams** as well as those substances considered on the basis of hazard considerations (i.e., **high hazard and LPE**), Health Canada is leading development of a multistakeholder process to identify priorities for management and/or assessment.

In the assessment and management phases, priorities will be health and/or environment led. This results from variations in priorities for human health versus the environment arising from DSL categorization, which offers gains in efficiencies through designation of a “lead department” for identified health and environmental priorities, respectively.

The simple and complex exposure and hazard tools developed for DSL categorization provide a risk-based framework that is relevant to prioritization of substances from any other “feeders” for screening health assessment. Such “tools-based decision-making” will be used to identify non-priorities for screening health assessment.

The conduct of screening health assessments for much larger numbers of substances permits profiling across data sets, leading to development of “right-sized” risk management.

For substances clearly posing low exposure potential and low hazard to human health, sufficient assessment documentation will be provided to fully and credibly support conclusions that a substance is not a priority for screening health assessment or does not pose a risk to human health.

The transparency for the tools-based assessments is supported by the robustness of the documentation associated with development of the methodology for the various tools, which lends itself to less substance-specific assessment documentation.

Work planning for screening health assessment will also take into account the priorities for assessment based upon the environment-related results from DSL categorization.

- There is commitment to full accountability on all health priorities identified from DSL categorization and public joint (with Environment Canada) schedules for screening assessment.
- Consideration of health-related priorities from among all existing substances in Canada represents a significant accomplishment that is leading internationally. It has integrated government leadership in the development of progressive tools, with continuing input of stakeholders and experts.