



CANADIAN ENVIRONMENTAL
LAW ASSOCIATION

**Comments on Health Canada's "Proposal for Priority Setting
For Existing Substances on the Domestic Substances List
Under the Canadian Environmental Protection Act, 1999:
GREATEST POTENTIAL FOR HUMAN EXPOSURE"**

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Executive Summary

Under Section 73 of the *Canadian Environmental Protection Act (CEPA)* 1999, Health Canada is required to identify those substances listed under the Domestic Substances List (DSL) that are of the Greatest Potential for Human Exposure (GPE) for the purpose of categorization. The following submission outlines the concerns and recommendations by member organizations of the Canadian Environmental Network's Toxics Caucus on Health Canada's proposal for fulfilling its requirements under CEPA 1999 for identifying substances that are of the greatest potential for human exposure. In general, the overarching concern expressed by the environmental non-governmental organizations (ENGOS) on Health Canada's proposal is the uncertainty of the proposed framework to identify ALL DSL substances that are of the greatest potential for human exposure. This uncertainty is based on the limitations of the parameters selected for determining the GPE list of substances. The importance of capturing ALL substances that are the greatest potential for human exposure is critical for priority setting in the Screening Level Risk Assessment process as required under Section 74 of CEPA 1999. If the GPE list fails to identify ALL DSL substances of GPE to humans, it must rely on the other stream of categorization outlined in section 73 of CEPA, which requires substances to meet the criteria for persistence or bioaccumulation and inherent toxicity to humans/non-human organisms or other feeders within CEPA to identify a substance for further assessment activities.

The ENGOS' concerns regarding the proposed GPE framework by Health Canada range from overarching themes such as the need to apply a precautionary approach to the GPE exercise, the need to consider classes of chemicals instead of a chemical by chemical approach, and the need for further consideration of the unique risk of exposure to children in the GPE framework. If considered, and incorporated in the GPE framework, these concerns aim to expand the GPE list from the current number of 849 DSL substances. Comments presented by ENGOS in this submission reflect specific parameters included by Health Canada in its GPE proposal. These parameters include creating a 10% cut off threshold that is applied to quantity/volume, the number of submitters to be considered, and use code values. By creating the 10% cut off threshold, the GPE list is significantly truncated resulting in the exclusion of substances that are hazardous to human health. In this submission we provided comprehensive comments for improvement of the current GPE proposal. It is important that early in this process an effective framework is established for identifying all substances of concern.. The following is a list of recommendations submitted by the ENGOS to improve Health Canada's GPE framework for categorization of DSL substances.

Recommendation 1: Early collaboration between Environment Canada and Health Canada on the DSL categorization process is paramount to ensure that all substances that are potentially hazardous to human, wildlife and environmental health are identified and considered for further screening assessment activities. Further, there is a need for documentation to consolidate the results obtained by Health Canada and Environment Canada in its categorization efforts. This

documentation should outline how the approaches undertaken by each department interrelates to produce the list of substances identified for further screening assessment.

Recommendation 2: ENGOs urge Health Canada to enhance and expand consultation efforts focused on categorization and screening assessments. Further consultation with ENGOs should be undertaken at the early phases of these processes.

Recommendation 3: The precautionary approach should be an underlying principle, applicable throughout the categorization and screening assessment process including the GPE framework and determination of inherent toxicity of DSL to humans.

Recommendation 4: In support of the precautionary principle, we reject the arbitrary measures used in the GPE framework, including the use of the 10% cut off threshold to select the substances that meet quantity cut off value ($Q = 1,000,000$ kg/year) and the number of submitters ($S = >4$).

Recommendation 5: Create a parallel process to the GPE framework that would identify those substances that are of greatest potential for exposure to children's health. This list of substances would be added to the current GPE list, identified by Health Canada as a priority in the categorization process.

Recommendation 6: Health Canada convenes a committee of experts on children's health that would include ENGO participation for the purposes of reviewing the use codes as they relate to exposure to children.

Recommendation 7: Health Canada should apply the class approach by grouping substances with similar exposure patterns and similar chemical properties. This approach would result in an increase in quantity and use code ranking for some substances that could not meet the original thresholds for quantity value or number of submitters.

Recommendation 8: It is imperative that both Departments of Health and Environment provide measurable information on the effectiveness of their actions in phasing out substances that are declared "toxic" under CEPA.

