

# Selecting the Next Round of Substances for Assessments: NGOs Interim Response to Government Approach

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December 6, 2010

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## **Introduction**

The Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) express our thanks for being able to attend and participate in the Workshop on Selecting the Next Round of Substances, sponsored by Environment Canada, held in Gatineau, Quebec on November 10, 2010.

We are extremely pleased that a workshop to discuss medium priority substances was convened. We hope that this workshop will initiate follow-up workshops to further discuss, with some more specificity, the government's approach. Throughout the workshop proceedings, stakeholders raised many issues and questions related to the initial proposals for medium priority substances' framework. These issues include on-going data gaps on a substance's toxicity; use applications and release; application of the precautionary principle; addressing vulnerable populations; application and role of the Significant New Activity (SNAc) provision; the proposed use of surveys under section 71 of the *Canadian Environmental Protection Act 1999* (CEPA 1999); and the rapid screening tool.

CELA and CSM as well as other Canadian public interest organizations have highlighted many of the above listed issues in submissions made to the government in response to the risk assessment and proposed risk management measures of specific substances under the Challenge Program.

Furthermore, our groups, in conjunction with other non-governmental organizations, submitted a letter dated October 21, 2009 outlining our expectations for government efforts to address medium priority substances (see attached). While the November 2010 workshop provided information on various aspects of the framework for medium priority substances and the government continues to seek stakeholder input, it is our view that many of the issues we have raised during the Challenge Program and in our October 21<sup>st</sup> 2009 letter were not adequately addressed during the workshop discussions. As a result, we are concerned that the government, in this next round of assessments on medium priority substances, may not take a rigorous approach to conduct assessments since these substances have not been classified as high priority for health and environmental effects.

The gaps that have been raised during the assessment of the high priority substances should be given further consideration as the government proceeds with work on the medium priority substances. These issues are just as pertinent, and even more so as the knowledge base on many of the medium priority substances could be very limited. As a result of considering the many issues previously raised, we hope that the government makes changes relevant to these issues and ensures that in this next phase of assessment work, those changes are reflected in its approach with emphasis on the application of the precautionary principle. We are of the opinion that this approach would have a positive impact on the next phase of the CMP.

The government should be guided by the principles outlined in CEPA 1999 in its efforts to proceed with medium priority substances for data collection, conducting assessments and implementing measures. Specifically, the provisions under CEPA that should be given priority are the following:

- Apply the precautionary principle in conducting assessments;
- Apply pollution prevention to eliminate or reduce toxic substances; and
- Where applicable achieve virtual elimination for persistent, bioaccumulative toxic substances.

The following are our comments on several significant issues and proposed recommendations based on the materials and discussion presented at the 'Workshop on Selecting the Next Round of Substances'.

## **Issues, Comments & Recommendations**

### ***Group assessment***

While we have expressed our general agreement that group assessments are appropriate under some circumstances and that they have the potential to promote greater efficiencies in the CMP system for risk assessment and risk management purposes, the basis for grouping substances should not be solely driven by creating efficiencies in the system. It would be counter-productive to health and environmental protection if this approach is used in early efforts to substantially reduce the number of substances requiring assessment. Rather, we support the efficiency created by an approach that takes information about the toxicity of an entire group of substances into account and responds with actions to reduce or eliminate exposure across the entire group, whether or not the same information base is available for each and every substance in the group.

Within the constant reality of insufficient data about toxic substances, we support the greater application of analogy and plausibility when comparing available scientific information. Where the toxicity of a single or a few substances within a group is relatively well understood, it is reasonable and prudent to take precautionary action for the other substances in the group regardless of the existence of other significant data gaps.

Recognizing that any group assessment must have efficiency as a factor, maximizing the benefits from a group assessment approach is just as important. This would require that careful consideration be given to the identification of the groups and their subgroups. There will be challenges in this approach as the number of substances within a grouping can be large; have diversity in chemical structure and properties; end use; volume usage; mode of action and hazard characteristics; among other variables. While similarities are important, it is also essential to note that any anomalies within a group should be clearly identified and assessed separately, particularly where such anomalies can significantly change the determination of toxicity.

Greater efficiency in the system will also come from greater application of the full scope of government authority to require the production of data necessary for decision-making. Such information, where it is generated for individual substances, can likewise assist in the assessment of additional substances in a larger group.

The following sub-sections discuss some aspects for consideration relating to group assessments for the medium priority substances:

### ***Biomonitoring***

It is not known if biomonitoring programs established by the government through the Canadian Health Measures Survey (CHMS) or through other groups or jurisdictions played any role in the government's approach for identifying groups of medium priority substances. However, in the draft group profiles provided by the government for selenium and its compounds and soluble zinc and its compounds, both included mention of recent available Canadian biomonitoring data to support human exposure. It is uncertain as to why this was not included for soluble copper compounds which are also covered under the CHMS biomonitoring program.

Phase I of the biomonitoring under CHMS included several metals and phthalates. Also included in the 3000 medium priority substances are organic metal salts, organometallics and phthalates. We want to ensure that the biomonitoring results for these metal moieties and the phthalates will play a significant role in the future assessment work on medium priority substances as groups, subgroups and priority setting amongst the groups are determined.

It is also necessary to increase the scope of biomonitoring efforts and include some other substances identified in the Challenge and on the medium priority substance list that could potentially have an impact on human exposure. This expansion of the biomonitoring program would be more representative of human exposure.

Finally, the timing for the assessments and the collection of biomonitoring results are of utmost importance. Some consideration as to the identification of substances for biomonitoring and the timing for releasing biomonitoring results should be coordinated so the data could be used when assessments for the medium priority substances are conducted. Guidelines for choosing these substances and timelines for biomonitoring should also be transparent and predictable.

### ***Isomers***

We are pleased that some consideration will be given to structural isomers and stereoisomers in the assessment process, particularly since there has been little consideration given to either of these in assessments conducted under the Challenge Program of the CMP. As a result, it is important for isomers to be on the radar for the medium priority substances noting stereoisomerism could result in some differences in chemical/physical properties.

## **Transparency in groupings**

In our October 21, 2009 letter, we highlighted the need to promote transparency throughout the decision process for the assessment and management of medium priority substances. This level of transparency should not be limited to public engagement but should extend to the process by which the government outlines its proposals for establishing criteria to determine groups and their subgroups in the assessment process. It is also important to include the data requirements as this would indicate the extent of the data gaps for groups and subgroups

We understand that the draft grouping profiles presented at the workshop are initial efforts to ensure stakeholders understand the rationale behind the groupings being considered. We appreciate these initial efforts. These grouping profiles also list elements of a risk assessment framework that provided information on current risk management measures underway in Canada or other jurisdictions. However, these documents did not include the range and quality of data for these substances, that is, the details on assessment results completed under CEPA and how this information may have informed the grouping of substances for an assessment.

