

**A Response to *Canada Gazette* Part I,  
Vol. 144, No. 23— June 5, 2010:  
NGO comments on the Notice of Intent to Assess  
and Manage Aromatic Azo Substances**

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## Introduction

The Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) are submitting the following comments in response to the *Canada Gazette* Part 1, Vol. 144. No. 23, June 5, 2010, Notice of intent to assess and manage the risks to the health of Canadians and their environment posed by aromatic azo substances which may break down to certain aromatic amines, substances which may break down to certain benzidines, and the corresponding aromatic amines or benzidines.

CELA ([www.cela.ca](http://www.cela.ca)) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are otherwise unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the areas of access to justice, pollution and health, water sustainability and land use issues. Under its pollution and health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act*, including the categorization process and implementation of the CMP.

Chemical Sensitivities Manitoba (CSM), a volunteer organization, was founded in 1997 by four individuals who saw the need to address the effects of toxic chemicals on human health and the possible link between the onset of chemical sensitivities and chemical exposure and, in particular, chronic low-level exposure. CSM raises awareness of the presence of toxic chemicals in the home and the environment and strongly advocates for the safe substitution of these toxins.

Our respective organizations have submitted substantial comments on assessment results and proposed management options for assessed substances under the Challenge Program of the Chemicals Management Plan (CMP). To date, our organizations have commented on substances under Batches 1 to 9 and provided substantial comments on the government's risk management approach on these substances. While our organizations support some of the proposed assessment results, we have elaborated on the gaps and limitations on specific aspects of the risk assessment conducted and the proposed management instruments for a number of specific chemicals. Consequently, we developed substantial recommendations to address these gaps and limitations.

In this submission, we will outline our concerns regarding the Notice of Intent announced by the Canadian government to assess 350 aromatic azo- and benzidine-based substances under a class approach. We also provide a list of elements that we identified as essential for completing assessments on these substances.

## Background

Aromatic azo- or benzidine-based substances can have similar structural features and, as a result, may have similar physical, chemical and toxicological properties. These substances are capable of environmental degradation and/or metabolism in organisms to aromatic amine metabolites, some of which may be hazardous to human health or the environment. Azo-based substances with aromatic amines can undergo a reductive cleavage of the azo linkage which would result in a free aromatic amine. Substances containing benzidine or benzidine congeners (with azo or other linkages) could react with active metabolites being produced. Aromatic azo- or benzidine-based substances could have similar commercial applications and possible, similar exposure patterns.

Some of these substances have already been prioritized during the categorization of substances and some of them have been identified during the Challenge of the Chemicals Management Plan. While it is expected that the assessments will be done in phases with those substances of highest concern being published first, some overlap of properties of toxicity is expected. For example, CELA and Ecojustice submitted joint comments in response to the application of the rapid screening tool to 754 substances considered substances of “low concern”.<sup>1</sup> In this submission, we highlighted (see Appendix 1) selected substances that may be probable carcinogens, estrogenic or teratogens. Some of these chemicals are listed in the Notice of Intent, for example chemicals with the following CAS numbers: 2429-71-2, 2829-42-7 and 2870-32-8. In order to understand the range of impacts on the environment and human health, a more rigorous assessment of these substances is necessary.

## Issues

We are submitting the following comments to provide government guidance on steps necessary to address the 350 substances covered under this Notice. At the moment, the Notice of Intent suggests taking a class approach. The comments below raise concerns about the class approach as well as essential components that should be included in the assessment of these substances.

- 1) **Lack of public dialogue on approach** – We do not oppose the use of the class approach generally to address specific classes of substances such as brominated flame retardants or perfluorinated compounds. However, It is premature to consider taking a class approach to address these specific 350 substances without a fulsome public dialogue on criteria used to establish the classes (for example, same use pattern or application, same structure/properties,

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<sup>1</sup> Canadian Environmental Law Association and Ecojustice. *NGO Comments on Government's Proposal to "take no further action" on 754 Low Ecological Concern Substances as published in the Canada Gazette Part 1, Volume 41, Number 25 (August 2007)*. Access at [http://s.cela.ca/files/uploads/590\\_1ecs.pdf](http://s.cela.ca/files/uploads/590_1ecs.pdf)

or specific sector use). To date, there has been very little public debate on how these substances should be addressed, let alone considering the use of a class approach. All approaches should be under consideration for further public dialogue to focus on how the assessments and management of these substances could be best achieved.