Recommendation 9: Health Canada should adopt the proactive approach, employed by EU's REACH Policy, to include all substances with quantity value equal to or greater than 100,000 kg/year in the categorization process.

Recommendation 10: Health Canada should employ a 21% quantity cut off value to include all substances on the DSL with potential of human exposure.

Recommendation 11: The use of number of submitters is inappropriate and should be eliminated from this proposed framework. In this proposal the use of quantity may suffice with consideration of other factors for determining GPE to humans.

Recommendation 12: Health Canada should abandon the process presented in their proposal and use the exposure index described above.

Recommendation 13: Health Canada should provide a comprehensive list of substances that are not included in the GPE list but are found in the US EPA's HPV Challenge Program List or ICCA HPV 2003 Working List.

Recommendation 14: Use codes should not be summed to determine the exposure potential of a substance. A preferred approach would be to use the value of the highest exposure code or the average of the values of all codes to obtain a value more reflective of the exposure potential for a substance.

Recommendation 15: The ranking of the use codes should be redone. Experts should rank the codes from highest to lowest exposure. Then the average of the rankings would provide a final use code index. This use code index then would be multiplied by the volume of use, to determine the relative GPE.

Recommendation 16: The factor of uptake potential can be considered in the GPE proposal. Molecular size of organic substances and solubility of minerals are good indicators for uptake potential.

Recommendation 17: The GPE process should identify and eliminate those substances from the process with known low or no exposure risk.

Recommendation 18: Health Canada should develop a list of substances that need further investigation based on other factors of exposure not considered in the current GPE proposal. Additional knowledge on exposure to substances is known by other government organizations and industry. This knowledge should be considered if Health Canada's approach is to capture all substances with GPE characteristics for further consideration.

Recommendation 19: Remove those substances identified through the Priority substances stream as GPE and are currently being assessed or have been assessed.

Recommendation 20: Health Canada should create a process that enhance the data collection activities and outline how further efforts will be undertaken to address the lack of data, required for the categorization and screening process.

Recommendation 21: Health Canada should provide the rationale for the developing the Tier system as well as outlining set of criteria, which includes timeframes by which, those substances listed as Tier 2 or 3 will be addressed for data collection.

Background

The Domestic Substances List (DSL) is a list of substances that were in Canadian commerce from 1984 to 1986. This list consists of approximately 23,000 substances. Most substances on the DSL have not undergone any environmental or human health assessment.

There is a requirement under Section 73 of the *Canadian Environmental Protection Act* (CEPA 1999) for Ministers of Environment and Health then to “categorize” the 23,000 on the DSL list and under Section 74 “screen” these substances to determine if the substances are “toxic” or capable of becoming “toxic” as defined by CEPA (in accordance with the toxicity criterion defined in the Act).

Under Section 73 of CEPA 1999, two streams are identified by which a DSL substance will be categorized for screening assessment.

- a) any substance which may present, to individuals in Canada, the greatest potential for exposure, and
- b) substances that are persistent or bioaccumulative in accordance with the regulations, and inherently toxic to human beings or to non-human organisms, as determined by experimental data or other studies.

The following submission highlights issues and concerns by Canadian environmental non-governmental organizations (ENGOS) relating to Health Canada's approach for determining those substances of greatest potential for human exposure. Under Section 73 of CEPA 1999 requirements, Health Canada is obligated to identify ALL substances that have the greatest potential for human exposure (GPE). The substances included in this “list” then will proceed to the next stage of the DSL categorization process. The GPE exercise is the first of three distinct processes by Health Canada to complete the DSL categorization requirements, therefore, it is an important step in the development of a framework that effectively identifies ALL DSL substances of concern. We strongly believe that current framework employed by Health Canada lacks many essential elements in order to effectively identify all the substances of concern.

As presented during the March 8th information session, Health Canada's efforts and its workplan on categorization and screening is severely limited by available resources and a legislative obligation to meet the September 2006 deadline for completing the categorization process. Despite these limitations, ENGOS recognize that the proposed GPE process will have a number of significant impacts to Canada's toxic management regime. We also recognize that an effective GPE framework is needed to maximize Health Canada's efforts on identifying substances that are inherently toxic to humans and ultimately set priorities for screening process. To ensure effective protection of human health and environment, we are urging Health Canada to make comprehensive changes to the current GPE framework in order to develop an effective system that puts human health in the forefront of the management of toxic substances in Canada.