In order to adequately assess the validity of the groupings, the details as mentioned above, the existing data gaps and the government's proposed action to fill these gaps are essential. The use of section 71 has been noted in the draft group profiles but specific details regarding the toxicity data have not been outlined.

***Recommendation: We are in general agreement with group assessments but would not want efficiency to be the driving force behind the decision for group assessments.***

***Recommendation: Efficiency and the better protection of human health and the environment should be promoted by requiring industry to submit relevant data to address existing data gaps on substances. Furthermore, we urge the government, in its assessments, to take the available information about the toxicity of an entire group of substances into account and respond with actions to reduce or eliminate exposure across the entire group, whether or not the same information base is available for each and every substance in the group.***

***Recommendation: We request that the government reviews pertinent biomonitoring data from the Canadian Health Measures Survey and use this data to inform human exposure but also clearly indicate how this data will influence the setting of priorities and groupings for assessments.***

***Recommendation: We also request that the biomonitoring program be expanded to include more Challenge and medium priority substances that will be pertinent to demonstrate human exposure.***

**Recommendation: We urge the government to coordinate the timing for the release of biomonitoring results so that the results are available when assessments are underway.**

**Recommendation: In the consideration for subgroups and the remaining groups for assessment, the government should continue to provide substantial profiles and rationale used for identifying these groups and subgroups for further discussions for stakeholders.**

**Recommendation: In the selection considerations for a group, we recommend that the government include some details as to sources used to derive the information.**

### **Data gaps**

With 3000 substances to assess, it is expected that there will be many data gaps. The Industry Challenge process has demonstrated that large data gaps and uncertainty in data continue to exist even for substances considered high priority. The presence of data gaps in the next set of assessments will reduce the level of flexibility when attempting to determine the groups and subgroups of substances. If a large group of substances is not data rich and there are attempts to identify subgroups, it is possible to introduce considerable uncertainty or add to the level of uncertainty already associated with the group. As a result, we have concerns as to the degree to which modeling and the use of analogues would have to be utilized to fill these gaps. Furthermore, we express concern that if this data is then utilized for further modeling, the uncertainty in the assessment becomes compounded. The quality of the assessment then becomes questionable.

One of the key issues we had raised in our October 21<sup>st</sup> 2009 letter was the need for government to increase its level of accountability from industry to provide the necessary data to complete these assessments. Where data about certain substances is limited or lacking, we recognize the need to make conservative estimates during assessments. However, we are concerned that the government will not attempt to fill data gaps for substances not characterized as high priority for health or environmental impacts. We again urge the greater use of section 71 to fill these gaps. As well, we urge the formation of groups of substances around data rich substances where there is a reasonable expectation that other substances are similar enough to form a group. The data rich substances should be used, with care, to inform the data poor substances with precautionary approaches applied to the group as a whole.

The following are some specific issues relating to data gaps:

#### **Low dose exposure (human & environment)**

Substances in the medium priority group will have limited data to consider for assessment. It is critical to understand how substances including those with more than

one moiety present, will be distinguished in a group, if a substance in that group exhibits low dose exposure toxicity, significantly lower than other substances in that group. In effect, how will these differences in exposure/effect to human health and the environment be weighted and differentiated in the group? Will these critical differences necessitate the formation of subgroups? Also, will a number of toxicity endpoints for selected substances in a group, if available, be considered based on the no observed effects level or will the most sensitive endpoint be considered for the entire group?

### ***Results from Industry Challenge and other Risk Assessments***

There may be situations where the results of a risk assessment conducted during the Industry Challenge of the CMP or from previous risk assessments completed under CEPA, may be able to provide additional information on a substance in the medium priority grouping. Definition is required as to the extent to which the results from these assessments will influence the assessments to be conducted on the medium priority substances, if at all.

With the assumption that there will be data gaps for the medium priority substances, it is of critical importance to understand how previous decisions made by the government will influence the decision making for these upcoming assessments. There have been decisions on substances made under the Industry Challenge that relied on the use of modeling, rather than experimental data, for estimating exposure potential. In the situation where no experimental data is available, modeling data would be appropriate. However, the government should take every necessary step to seek experimental data. We are concerned that these Industry Challenge decisions could contribute to a very high level of uncertainty in this new set of assessments on medium priority substances.

As a result, the government should make all efforts to reduce the uncertainty in the data through better use of its authority under *CEPA 1999*, to obtain pertinent quality data for decision-making purposes.

### ***Relevant Issues Related to Petroleum Stream Sector and Azo Dyes and Pigments***

We have responded to the government's efforts on other group assessments - Petroleum Sector, Stream 1 – substances<sup>1</sup> and Stream 1, 20 substances<sup>2</sup> as well as

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<sup>1</sup> A response to the *Canada Gazette* Part 1, Vol. 144, No. 22, May 29, 2010: NGO Comments on Draft Assessment for Stream 1 of the Petroleum Sector Stream of the Chemicals Management Plan. Accessed at <http://www.cela.ca/sites/cela.ca/files/735%20-%20CELA%20and%20CSM%20on%20CMP%20petroleum%20stream%201%28July%202010%29.pdf>.

<sup>2</sup> A Response to the *Canada Gazette* Part 1, Vol. 144, No. 23, June 5, 2010: NGO Comments on the Notice of Intent to Assess and Manage Aromatic Azo Substances. Accessed at <http://www.cela.ca/sites/cela.ca/files/736-CELA%20and%20CSM%20resp%20to%20CMP%20NOI%20on%20AZO%20substances%20%28Aug%202010%29.pdf>.

the Note of Intent to assess and manage aromatic azo substances (pigments and dyes).<sup>3</sup>

The government has indicated that it will take into consideration the format used for the Petroleum Sector approach when deciding on the format for assessing the medium priority substances. The first two assessments conducted for the Petroleum Sector substances were done so on the basis that the substances were site-restricted. We expressed our concerns that this approach had many flaws which were noted in our responses to the draft risk assessment reports.

The risk assessment conclusions were based on very limited data on the individual substances and the scope of the assessments did not include consideration of occupational exposure to the substances, cumulative impacts of these substances at the facility level, and the impacts to the neighbouring communities located in close proximity to the facilities. There has been no dialogue for discussions on this approach with the exception of the public comment period required under CEPA 1999. We urge the government not to establish groups of substances that follow the rationale and procedures used for the Petroleum Stream Sector until the many limitations in the approach have been discussed and addressed. We are very concerned about this approach since there are approximately 218 petroleum sector substances that have been classified as medium priority.

Similarly, we have raised issues for the government to consider with the grouping for azo dyes and pigments. The following are some of the issues that we have raised on the azo dyes and pigments and the Petroleum Sector:

#### Azo dyes and pigments

- lack of public dialogue and guidelines for grouping 350 azo dyes and pigments;
- the use of the precautionary principle in the absence of scientific data;
- the possibility that a group assessment may weaken the strength of the risk management.