***We urge the government to establish a public process to discuss how these substances should be assessed.***

**2) Applying the precautionary principle in the absence of scientific data** – We have long advocated and supported the evaluation of substances through a class or group approach where the substances exhibit similar modes of action. However, it remains unclear how the government plans to identify the classes of substances in the Notice of Intent. While there are significant benefits to taking the class approach on these substances, such as promoting efficiency in the process and reducing the time required to conduct the assessment, there are also concerns that this approach will not aggressively seek the toxicity data and other information on the individual chemicals needed from stakeholders that use, manufacture, dispose and treat these substances. Full toxicity data submission will contribute to a better understanding of the differences between substances under evaluation as well as the potential environmental and health impact of each substance. In applying the precautionary principle, we urge the government to undertake assessments that will not promote the lowest common denominator approach. That is, we urge the government to seek full accountability by the industry stakeholders that benefit from the use, manufacture, disposal and treatment of these substances. The availability of data that shows the lowest toxicity of individual substances within a class should not be assumed to be representative of an entire class. Rather, a precautionary approach, in the absence of full information about the entire class of substances, should consider data representing the greatest toxicity threat and assume that is the toxicity for the entire class.

There are evolving integrated approaches that require further consideration in this context for assessing and testing substances. For example, new techniques are being developed to address evaluation of pesticides such as the new Strategic Direction for New Pesticide Testing and Assessment Approaches by the US Environmental Protection Agency (see <http://www.epa.gov/pesticides/science/testing-assessment.html>). Further discussions on how these new approaches can be applied in the CMP assessments is valuable.

In support of the precautionary approach, on-going efforts by government to improve the dataset on each substance are necessary. Without full public dialogue on whether these substances should be assessed as a class or to identify the toxicity data required to evaluate them effectively, there is some concern that a class approach may not adequately promote the disclosure and submission of toxicity data for all the substances under consideration. We have seen in assessments conducted through the CMP in the past three years that significant data gaps continue to exist for chemicals identified as high concern. For this grouping of substances, we urge the government to make

significant and meaningful reductions in the data gaps. We also urge the government to commit to address the uncertainties associated with data gaps as it proceeds to address other substances identified through the categorization process.

**3) Address Data gaps in a comprehensive manner using Section 71 (1)(c)** - In addition to our comments above and based on the experience gained through the implementation of the Challenge Program of the Chemicals Management Plan, there has been very limited evidence of the submission of empirical data for physical and chemical properties for many substances - data that are considered fundamental to the assessment of a substance or a class of substances. We hope the government takes this opportunity to address these gaps in the assessment of the aromatic azo- and benzidine-based substances. The government should reduce its reliance on data generated from modelling or analogues by using its full authority under section 71(1)(c) of CEPA to fill these data gaps in order to reduce the level of uncertainty in the assessments associated with these substances.

It is also uncertain how the government will deal with insufficient toxicological data for all the breakdown products or metabolites of these substances. This should be clearly articulated in the Notice of Intent.

**4) Class action approach may weaken quality of risk management** - Depending on how substances are grouped together in this class action approach, there is the possibility some elements of risk management may be overlooked or underdeveloped. For example, in the review of persistence or bioaccumulation data for a number of pigments and dyes assessed under the Industry Challenge (for example under Batch 3 and Batch 6), analogues were identified and used to make conclusions instead of empirical data because of similarities in physical structures, properties and use patterns. When there is the potential that the assessment will rely on the use of analogues to make decisions on specific physical and chemical properties for some of the substances, it is essential that the process should include a clear and full justification on how these analogues were identified, ranked against other analogues and eventually selected in order to make the necessary decisions. This will promote transparency and identify where the data gaps exist. There is also a need for assessors to indicate where data, including toxicity data, were not made available by stakeholders that manufacture, use or sell these substances.

It is hoped that each grouping of substances will be critically assessed and that attention will be paid to any anomalies within a grouping.

**5) Lack of capacity for public to review adequacy of assessments** - The public may be significantly challenged to review risk assessments for these substances under a class approach given the number of substances to be covered. The scope and details of the assessment would be expected to be substantial. The quality of public engagement to review and comments on class assessments is compromised when the government releases these assessments for a 60 day comment period as required

under CEPA since there is the additional burden of public comment period on on-going assessments conducted on other substances under the CMP.