Positive Development

As members of the Canadian Environmental Network Toxics Caucus, we are pleased to have this opportunity to comment on this document. Faced with the task of categorizing 23,000 chemicals within a 7-year timeframe, we can appreciate Health Canada's need to develop a methodology that provides a balance between facilitating maximum efficiency of effort, and maximum protection of human health. Given that there is very limited data available for many of the substances listed under the DSL, member organizations of the CEN Toxics Caucus support all efforts by Health Canada and Environment Canada that raise the current knowledge base on chemicals in Canada. In particular, we are supportive of efforts to reduce the amount of time needed to identify substances of concern for further assessment as being undertaken with Section 73 and 74 requirements.

We note, however, that the deadline of September 14, 2006 for completing Section 73 requirements for categorization is fast approaching. With less than three years remaining to complete this process, Health Canada is still faced with completing the assessment of the inherent toxicity of these substances to human health. At the conclusion of this effort, it is expected that the resultant findings will be consolidated with Environment Canada's effort on categorisation of substances based on persistence, bioaccumulation and inherently toxic to non-human organisms. This consolidation effort would provide stakeholders with an overall rationale for these efforts as well as a comprehensive list of DSL substances to be considered for screening level risk assessment process. As important this process consolidation process is, unfortunately, at the present time, a level of collaboration between the two Departments of Health and Environment is not apparent.

Since the categorization process is lengthy and needs timely consultation with various stakeholders, it is of utmost importance that an appropriate approach is adopted in order to ensure that issues identified in this submission are taken into consideration. Recognizing that there are a number of improvements that must be made, we are concerned that completion of a fully effective and protective categorization will not be realized within this timeframe. We are concern that the foundation of the current categorization process is flawed and therefore would not encompass or guarantee the inclusion of ALL substances that are potentially hazardous to human, wildlife and environmental health.

Recommendation 1: Early collaboration between Environment Canada and Health Canada on the DSL categorization process is paramount to ensure that all substances that are potentially hazardous to human, wildlife and environmental health are identified and considered for further screening assessment activities. Further, there is a need for documentation to consolidate the results obtained by Health Canada and Environment Canada in its categorization efforts. This documentation should outline how the approaches undertaken by each department interrelates to produce the list of substances identified for further screening assessment.

Overarching Themes

Public Consultation Process

To date, Health Canada's efforts to engage public interest groups to discuss the DSL categorization process has been very limited. The extent of public engagement has been restricted to two formal information sessions (December 2002 And March 2004) sponsored by Health Canada. Due to the limited level of engagement and input by ENGOs, it is difficult to support the rationale used by Health Canada to reject or accept substances under the GPE proposal for further assessment based on the information currently available to the public. However, we are encouraged by recent dialogue with Health Canada to suggest that further opportunities will be available for public engagement and increase transparency on these matters will be pursued.

Engaging in meaningful dialogue with Health Canada staff is both supported and encouraged by the ENGOs. However, ENGOs are concern that this level of consultation remains limited to providing comments at the conclusion of Health Canada's assessment processes. Based on our past experiences, it is difficult to assess the level of the impact of the public comments and recommendations have on the final framework. It is unclear how ENGO submissions are considered in the final assessment process. Therefore, it is imperative that Health Canada provides information showing the extent of which these comments have been considered as well as rationale upon rejection.

Recommendation 2: ENGOs urge Health Canada to enhance and expand consultation efforts focused on categorization and screening assessments. Further consultation with ENGOs should be undertaken at the early phases of these process.

Precautionary Approach

The precautionary approach is a CEPA guiding principle stated in the Preamble section of the Act, as well as, being one of Canada's International commitments. At the June 1992 United Nations Conference on Environment and Development (UNCED) meeting, countries agreed by consensus to the Rio Declaration on Environment and Development which binds them to implementing the precautionary principle to protect the environment. This approach states "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as reason for postponing cost-effective measures to prevent environmental degradation" (Principle 15). It is both unfortunate and disappointing that despite the commitment for a precautionary approach made within CEPA 1999 and in other international agreements focused on managing toxic substances, the process proposed by Health Canada on GPE does not fully demonstrate a precautionary approach. On the contrary, the GPE framework has been solely based on considering arbitrary measures (i.e., number of submitters, assigning use codes and quantity cut offs) for determining the list of GPE substances. The use of arbitrary measures inadvertently leads to a shorter or abbreviated list of substances regardless of their potential risk to human health and the environment. In this

categorization effort, we understand that the lack of reliable or sufficient scientific data was a limiting factor, however, we believe that considerations of other factors relating to exposure potential for the proposed GPE approach should have been undertaken to ensure that the precautionary approach was sufficiently followed and integrated into the categorization process.