#### Petroleum Sector

- lack of release data;
- application of SNAc provision;
- disposal of site-restricted substances;
- consideration of vulnerable populations;
- the use of the precautionary principle in the absence of scientific data;
- carcinogenicity of residues.

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<sup>3</sup>A Response to *Canada Gazette* Part, Vol. 144, No. 33, June 14, 2010: NGO Comments on Draft Assessment for Stream 1 of the Petroleum Sector Stream (20 substances) of the Chemicals Management Plan. Accessed at <http://www.cela.ca/sites/cela.ca/files/743-Stream1Petsector20chemicals.pdf>.

The points listed above are not significantly different from some of the issues we have addressed in this document. While we continue to raise these issues in written submissions during the public comment period and have also voiced them at the workshop, we hope that the government would see the merit of a comprehensive review of these matters as it moves towards the second phase of the CMP.

***Recommendation: We urge the government to use its authority under Section 71(1) (c) of CEPA 1999 to fill the data gaps and thereby reduce the level of uncertainty that would exist in an assessment when there are such data gaps. Specifically, the government should seek the following toxicity information from industry: carcinogenicity, mutagenicity, reproductive and developmental toxicity, neurotoxicity including developmental neurotoxicity, endocrine disruption toxicity, chronic and acute toxicity, and sensitivity data.***

### ***Role of the precautionary principle***

It is our view that the application of the precautionary principle is integral to the assessments to be conducted as well as any management measures to be developed on the medium priority substances to ensure the protection of human health and the environment.

### ***Public Engagement***

In the presentation titled, “Overview of Considerations for the Next Phase of the Chemicals Management Plan,” slide 10 addressing ‘Predictability,’ provides some insight into stakeholder engagement with specific focus on sectors. It is our view that public engagement should be given equal focus throughout the process. While no further details are available on this matter, public interest engagement under the Industry Challenge has been consistent and substantial. We would like to see the level of public engagement strengthened to include stakeholder meetings to address current approaches and issues emerging from assessments of substances, in addition to the focus on risk management process (as noted in slide #10) or stakeholder workshops/webinars (as noted in slide #11).

***Recommendation: The government should ensure the use of the precautionary principle throughout the assessment process. Efficiencies in the process will be recognized through the government’s efforts to use its full legislative authority to obtain data from affected proponents.***

### ***Safe Substitution***

In the presentation titled “Overview of Considerations for the Next Phase of the Substances Management Plan,” slide #14, refers to “assigning higher priority to address substances could be those with informed substitution.” While the use of substitution and establishing some dialogue on substitution in Canada are welcomed, the concept of “informed substitution” is unclear. In this context, we are asking for clarification on this

use. Will the substances identified in the medium priority category be considered substitutes for other toxic substances, with a focus on Schedule 1 toxic substances only or would the government consider a few of these medium priority substances as case studies to investigate potential safe substitutes?

It is possible that substances assessed under the Challenge Program could have substitutes that would be eligible for group assessment in this upcoming phase of the CMP. In the Challenge Program, the information on substitutes in assessment reports has been limited or absent. It is our view that the identification of all substitutes should be included in any assessment process.

The principle for substitution should be interpreted as choosing inherently safer substance(s), processes or technologies that do not exhibit the same toxicity to health or the environment as the one it replaces. These substitutes should also go through a rigorous testing of their safety. Hence, it would seem on the whole, to be inappropriate that the government focus on the medium priority substances to identify potential substitutes for toxic substances as these substances, through categorization, also met the criteria for persistence, bioaccumulation and inherent toxicity or have a potential for exposure.

There are close to over 18,000 substances on the Domestic Substances List that do not meet the above stated criteria and as a result, are not required to be assessed under CEPA. As a starting point, it is more appropriate to investigate these substances as potential substitutes for toxic substances rather than focus on the medium priority substances for viable substitutes since these substances exhibit fewer concerning traits. Furthermore, there are opportunities for using “green chemistry” practices to promote substitutes that have yet to be explored.

While there are substances that remain on the DSL that are not targeted for assessment under the Industry Challenge or medium priorities, there is a significant opportunity available through this process to gain better insight into possible substitutes.

***Recommendation: While there is general agreement with group assessments for the upcoming phase of the CMP, (under conditions as previously described), there is significant reservation to recommend this process mainly for determining substitutes for toxic substances, including those on Schedule 1 of CEPA. Assessment of substitutes require rigorous screening which is better achieved under an individual assessment process as compared to a group assessment unless the group is extremely small with physical/chemical properties and modes of actions being very similar.***

***Recommendation: The government should investigate the substances that remain on the DSL that have not met the criteria for categorization under CEPA, as a pool of potential substitutes for CEPA-toxic substances.***

## **Analogues**

Many data gaps are expected for the 3,000 substances remaining to be assessed. It is expected that analogues would be widely used in an attempt to fill some of these data gaps. While we appreciate that analogues play a role in this regard, based on experience gained from the Industry Challenge, it would appear that the need to fill the data gaps by industry is urgent, particularly for empirical physical/chemical data that are considered essential data elements of a substance. Such information appears to be made available only in situations where a toxicity finding under CEPA is eminent. This approach was evident in the assessment of many pigments and dyes in the early Batches. Because of the lack of experimental data, the extensive use of analogues possibly contributed to the decision that these substances do not meeting the criteria for toxicity under section 64 of CEPA 1999.

The concerns our organizations have expressed on the use of analogues in the Challenge Program remain valid for this next phase of the CMP. We question the use of analogues to make a determination on persistence, bioaccumulation or inherent toxicity, in particular during the phases of the assessment process when the opportunity to identify analogues was available during categorization, and again through the data collecting phase of the Challenge Program.

In some cases in the Challenge Program, the rationale and the information to demonstrate the chemical structure for the analogue was not provided in an adequate manner in the final screening level risk assessment. This is a significant gap in the risk based approach.

In the Challenge, some of the assessment reports did not provide a specific rationale on why the analogues chosen were the most appropriate for a specific physical/chemical property, particularly since several analogues could be used for one substance. Assessments should always clearly detail the source for the choice of the analogues and the rationale in support of the choice.

***Recommendation: We request that the government use its authority under section 71(1) (c) to expand the data requirements for the 3,000 substances that require assessments so that the use of analogues in the assessments could be reduced.***

***Recommendation: Establish clear and definitive rationale for the sources, choices and acceptance of analogues. These decisions should be transparent in an assessment report.***

## **Rapid Screening**

In our letter dated October 21, 2009, we also expressed our objections regarding the use of rapid screening for substances considered low concern. The purpose of the rapid screening tool for these substances is to set them aside from substances that require

more substantial assessments. The use of this tool simply reduces the number of chemicals that should be assessed using a very limited scope of data but does not respond to the continuing data gaps for these substances.

The substances expected to be tracked for rapid screening will most likely have substantial data gaps. It is our view that this approach does not provide the necessary evidence that these substances will not harm the environment or human health. Therefore, it may be more appropriate for the government to direct its efforts and resources to fill in the data gaps as is being done for other substances. Once a substance has been found to be low risk to health or the environment using the rapid screening tool, there is no provision under the CEPA regime that creates an automatic trigger to require a re-evaluation of the substance. The onus falls squarely on the public to track such substances and therefore we would like to see a process in place to remedy this gap.

However, we are pleased to know that additional efforts by Health Canada have been undertaken to review the substances identified as low priority on an ecological basis (1066 substances) for their potential to impact human health. While we have on-going concerns with the arbitrary use of the volume threshold of 1000 kg to determine if rapid screening should be conducted, we are pleased to see that the efforts of Health Canada to review the list of substances have resulted in a number of substances (65 substances) that will be tracked for assessment.<sup>4</sup>

Our preference is for the government to have all substances remain on the list for information update (e.g. DSL inventory update) rather than be set aside based on the rapid screening tool. This will require the government's attention to determine if use, release and scope of application have changed for these substances. This represents a more precautionary approach and reduces the burden on the public.

For substances that the government has determined to be of lower concern, we suggest that industry be required to provide data using section 71 of CEPA to seek information on use, quantity, application, release and toxicity. The decisions made during the categorization process relied on 20 year old data. This warrants gathering updated, relevant data before screening tools are considered.

The government should establish a diverse stakeholder task force, which would have a mandate to identify the type of data required for section 71 surveys. This would require the task force to review the quality and quantity of data submitted and advise the government as to what type of assessments should be conducted on those substances. This would allow the government to make a more informed decision as to the suitability of a substance for rapid screening.

The use of rapid screening for these substances should be considered a tool that could be used after substantial tracking of the substances through section 71 has been

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<sup>4</sup> Personal communication with Christine Norman and Eeva Leinala, Health Canada dated November 15, 2010.

undertaken to determine if there have been changes in use, release, range of application and toxicity.

***Recommendation: We urge the government to delay its use of the rapid screening tool as a means of setting substances aside.***

***Recommendation: We urge the government to develop and release for public comments, its rationale (including guidelines) for the application of the rapid screening tool.***

***Recommendation: A survey under section 71 of CEPA should be undertaken for those substances identified as low priority substances in the medium priority groups for the purposes of obtaining current information on quantity and range of application, release levels and available toxicity data associated with these substances in order to justify their designation as low priority.***

***Recommendation: The government should establish a multi-stakeholder task force for data collection under section 71 of CEPA. The task force would be responsible for:***

- ***identifying the type of data to be submitted under section 71;***
- ***reviewing the amount and quality of the data submitted under section 71; and***
- ***providing advice to determine what level of assessment is appropriate (i.e., rapid screening versus screening level risk assessment).***

***Recommendation: The Rapid Screening tool should be considered as a last resort for assessment for those substances that have demonstrated a decrease trend in type of uses, release levels or toxicity data demonstrating little impacts to health or the environment.***

### ***Cumulative, synergistic impacts & aggregate exposures***

It is our view that the discussions to consider cumulative impacts for medium priority substances represent a significant opportunity in Canada to improve the quality of assessments conducted on substances in use in Canada. We greatly encourage additional dialogue with the government on the approach to be taken.

The grouping of substances will facilitate consideration of aggregate or cumulative exposure in conducting risk assessment as well as moiety-based assessments. This grouping process will also assist in the identification of additive or synergistic impacts of substances to human health and the environment. It will also allow consideration of antagonistic effects between substances.

While the strategic grouping of substances will have some inherent problems, it is hoped that a cumulative risk approach will be given serious consideration as it is better

able to evaluate and estimate the potential risks to human health and the environment associated with multi-chemicals and multi-pathway exposures of the substances within a group, where substances share a common mechanism for toxicity or where they are associated with a similar health endpoint.

Though these approaches are challenging and evolving, the knowledge gained from these approaches would be more pointed and relevant as the government makes decisions for the purpose of protecting human health and the environment and in particular, vulnerable populations such as indigenous communities, workers and children—including *in utero* exposure. Under the Challenge, the government had not included a mandatory requirement for this information, with particular focus on *in utero* and worker exposures.

The cumulative risk approach on substances sharing a common mechanism for toxicity would likely require the government to initiate an aggregate risk assessment for each substance within the common mechanism grouping.

Canada and other jurisdictions have identified the value of estimating the cumulative impact of substances. In Ontario, the Environmental Commissioner of Ontario (ECO) annual report for 2005-2006 discussed the inadequacy of the current regulatory framework in Ontario, with specific attention to *O.Reg. 419/05* designed to develop air standards for high priority contaminants to address cumulative and synergistic impacts of persistent toxic substances including lead, chromium, and mercury. While the efforts for developing air standards in Ontario continue to progress, it is important to note that the Environmental Commissioner identified the need to address cumulative and synergistic effects of toxic substances within this regulatory framework.<sup>5</sup>

Historically, the US Environmental Protection Agency (EPA) has generally evaluated the safety of pesticides on the basis of single-substance and single-exposure pathway scenarios.<sup>6</sup> The approach in Canada is similar, including following the US in exploring the application of aggregating exposure and cumulative effects assessment. At present, the EPA is conducting cumulative risk assessments for four different mechanism groups of pesticides (organophosphates, N-methylcarbamates, triazines, chloroacetanilides).<sup>7</sup> For any one group, this approach has allowed the EPA to more accurately predict exposures from all sources, including regional variations, therefore approximating more accurate and realistic human exposure and risk for the group.<sup>8</sup>

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<sup>5</sup> Environmental Commissioner of Ontario. Annual Report 2005-2006. Neglecting our Obligations. Page 95. Accessed at: [http://eco.on.ca/eng/uploads/eng\\_pdfs/ar2005\\_en\\_report\\_01.pdf](http://eco.on.ca/eng/uploads/eng_pdfs/ar2005_en_report_01.pdf).

<sup>6</sup> U.S. Environmental Protection Agency (EPA): Guidance on Accumulative Risk Assessment of Pesticide Chemicals that have a Common Mechanism of Toxicity. Page 5. Accessed at: <http://www.epa.gov/scipoly/sap/meetings/2003/december11/cumulativeguidance2002.pdf>.

<sup>7</sup> U.S. Environmental Protection Agency (EPA): Pesticides: Health & Safety – Assessing Pesticide Cumulative Risk. Accessed at: <http://www.epa.gov/pesticides/cumulative/index.htm>.