Recommendation 3: The precautionary approach should be an underlying principle, applicable throughout the categorization and screening assessment process including the GPE framework and determination of inherent toxicity of DSL to humans.

Recommendation 4: In support of the precautionary principle, we reject the arbitrary measures used in the GPE framework, including the use of the 10% cut off threshold to select the substances that meet quantity cut off value ($Q = 1,000,000$ kg/year) and the number of submitters ($S = >4$).

Consideration of Children's Health in GPE Framework

The disproportionate level of impact to the health of children from exposure to toxic substances is an important guiding principle that should be applied throughout the development of the GPE framework as well as other aspects of the categorization process undertaken by Health Canada. In particular, consideration of children's health should be integrated into the GPE framework to recognize and emphasize that children's activity patterns are unique and result in different pathways for exposure to toxic substances. While Health Canada's presentation at the March 8th information session makes note that children's health is considered at all points of categorization including determination for inherent toxicity, the rationale presented in the GPE document for consideration of children's health is insufficient and does not fully encompass uniqueness of children's health issues with respect to exposure to toxic substances. Mainly the recognition of children's health in the GPE framework is considered in the use codes assigned by "experts." This exercise in and of itself is not guided by a stringent set of criteria for assigning use codes. Health Canada noted that it would consider children's health in subsequent phases of the GPE exercise, however, it is of concern that the current three-Tier system proposed by Health Canada for the categorization process will not capture all substances that may pose a risk to children's health. Currently, Health Canada's Tier system aims to establish priorities for assessments. However, the Tier system may not reflect the current concerns around substances of greatest potential for exposure as it relates to children as it was developed using the parameters used in GPE framework (i.e. $Q = 1,000,000$ kg/year, $S = >4$ and $U =$ sum of the weighted use code indices). If substances that are of concern to children's health are not captured in the Tier 1, then there are no further measures to capture these substances during the categorization process.

We believe that children's health should be weighed differently in the GPE framework. Health Canada should consider creating a parallel process to the proposed GPE

framework that would identify those substances that are of highest potential exposure to children. These substances then should be added to the list of GPE substances currently identified by Health Canada. This process would require a committee of experts on children's health to convene for the purposes of reviewing the use codes as it relates to exposure to children. By following this approach a signal is sent to Health Canada on the efforts needed to adequately consider children's health. Further, by including this effort Health Canada is given a tool for identifying priorities in the screening process should a substance appear in both the proposed GPE list and in the parallel list created to protect children's health.

Recommendation 5: Create a parallel process to the GPE framework that would identify those substances that are of greatest potential for exposure to children's health. This list of substances would be added to the current GPE list, identified by Health Canada as a priority in the categorization process.

Recommendation 6: Health Canada convenes a committee of experts on children's health that would include ENGO participation for the purposes of reviewing the use codes as they relate to exposure to children.

Class Approach Versus Chemical-by-Chemical Approach

The Health Canada proposal on GPE embraces the chemical-by-chemical approach in managing toxic substances. This approach is both time consuming and resource intensive. Given the limited time and resources and the lack of data availability, consideration should be given to the class approach. By undertaking a class approach, all chemicals with similar properties and exposure patterns will be considered under the same class, resulting in capturing more substances with possible risk to human health, regardless of the quantity of use or number of submitters. To address this concern, the quantity levels and the number of submitters can be summed for substances found in the same class. This would result in inclusion of more DSL substances for further consideration.

Recommendation 7: Health Canada should apply the class approach by grouping substances with similar exposure patterns and similar chemical properties. This approach would result in an increase in quantity and use code ranking for some substances that could not meet the original thresholds for quantity value or number of submitters.