<sup>8</sup> Ibid

However, this approach is not always feasible if substances within a substance group do not have the same mechanism for toxicity within the human body, as in the case of the thiocarbamate and dithiocarbamate pesticides.<sup>9</sup>

A similar, though more comprehensive approach, taking into account variable mechanisms of toxicity but common health endpoints, has been recommended in the US for phthalate esters, and other antiandrogenic substances. Phthalate esters belong to one class and have diverse usage in consumer products including cosmetics, personal care products, children's toys, pharmaceuticals and medical devices, building materials, food packaging, and cleaning products. Recent studies show widespread human exposure to multiple phthalates and indicate that effects on the development of the reproductive system of laboratory animals occur at much lower doses than were predicted in earlier studies.<sup>10</sup>

From the US National Research Council's recent report on the "Health Effects of Phthalates," the committee recommended that a cumulative risk assessment be conducted for phthalates and that the assessment includes other antiandrogens.<sup>11</sup> Therefore, it recognized that other substances, not in the phthalate ester chemical group could have the same effect. This is important as it echoes the opinion of concerned stakeholders in this regard but at the same time, questions how this scenario is best resolved in a group assessment. While it is important to recognize this finding, it creates challenges to the cumulative risk assessment approach.

However, in the draft group profile for phthalates, dated October 25, 2010, it is noted that within the phthalates group assessment, there are three potential sub-groups. These are based on molecular weight groupings – low to high and also, the number of carbon atoms in the backbone. While this grouping is consistent with other jurisdictions for human health considerations because of observed differences in developmental toxicology, the draft group profile for phthalates does not indicate if these observed differences are due to the timing of the exposure, the intensity of the adverse effects, or the absence of effects under certain conditions. Therefore, some clarification is required. The document did not indicate if a cumulative risk assessment for health would be considered. However, it was indicated that from an ecological perspective, the initial approach may be to view the phthalates as a single broad group with sub-groups defined according to persistence, bioaccumulation and log Kow properties.

Although mentioned, the government's presentations failed to provide insight into the consideration of the aggregation of substances through the group approach. This, too, should be adopted in the government's approach. The consideration of exposure to one substance via different sources will highlight the need for a more comprehensive approach to address all uses and release sources of a substance.

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<sup>9</sup> Ibid

<sup>10</sup> National Research Council, US Federal Government. Phthalates and Cumulative Risk Assessment The Task Ahead (Free Executive Summary). Page 3. Assessed at: <http://www.nap.edu/catalog/12528.html>.

<sup>11</sup> Ibid. Page 7

As the government continues the process in classifying and determining the groups to be assessed, it is hoped that there will be consideration given to expand upon the current health endpoints. It is hoped that such an expansion of human health endpoints will also result in a stronger knowledge base for health impacts and a more robust set of exposure data for toxic substances.

While we recognize the many factors to be reviewed when considering cumulative effects, synergies and aggregates, it is important that the government has continued dialogue with interested stakeholders, on these issues. This would promote transparency and a better understanding of the government's intentions on these many issues.

***Recommendation: We support government's approach to conduct cumulative risk assessment in this next phase of the CMP.***

***Recommendation: We urge the government to conduct a national workshop to discuss the options for a cumulative impact assessment approach on substances.***

***Recommendation: We urge that all rationale associated with the groupings be clearly identified and transparent.***

***Recommendation: We urge the government to identify and consider all cumulative effects, synergies and aggregates for substances considered medium priority.***

***Recommendation: We support additional dialogue that will promote the consideration of cumulative effects within a group and synergistic impacts from within or outside of the group, for substances listed as medium priority.***

### ***Inclusion of additional human health endpoints***

The NGO community has serious concerns about the lack of inclusion of key health endpoints not currently used by the government in the screening assessments under the Challenge Program. The current health endpoints of carcinogenicity, reproductive and developmental toxicity, and mutagenicity do not accurately portray the total picture of the acute and chronic human health effects resulting from exposure to toxic substances. Other health end-points such as endocrine disruption, neurotoxicity including developmental neurotoxicity, and various forms of sensitivity have been excluded, but represent the reality of the possible and/or actual health impacts of some substances.

These health endpoints should be considered fundamental elements to the toxicity dataset for any substance that is in commerce. Such data have not been explicitly requested in the surveys conducted under section 71 for substances targeted under the Industry Challenge nor were they required under the voluntary questionnaire. The

inclusion of such toxicity data during the screening assessment process would allow for a more informed decision on the toxicity of a substance and also, inform the government of these significant health outcomes much earlier on.

The substance bisphenol A (BPA) is a case in point. BPA is known to disrupt the endocrine system at very low concentrations and it is associated with developmental neurotoxicity. Although it has been declared CEPA-toxic and listed on Schedule 1 of the CEPA 1999,<sup>12</sup> regulatory action has been limited to its use in baby bottles as a result of only a limited consideration of the available scientific evidence. However, serious concerns remain as to the potential for multiple latent health effects (or their biochemical precursors) of this substance as a result of exposure *in utero*, including as a carcinogen, a reproductive and developmental toxicant and an obesogen. BPA illustrates the need for a comprehensive approach to data requirements to ensure a full assessment of multiple toxic endpoints.

***Recommendation: We urge the government to include other health endpoints such as endocrine disruption, neurotoxicity, including developmental neurotoxicity, and various forms of sensitivity. These should be considered as important endpoints with respect to the chemical exposure.***

### **Carcinogenicity**

It is likely that some substances would be identified as likely human carcinogens, possible genotoxic, or as reproductive or developmental toxicants and having the potential to do harm at any level of exposure. If similar substances with these properties are grouped together for assessment, we are of the opinion that the establishment of safe levels for human exposure to these substances cannot be accurately determined.

During the Industry Challenge, those substances that were found to be CEPA-toxic on the basis of carcinogenicity, or developmental and reproductive toxicity, were not identified for regulatory measures that generally resulted in a phase out of these substances in industrial applications or consumer products. We continue to disagree with this approach. The government should consider taking stronger regulatory action on these substances.

For any substance found to be carcinogenic or having the potential to be carcinogenic, we maintain that the appropriate government approach to it should be to phase it out with the goal of ultimate elimination. In exceptional cases where there is an essential use of a substance and where safe substitutes may not currently exist, a time limited exemption to a phase out may be considered. However, this is only recommended on a case by case basis with a goal to phase out the carcinogen in a time specified period.

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<sup>12</sup> Canada Gazette Part 11: Order adding a toxic substance to Schedule 1 of the Canadian Environmental Act 1999. See <http://www.gazette.gc.ca/rp-pr/p2/2010/2010-10-13/html/sor-dors194-eng.html>.

**Recommendation: We urge the government to consider a phase out with the intent to eliminate those substances that are found to be carcinogenic based on the results of assessments.**

### **Vulnerable populations**

Under the Challenge Program, the government requested information on potential exposure to children only through a voluntary questionnaire. Hence, exposure levels for children were considered in screening assessments when information was available through this process. Unfortunately, this information was not available for many of the substances in the Challenge Program with a noted exception of Bisphenol A (BPA). The screening assessment report on BPA included limited information for *in utero* exposure.

Vulnerable populations should be expanded to include children in utero, people of low income, aboriginal populations, the elderly, remote northern communities, workers, communities in close proximity or downwind/downstream of manufacturing facilities and those who are chemically sensitive.

While it is appreciated that there may not be information for all these subpopulations, their vulnerabilities in regard to chemical exposure require consideration by the government. By recognizing these subpopulations and requesting data under s.71 of CEPA 1999, the government sends a message to industry that it is more aware of potential or actual adverse health effects in these subpopulations as compared to the general population, if they are exposed to toxic substances.

Low income families are often more exposed to toxic substances as compared to families of higher income by virtue of where they live, their housing and other social circumstances, and occupations. This subset of the population has been ignored in the risk assessments and as a result, requires consideration in this phase of the CMP.

We understand that it may be difficult to determine the extent to which toxic chemicals cross the placenta and affect the developing fetus, the presence of toxic chemicals in cord blood and breast milk, even in remote northern communities, warrant a more precautionary approach for vulnerable subpopulations.

As occupational health is under the jurisdiction of the provinces and territories, it generally has not been assessed in detail in the Challenge Program although for some substances, information from available occupational studies has been used in the risk assessments. There is a need for the federal government to commit to significantly improve their consideration of occupational health in risk assessments with emphasis on chronic low level exposure to chemicals in the workplace. The effects of chronic and acute workplace exposure for pregnant women should also be included.

Exposure to toxics in the workplace go beyond the effects of the worker's exposure, it can possibly implicate other health issues such as reproduction and the transfer of toxic substances to a fetus or a baby. Unfortunately, these are not always considerations

within the scope of occupational health. While there are several other considerations with respect to occupational health, we urge the government to consider the inclusion of worker exposure as an urgent issue in the context of vulnerable populations.

Aboriginal and remote northern communities should be also considered vulnerable because of their lifestyle and links to the environment. This becomes even more relevant as persistent and bioaccumulative substances with the potential for biomagnification, are being detected in food sources and human breast milk, in the far north.

Also, for communities within the close proximity, downstream or downwind from industrial releases, there is a need for further consideration by the government as their exposures would be considerably greater than other communities that are not in locations are described above.

***Recommendation: We ask that the government, prior to the next stage of the CMP, expand their definition of vulnerable populations. It should be expanded to include fetal vulnerability, as well as people of low income, aboriginal populations, the elderly, remote northern communities, workers, communities in close proximity or downwind/downstream of manufacturing facilities and those who are chemically sensitive.***

***Recommendation: We urge the government to use section 71 under CEPA 1999, to request information on these subpopulations prior to risk assessment.***

### ***Inclusion of other chemical groups or substances***

From the 3000 substances to be identified, it was concluded at the meeting that other groups still have to be identified. It was assumed that the other groups that are being scoped would include other metals, not already identified. Also, there is the possibility that some of the groupings already determined may have to be expanded. Listed below are some recommendations for grouping (if these substances are included in the 3000 substances) but recognizing that this is just a partial list.

#### ***Recommendation:***

- ***Expand list of diisocyanates to include hexamethylene diisocyanates (HDI);***
- ***Create a separate grouping for alkyl benzene sulphonates (LAS);***
- ***Create a separate group for parabens; and***
- ***Create a separate group for chlorinated substances that are used as anti-microbial or anti-bacterial.***

## **Using data from other jurisdictions and organizations**

While we see the benefits of working and communicating with other jurisdictions for data sharing to promote efficiencies of the overall system, we do encourage the government to direct resources and necessary budget so there is no decline in commitment to complete the work required on the remaining 3000 substances. There are tools that are available to Canada under CEPA that can be utilized to make progress on these substances. The data obtained from other jurisdictions and organizations should be accurately identified in the assessments and separate from data obtained through section 71 of CEPA.

## **Coordinating with other jurisdictions on assessments**

We understand that other jurisdictions, particularly the US and Europe, are undertaking a number of assessments or preparing chemical profiles for many of the substances listed under the medium priority category. We encourage consideration of the results from the efforts of other jurisdictions. However, it should be noted that we recommend the government create a framework that describes the timeframe and approach that will be applied by the government to consider the decisions reached by other jurisdictions on specific chemicals. This is of importance as CEPA 1999 section 75(2) outlines that:

*The Minister shall, to the extent possible, cooperate and develop procedures with jurisdictions, ....., to exchange information respecting substances that are specifically prohibited or substantially restricted by or under the legislation of those jurisdictions for environmental or health reasons.*<sup>13</sup>

Furthermore, section 75(3) also states:

*...Ministers shall review the decisions in order to determine whether the substance is toxic or capable of becoming toxic, ...*<sup>14</sup>

**Recommendation: To promote efficiency, the government should articulate the time frame and the approach to be applied when decisions by other jurisdictions are used in the identification or management of toxic chemicals. This approach, when used by the government, should be transparent.**

## **Long range transport potential**

In many of the assessments under the Challenge Program, there was a lack of information for the long range transport potential and deposition of persistent substances. As a result, there was a dependence on modeling to make this determination because of the lack of monitoring data.

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<sup>13</sup> Canadian Environmental Protection Act, Section 75.

<sup>14</sup> Ibid.

In the assessment for D5, Lake Opeongo, the largest lake in Algonquin Provincial Park, Ontario, Canada, was considered remote as the lake is relatively remote from potential sources of cVMS from sewage and runoff. Therefore, it was assumed that the only significant source of cVMS to the lake would be from atmosphere deposition (Powell 2008).<sup>15</sup> It is questionable if such a location is actually sufficiently remote for all monitoring purposes with respect to long range transport potential. While this location may have given the preliminary data needed, it should not be assumed that such a location is the equivalent to a remote northern community without validation of data.

Remote northern communities are concerned about the effect that some chemicals could have on their communities and ecosystems because they partially depend on wildlife and some wild plants as food sources. Substantial monitoring should be undertaken in remote northern communities to demonstrate the presence or absence of substances in these regions. Greater consideration should be given to how the Northern Contaminant Programs or other monitoring programs should be expanded to consider the inclusion of other substances for monitoring remote northern communities. This is necessary in light of the number of substances identified in the medium priority category.

Although the next phase of the CMP will address medium priority substances, the section of the assessment that focus on long range transport should be strengthened. Assessments should include context that provide the rationale for long range transport potential, address deposition of these substances or their breakdown products as well as determine the level of toxicity of any of the breakdown products.

***Recommendation: The government should ensure that current data gaps for long range transport potential and deposition of persistent substances be addressed in the next phase of the CMP. Consideration for long range transport potential and its impact on northern remote communities and their ecosystems are crucial to assessments conducted for medium priority chemicals.***

### ***Significant New Activity (SNAc) provision***

This upcoming phase of the CMP will deal with the medium priority substances, the possibility of an increased use of the SNAc provision appears to be likely. As a result, we see the need to reiterate our concerns about this process.<sup>16</sup>

Under the CMP, SNAcs have been proposed for approximately 180 substances with many of them being high hazard, low volume existing substances that have not been

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<sup>15</sup> Final Assessment for D5 – Health Canada and Environment Canada. Accessed at <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=13CC261E-1>, pages 21, 22.