Evaluating Effectiveness of Canada's Toxic Management Strategies

The categorization process is intended to expedite the efforts for identifying those substances that are "toxic" under CEPA 1999. This requirement demonstrates a valiant effort to address the length of time required to identify and assess chemicals for toxicity and one that is supported by ENGOs. However, despite these efforts, Canadians are

concerned that the activities currently undertaken by the Health Canada will not meet the intended goal, which is to effectively eliminate and reduce CEPA “toxic” substances. For Canada's management strategy on toxic substances to be truly effective, all phases of categorization, assessment and management must adhere to high standards that aim to fully protect human health and the environment. The foundation established by the GPE and other categorization processes is a critical first step for the toxic management regime in Canada and can implement a system that is truly protective of human health and the environment from exposure to toxic substances.

Currently, very little information is available to the public to draw conclusions on the effectiveness of efforts by Environment Canada and Health Canada in managing CEPA "toxic" substances through the Priority Substances List stream. It is not clear how much these efforts helped to reduce or eliminate substances that have been declared “toxic”. This lack of information is a cause for concern, especially if the intent for the current categorization and screening assessment process is to identify, assess, manage and eventually phase out toxic chemicals more efficiently. For example, there is no transparent process or reporting requirement that provides a regular update on the status of the efforts undertaken to implement the management options for toxic substances identified through the Priority Substances stream. Further, these efforts do little to suggest whether there are improvements, or despite the recommended measures, whether the environment and human health remain at risk from exposure to these toxic substances.

The exercise for categorization provides the opportunity to reflect on the current efforts on managing substances. In the context of their current obligations, Environment Canada and Health Canada should use this opportunity to consider their past experience with managing substances through the Priority Substances stream and draw on this experience to ensure the categorization process can effectively achieve the intent of the CEPA obligations which is to expedite the process by which toxic substances are assessed and managed in Canada.

Recommendation 8: It is imperative that both Departments of Health and Environment provide measurable information on the effectiveness of their actions in phasing out substances that are declared “toxic” under CEPA.

Main Issues of Concern Regarding Proposed Framework for Determining Greatest Potential for Human Exposure

The proposed framework for GPE is limiting and simplistic in its approach. These limitations raise doubts as to the effectiveness of the GPE framework to identify all substances with the greatest potential for human exposure. The issues highlighted below contribute to the limitations of the proposed GPE framework.

Establishing Top 10% Cut-off Threshold for Inclusion

The most disconcerting aspect of Health Canada's GPE proposal is the selection of a 10% cut off threshold that essentially creates limits in the GPE proposal at the onset of the process and does not adequately result in a comprehensive list of substances with the greatest potential for human exposure. The selection of a 10% cut off threshold was applied to a number of parameters such as quantity/volume, number of submitters and use codes to determine the list of GPE substances. AS noted in an earlier section, we reject the adoption of proposed 10% cut off threshold for selecting substances for the GPE list.

Quantity/Volume Parameter

Health Canada's GPE report does not provide a rationale for selecting 10% cut off threshold, other than that presented to explain the number of substances with volumes greater than one million kg was 10.8% of the substances on the inventory. There are two fundamental problems with the use of the volume data in this proposal. First, the proposal (page 7) claims that the current proposed GPE criterion for quantity of use “prioritize all substances definitely in use at over 100,000 kg/year.” This figure is contrary to approach presented in figure 1 (page 5) showing that only substances with 1,000,000 kg/year or more are considered for the GPE categorization. Second, the 10% cut off threshold was applied to the volume/quantity threshold to capture substances for inclusion on the GPE list. Hence, the substances may be of greatest potential for human exposure but will not be captured due to this threshold.

As required under the European Union's REACH Policy on toxic substances, Health Canada should adopt a similar approach for the GPE proposal and include all substances meeting the 100,000 kg/year threshold not 1,000,000 kg/year as currently proposed.

Recommendation 9: Health Canada should adopt the proactive approach, employed by EU's REACH Policy, to include all substances with quantity value equal to or greater than 100,000 kg/year in the categorization process.

Recommendation 10: Health Canada should employ a 21% quantity cut off value to include all substances on the DSL with potential of human exposure.

Number of submitters

The number of submitters is used as a parameter for prioritization “on the premise that, if a substance is being used by a large number of submitters, then it is likely to have more widespread distribution in Canada than a substance used by a smaller number of submitters.” This premise is not known to be true. Health Canada's GPE does not provide data or references to substantiate this statement. We know that one producer could have more facilities than 5 producers, and thus would be left off this list.

There are other problems with using the number of submitters in the GPE proposal. It is likely that the number of submitters is correlated with the volume, however, the level of correlation is not presented in Health Canada's GPE proposal. If volume and number of submitters is correlated, then essentially volume parameter is being used twice as a parameter to prioritize: once as volume and once as volume under the designation “number of submitters.”

There is another problem with this approach. The number of submitters ranges from 1 to 104, but volume ranges over 1-7. In the body of the proposal it says the range is 1-104 but in figure 1 it reports the range in log units. Health Canada's GPE proposal does not provide a clear explanation whether absolute values or logs of the number of submitters were used in determining the GPE list of substances. If the absolute values were used, then the differences in ranges weights number of users heavier than volume. This approach is a very poor predictor for identifying substances of greatest potential for human exposure.

Recommendation 11: The use of number of submitters is inappropriate and should be eliminated from this proposed framework. In this proposal the use of quantity may suffice with consideration of other factors for determining GPE to humans.

Intersection of Parameters

Health Canada's proposal to intersect the lists for the following parameters: volume/quantity, submitters and use codes is not appropriate nor is the application of the 10% cut off threshold in this matter. Exposure is a product of volume and percentage of that volume to which we are exposed. If developed appropriately, a use index can provide a measure of the percentage of a substance to which we are exposed. The product of the use index and volume gives an index of exposure, whereas, the intersection of the top 10% of the values for each parameter does not. This exposure index would provide a scoring for the whole inventory that would be the basis for ranking substances. The identification of the GPE substances would be done using benchmark substances comprising of a list of substances known to pose high exposure. They would include high volume substances and substances found in human tissues. They would be identified in the ranked inventory, and then all substances that have a higher ranking than the lowest ranked benchmark substance would be identified as GPE.

Recommendation 12: Health Canada should abandon the process presented in their proposal and use the exposure index described above.

As currently proposed, the results of intersecting the parameters under the GPE proposal will result in targeting 849 substances. According to Health Canada, these 849 substances represent 55% of the substances listed under US Environmental Protection Agency's High Production Volume Challenge Program List or about 37% of the ICCA HPV 2003 Working List. What Health Canada has failed to provide in this proposal is the list of chemicals that are found on these two specific lists but not included in the final GPE list. Health Canada provides a brief rationale on the differences between the lists, however no rationale is provided on how the other substances on these two lists can be addressed effectively by the GPE proposal.

Recommendation 13: Health Canada should provide a comprehensive list of substances that are not included in the GPE list but are found in the US EPA's HPV Challenge Program List or ICCA HPV 2003 Working List.

Inadequacy of the Use Code Ranking/Scaling

Like the other parameters in the GPE proposal, there are concerns with regards to the use of use codes indices. As currently proposed, the use code ranking are poor indicators for GPE, since it fails to fully demonstrate the relevance to human exposure.

There are two major problems with the approach used to determine the use code values. The first is the attempts made to rank the codes as high, medium, and low. The result of this ranking does not reflect the sensitivity of human exposure to toxic substances. To address this lack of sensitivity, the codes should be ranked from the highest to the lowest by a variety of experts and then the average should be used as one of the exposure indices for determining GPE. By applying this approach, the ranking, based on high medium and low score, still remains in tack.

Our second concern The second major problem is that the use code parameter is the result of summing of all the use codes. By applying this approach, higher exposure index value is designated to substances with more uses, even if all uses are of low exposure. For example, a chemical with four low exposure uses (with score of 1 for low exposure) would score 4 (sum of the use code scores) in the ranking process. Whereas, another chemical with one use of high exposure (with score of 3 for high exposure) would have a score of 3 and, therefore, falls below the first substance, even though its potential for exposure is much higher than the first one. The proposal to sum the use codes is inappropriate and leads to misrepresentation of the true exposure potential of a substance. A preferred approach would be to use the value of the highest exposure code.

Recommendation 14: Use codes should not be summed to determine the exposure potential of a substance. A preferred approach would be to use the value of the highest exposure code or the average of the values of all codes to obtain a value more reflective of the exposure potential for a substance.

Recommendation 15: The ranking of the use codes should be redone. Experts should rank the codes from highest to lowest exposure. Then the average of the rankings would provide a final use code index. This use code index then would be multiplied by the volume of use, to determine the relative GPE.