<sup>16</sup> For example: Letter by the Canadian Environmental Law Association dated February 14, 2007 in response to *Canada Gazette*, Part 1, Vol. 140, No. 49, December 9, 2006 Notice of intent to amend the Domestic Substances List to apply the Significant New Activity provisions under subsection 81(3) of the *Canadian Environmental Protection Act*, 1999 to 148 substances. Accessed at [http://s.cela.ca/files/uploads/561\\_SNAc.pdf](http://s.cela.ca/files/uploads/561_SNAc.pdf).

designated as being CEPA-toxic. Our organizations continue to raise concerns about the use of the SNAc provision for such substances as they continue to be used in commerce under the trigger volume without any risk management procedures in place. These are the same substances that would be of concern to the government if volume usage increased or use pattern changed.

The SNAc provision was originally designed to address 'new' substances to Canada and assessed under the New Substances Program and was not meant to address existing substances on the Domestic Substances List (DSL). Also, the use of the SNAc provision would not allow for a public comment period and, as a result, lacks in transparency.

***Recommendation: The government should release a comprehensive policy dialogue to assess the applicability of SNAcs to existing substances under the CMP, beginning with the release of a guidance document.***

***Recommendation: The government should make revisions to the New Substances Program to ensure public engagement on substances that are notified under the SNAc provision.***

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*Acknowledgement: Leah Harms for assisting in the final production of this submission.*

**APPENDIX – Letter on Medium Priority Chemicals dated  
October 21, 2009**

October 21, 2009

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Dear Mr. Enei and Ms. Lloyd:

***Re: Looking Forward: Recommendations concerning the workplan for medium priority chemicals under the Chemicals Management Plan***

This letter is written by environmental non-governmental organizations (ENGOS) and Aboriginal members and alternates of the CMP Stakeholder Advisory Council (SAC) in response to the Government of Canada's (GOC) request to the SAC at its October 2, 2009 meeting for advice on considerations moving forward after the Challenge phase of the Chemicals Management Plan (CMP).

It is crucial that Environment Canada (EC) and Health Canada (HC) continue their chemicals management work in the period following the completion of the Challenge phase in order to address the 2,600 medium priority chemicals remaining from the categorization exercise, along with the approximately 350 chemicals that have been moved up to medium priority from low priority and the approximately 100 added as a result of recent categorization decisions, by the target date of 2020.

First and foremost, our advice to the Government of Canada is to ensure that its activities on these substances support the following key principles outlined in the *Canadian Environmental Protection Act 1999* (CEPA):

- Pollution Prevention
- Virtual Elimination
- Precautionary principle

Second, this is an ideal time to apply the lessons learned about what did and did not work well in the Challenge phase of the CMP. In this letter, we focus on the assessment and management of the medium priority chemicals, rather than all of the wide-ranging questions and issues that were raised in the deck "Chemicals Management: Looking Forward," presented at the October 2, 2009 Stakeholder Advisory Council meeting. Also, we do not express an opinion about the scope, details and timing of the DSL Inventory Update that has just been initiated. We limit our comments to what is required to address the chemicals in the medium priority category for the protection of human

health and the environment, and base our recommendations on our observations about the strong and weak features of the Challenge phase.

Overall, we seek to support a government plan on medium priority chemicals that:

- is committed to substantial reduction and elimination strategies to effectively protect human health and the environment;
- increases accountability of manufacturers, producers, releasers and sellers of targeted substances;
- addresses substantial data gaps, in particular toxicity data for targeted health endpoints and impacts to vulnerable populations (i.e., children, workers, Aboriginal communities, such as Inuit communities, and people with chemical sensitivities);
- promotes transparency and effective public engagement; and
- uses its full authority under CEPA to achieve the above.

## **1. Workplan**

We recommend that the government develop a comprehensive workplan with specified timelines to address and report on activities to be undertaken on all medium priority chemicals.

All medium priority chemicals may be capable of being toxic, since the evidence gathered during the categorization process outlined that they all meet specific hazard and exposure criteria for inclusion in this category. Therefore, a workplan is required to assess and manage the full suite of the approximately 3,100 chemicals referred to above, by the target date of 2020, as supported by the international policy framework, Strategic Approach to International Chemicals Management (SAICM). This is also in keeping with statements made by government in various presentations on the CMP. The workplan should outline:

- government objectives for management of chemicals, including elimination and reduction;
- specific timelines for the submission of new data by industry, including toxicological data (see below);
- timelines for the completion of assessments; and
- timelines for the implementation of management regimes as required for all chemicals in this group.

## **2. Goals for elimination and reduction of specific chemicals**

For the purposes of protecting Canadians and the environment, we propose the following goals:

- The government should seek to phase out chemicals that are carcinogenic, reproductive, developmental, endocrine disruption or neurodevelopmental toxicants by 2020, with a 75% reduction by 2015.
- For chemicals that are persistent or bioaccumulative and inherently toxic, the government should seek a reduction of 90% by 2020, with an interim goal of 75% reduction by 2015.

### **3. Batches**

Grouping high priority substances in batches, to be assessed and managed at predetermined intervals according to a set timetable, worked reasonably well in the Challenge phase. Members of the public, ENGOs, Aboriginal representatives, government assessors and managers, and industry had a reasonable amount of time to prepare or respond to requests for information, draft and final risk assessments, and draft and final risk management scope documents, although the frequency of the release of batches was challenging at times.

### **4. Sectors**

In our view, the sector approach is limited as it may not consider the full scope of uses and impacts of any given chemical used in the sector on health and environment. We recommend that if the sector approach is used, special care is taken to ensure that the full range of uses and impacts of each chemical, wherever and however used, are taken into consideration.

Furthermore, based on the activities undertaken within the petroleum sector approach, the level of engagement, transparency and input by the public has not worked at all well to date in the Challenge phase. There has been little transparency as to how this group of substances is being handled. Information was placed on the CMP website only recently, and it does not contain the process or timelines for the release of assessments. The presentation at the SAC meeting on June 18, 2009 was helpful, but it was very disconcerting to learn, in light of the government's efforts to promote effective and transparent public engagement, that the first set of assessments would come out in December 2009, covering 55 chemicals. This information is not on the CMP website, and the assessments will come out right in the middle of the high priority batch process, leaving interested parties almost no time to respond. We recommend that if more than one approach is taken to assess and manage the medium priority substances, the approaches be integrated in an overall workplan so that the scheduling and timelines are explicitly outlined, thereby allowing full transparency.

### **5. Accountability through the supply chain (producers, manufacturers, sellers, and releasers) using the full scope of CEPA section 71(1)(c)**

We recommend that gaps in toxicity data be addressed and that greater emphasis be placed on hazard in assessments.