Inadequate Definition for Exposure

According to Boethling et al. (1995): “The amount of exposure depends on several factors, including the amount of chemical used or released, chemical fate and transport, chemical concentration at point of exposure, the routes and rates of uptake, the exposure setting and the characteristics of receptors potentially exposed to the chemical.” In Health Canada's GPE proposal most of parameters mentioned in this definition were not considered. We understand that some of the parameters for defining exposure would be very difficult to determine for a large list of substances. For example, a rate by which a chemical is taken up is a complex process and difficult to measure since all three-exposure routes (dermal, inhalation and digestion) should be considered. In the GPE proposal, the factor or likelihood of uptake has not been considered. By simply indicating that uptake is likely or improbable, the issue of uptake can be easily integrated into Health Canada's GPE proposal. By following this approach, information gathering and calculations are minimal.

Based on molecular size of substances or solubility, the factor of uptake can be assessed. For instance, it is generally agreed that chemicals with high molecular mass (i.e. >1000 amu) have little or no human exposure potential and therefore could safely be eliminated from the process. However, measures should be taken to determine if there is a potential for the metabolites of these substances to pose a risk to human health. Further, chemicals such as insoluble inorganic salts would likely pose little exposure and therefore can be eliminated from the GPE list (unless, there is a chance for the metabolites to become soluble).

Recommendation 16: The factor of uptake potential can be considered in the GPE proposal. Molecular size of organic substances and solubility of minerals are good indicators for uptake potential.

Equal Consideration of Substances

On page 7 of the GPE report an argument is presented to consider the same data for all substances on the inventory. We are concerned with this approach, substances with known low exposure potential may rank high in the GPE list. We suggest that substances with low exposure potential should be removed from the categorization process to make way for inclusion of other chemicals on the GPE list. Furthermore, Health Canada should develop a list of substances that are currently excluded from the GPE process, however, have potential for human exposure.

Recommendation 17: The GPE process should identify and eliminate those substances from the process with known low or no exposure risk.

Recommendation 18: Health Canada should develop a list of substances that need further investigation based on other factors of exposure not considered in the current GPE proposal. Additional knowledge on exposure to substances is known by other government organizations and industry. This knowledge should be considered if Health Canada's approach is to capture all substances with GPE characteristics for further consideration.

Other Limitations in the GPE Proposal

1. Through the Priority Substances stream, there are a number of DSL substances that are currently undergoing assessment or have already been assessed. To ensure that efforts and resources are focused on identifying other substances of greatest potential for exposure, the current PSL substances should be removed from the GPE exercise.

Recommendation 19: Remove those substances identified through the Priority substances stream as GPE and are currently being assessed or have been assessed.

2. Health Canada identified that the lack of information or outdated information available from the DSL exercise was a limiting factor in developing a comprehensive GPE list. Throughout the GPE exercise and the efforts to determine the inherent toxicity to humans, Health Canada learned many valuable lessons that can assist them in future work around categorization and screening assessment. Based on this experience, the value of comprehensive databases became more and more evident to Health Canada. Despite the lack of legislative obligation to gather data and the limited resources available, Health Canada should propose a process that enhance the data collection activities and outline how further efforts will be undertaken to address this lack of information.

Recommendation 20: Health Canada should create a process that enhance the data collection activities and outline how further efforts will be undertaken to address the lack of data, required for the categorization and screening process.

3. We are concern that Health Canada’s proposed Tier system for “priority setting for potential for exposure” is not adequate to include all substances of concern.

Recommendation 21: Health Canada should provide the rationale for the developing the Tier system as well as outlining set of criteria, which includes timeframes by which, those substances listed as Tier 2 or 3 will be addressed for data collection.

Conclusion

Health Canada’s proposal for categorization of the 23,000 DSL substances based on their greatest exposure potential suffers from both faulty thinking and trying too hard to rationalize a method that produce a short list of substances for assessment. It is important that Health Canada take proper action to correct this shortcoming. The inadequacy in the current GPE approach will be all too apparent should Health Canada's final GPE list present fewer number substances than current list of substances proposed by the US Environmental Protection Agency's and other International agencies for High Production Volume. The inadequacies of the GPE framework will be further heightened should the list include many of the low uptake substances that do no pose significant risk to human health.

Health Canada has time to reflect on these shortcoming to ensure that all the substances that must be identified for further screening assessing are effectively captured through the GPE framework. The ENGO comments and recommendations presented in this document are to provide support to reviewing and revising the current GPE proposal.