The current approach taken by the GOC for collecting toxicity data needs to be strengthened. The categorization process showed that experimental test data are limited for many chemicals. Significant data gaps continue to exist on many chemicals, and the quality of data used to make decisions about toxicity remains uncertain in many cases. The GOC has relied on modelled data and QSARs during the Challenge phase to complete assessments (i.e. pigments and dyes). The use and reliance on modelled or QSAR data may increase the level of uncertainty regarding the toxicity of some chemicals. High uncertainty and data gaps continue to provide a significant challenge in assessors' efforts to apply the precautionary principle.

The Industry Challenge has not been effective in filling the significant data gaps on high priority substances, and unless the GOC requires toxicity data from industry with respect to the middle priority substances, the situation is likely to further deteriorate. Furthermore, these gaps may have implications for other chemicals being assessed under the current process as well as "new" substances subjected to the New Substances Notification Regulations.

Greater emphasis should be placed on filling in the data gaps and reducing uncertainty, especially in light of European Union (EU) REACH legislation and possible changes in the chemicals management regime in United States. The GOC should require industry to submit specific toxicity data using section 71(1)(c) to fill in data gaps rather than relying on the use of modelled data. Specifically, the government should seek experimental data that demonstrates the safety of chemicals based on the criteria of carcinogenicity, reproductive and developmental toxicity, endocrine disruption, neurodevelopmental toxicity, persistence, bioaccumulation, and inherent toxicity.

Lack of data should not preclude the GOC from regulating these substances, and in fact, the goal should be to phase out from industrial sources and consumer products all carcinogens, reproductive and developmental toxicants, endocrine disruptors, neurodevelopmental toxicants, and persistent or bioaccumulative and inherently toxic substances, with special attention paid to substances capable of long-range transport. Accountability on the part of industry requires that it provide this additional data to demonstrate the safety of the middle priority substances to the environment and/or human health.<sup>17</sup>

## **6. Effects on and protection of vulnerable populations**

Specific attention should be paid to mandatory toxicity data submission on vulnerable subpopulations such as the developing fetus, infants and children, the elderly, workers,

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<sup>17</sup> See Principle 2 of the US EPA's "Essential Principles for Reform of Chemicals Management Legislation:" "Manufacturers Should Provide EPA with the Necessary Information to Conclude That New and Existing Chemicals are Safe and Do Not Endanger Public Health or the Environment."  
<http://www.epa.gov/oppt/existingchemicals/pubs/principles.html>

people of low income, Aboriginal communities and people with chemical sensitivities. The absence of such data should not be considered a good reason to take no action. Furthermore, the government's approach undertaken through the DSL Inventory update on products intended for children is limiting and does not provide information on the full range of vulnerable populations.

## **7. Synergistic and additive effects**

We recommend that priority focus be placed on determining the possible cumulative and synergistic effects of exposure to multiple substances. The chemical-by-chemical approach leaves many questions unanswered about the hazards of multiple exposures. The lack of insight in this area continues to hamper the quality of assessments being undertaken by the government and the strength of its management proposals.

## **8. Support safe alternatives using pollution prevention strategies, including green chemistry**

If there are, at present, no safe alternatives to given toxic substances, efforts should be made to develop them. The CEPA framework does not address the need for safe alternatives to support prevention and prohibition efforts on toxic chemicals. Substantial progress can be made if pollution prevention strategies are undertaken to promote elimination of toxic chemicals. This effort should include the use of green chemistry. The area of green chemistry is emerging as an opportunity to address and replace some toxic chemicals in the market today. However, we are not aware of any substantive discussions at the policy level in Canada on the key principles guiding green chemistry. To ensure that green chemistry produces safer alternatives that do not cause adverse health and environmental impacts, substantial policy discussions need to be undertaken and research supported.

## **9. Rapid screening**

We urge the government not to apply a rapid screening tool to complete assessment on medium priority substances.

A rapid screening tool, which was applied to low priority chemicals identified through categorization, will result in on-going data gaps concerning the impact on human health and the environment of these chemicals, their fate in the environment, the route of exposure, the range of uses and applications and the quantities in use. Furthermore, the use of the rapid screening tool does not require accountability on the part of industry for demonstrating the safety of their products.

## **10. Public engagement and capacity building**

The government must ensure broad, transparent and effective public engagement throughout the assessment and management process for medium priority chemicals. The public engagement undertaken through the initial Industry Challenge has not been

sufficient and needs to be strengthened. Effective engagement by public interest organizations from health, environment, labour organizations and first nation and aboriginal communities is essential to implementation efforts on chemicals management. Experience in the Challenge phase has shown that it is imperative to support environmental, health and aboriginal groups in their capacity building and outreach work to help their constituencies engage in a meaningful way in the assessment and management of chemical substances.

Further, it is essential that the Stakeholder Advisory Council (SAC) be carried forward to this new phase of work on the CMP. The SAC was established in 2007 to provide advice to the government on the implementation of the CMP. Such an advisory body will continue to be relevant and appropriate for work to be completed on medium priority chemicals, and we recommend its continuance. However, the role of the SAC could be enhanced to enable substantial input and recommendations on key elements of the workplan on medium priority chemicals.

### **11. Domestic Substances List (DSL) and National Pollutant Release Inventory (NPRI)**

We recommend that DSL inventory updates and the NPRI be used to gather data on the importation, manufacture, use, volume, release and transfer of *all* the medium priority chemicals through mandatory reporting and that this information be made public on an annual basis.

As part of the data collection required for assessment and management, the GOC is undertaking an update of the DSL for the medium priority substances. (As noted above, we have not provided comments about the scope of this exercise in this letter.) Similarly, medium priority chemicals should be targeted for improved reporting under NPRI. Since the announcement of the CMP, there has been no progress to update the reporting requirements for NPRI for chemicals identified under the categorization process. This program should be updated immediately to improve reporting of releases and transfers of these chemicals in Canada. Furthermore, reporting thresholds should be lowered to ensure that all releases or transfers of these substances are tracked and reported to the public.

### **12. CMP Annual Report**

Similar to the CEPA Annual Report, a report to outline the progress on assessment and management of chemicals should be released to the public for comment on an annual basis. An annual report can be a significant resource to identify areas of success and areas of possible improvement for managing toxic chemicals. An annual report can also outline the roles of the various federal laws focused on toxic substances in implementing management activities on CEPA toxic substances.

### **13. Funding**

There are two issues relevant to funding. First, the assessment and management of the medium priority substances is a very large undertaking. We recommend that the GOC provide Environment Canada and Health Canada with additional funding for this specific purpose, similar to the funding provided for the Challenge phase for high priority substances.

Second, it is equally important that adequate resources are directed for public engagement in the process (see number **10**, above). The involvement of stakeholders in the discussions of the Stakeholder Advisory Council has been a major vehicle for providing input on government efforts, and the current federally-funded capacity building projects have been essential for outreach and helping constituencies engage in a meaningful way in the CMP process. However, we recommend that additional funds be provided to address specific issues and emerging proposals made by government throughout the CMP process.

We would welcome the opportunity to discuss the above elements in greater detail. You may contact us at the numbers below.

Sincerely,

Fe de Leon

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