## Elements for Assessments on Target Substances

We are pleased to see that:

*The Ministers intend to consult with stakeholders on this list of aromatic azo- and benzidine-based substances, potential substance groups, and information gaps to inform future information gathering exercises under section 71 of the Act. The Minister of the Environment intends to use section 71 to collect further information from those that may be involved in the manufacture, import and use of the aromatic azo- and benzidine-based substances and related substances in Canada. Generation and submission of other information to inform decision-making may also be requested, including, but not limited to, the following: degradation and metabolism data; type of mixture, product or manufactured item; as well as concentration or range of concentration of the substance by weight in the manufactured item or product.<sup>2</sup>*

While the use of section 71 of CEPA will result in useful information, the government should assume there is a suspicion of toxicity associated with these substances because of the results obtained from categorization and, for substances already identified in the Industry Challenge. Therefore, we urge the government to use section 71 (1)(c) to fill in necessary toxicity data, for example, to determine the potential for endocrine disruption of these substances. Hence, our organizations expect rigorous assessments to be conducted on the 350 aromatic azo- and benzidine-based substances with the application of the precautionary principle in the absence of toxicity data.

Below are essential elements that should be included in the assessments to be conducted.

**a) Applying the precautionary principle in the absence of toxicity data and seeking assessment process that will provide full identification and record of all data for all chemicals covered under the assessments** - A class approach may minimize the importance of presenting the full scope of data as details on chemicals can become lost. It is critical that the government seek full disclosure of toxicity data by industry stakeholders for these substances. Furthermore, assessment decisions should apply the precautionary principle in the absence of toxicity data or scientific uncertainty.

**b) Recognize and address the full life cycle of the substance** - This should include the use of the substance as a feedstock or raw material to its release in the environment

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<sup>2</sup>Government of Canada. *Canada Gazette*, Part I, Vol. 144, No. 23 (June 5, 2010). Access <http://www.gazette.gc.ca/rp-pr/p1/2010/2010-06-05/html/notice-avis-eng.html#d101>, dated July 30, 2010.

at all phases of applicable process to disposal methods used for these chemicals including impacts from incineration practices or recycling processes, if applicable. While we recognize that there would likely be provincial regulations that apply to the waste disposal of these substances or products containing them, we stress that consideration of the disposal methods is a critical aspect of completing the assessment on these substances. Consideration of the life cycle approach for chemicals addressed under the CMP has been protracted. The government should take steps to ensure that disposal and any breakdown by-products associated with these processes are considered in the assessment of these substances.

**c) Need to address all metabolites/break-down products** - Taking a class action approach on 350 aromatic azo- or benzidine-based substances, it is assumed that the focus should be on the degradation to free aromatic amine metabolites. However, based on the Notice of Intent, we are uncertain if the government's approach will give consideration to identify the full range of breakdown products/metabolites and how they will be addressed in this approach since substances will be grouped together for assessment. It is essential that the assessments consider the toxicity of all metabolites and by-products from these substances as they may be potentially more toxic and can have wider range of impacts to the environment and health than just the aromatic azo or benzidine-based substances that are the focus of assessments. To date, no assessments under the CMP have adequately addressed metabolites and by-products and their toxicity. This is a significant gap and the present assessment approach should be modified to address this gap.

**d) Emissions data** - The government should obtain and present all emissions data to water, soil and sediment from industry on all substances to be assessed. It cannot be assumed if some substances have low releases they have no or little impact on human health and the environment. Regardless, the level of releases should be documented in the assessment. It is not unknown if the National Pollutant Release Inventory (NPRI) data is sufficiently accurate to report all releases to the environmental media mentioned. The NPRI has specific criteria for reporting so that there is some concern that many of these substances may be used in volumes that will not meet the reporting thresholds. While the government should undertake to address the limitations to NPRI program and efforts should be taken to expand the scope of reporting, additional methods to seek emissions data are urgently required for these substances.

**e) Data relevant to occupational health and vulnerable populations** - Consideration of vulnerable populations, particularly in occupational settings, women, infants and children, and communities that may be in close proximity to facilities that manufacture or use these substances should be included in the assessments of these substances. While we recognize that occupational health is addressed primarily under provincial jurisdiction, there is still a need to conduct these assessments with a consideration of the impacts to occupational health. This level of information would be promoting efficiency within the federal-provincial process as this information is then disseminated to provincial authorities.

**f) Consideration of synergistic and cumulative impacts** – None of the assessments conducted under the Industry Challenge have made any observations on the potential effects to the environment or health from cumulative impacts or synergistic effects. The absence of considering cumulative or synergistic impacts continues to be a significant gap in the assessments conducted on substances. We urge the government to take steps that will address these gaps. Given that the 350 substances to be assessed are used in a wide range of applications that include consumer products and industrial applications, the potential for impacts on the environment and human health from these substances and their breakdown products remain relatively unclear. Therefore, further consideration under the CMP implementation activities should be given to ongoing efforts to assess the cumulative or synergistic impacts of specific substances. For example:

i) pesticides (see [http://www.hc-sc.gc.ca/cps-spc/pubs/pest/\\_pol-guide/spn2001-01/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2001-01/index-eng.php));

ii) the recommendations by the national research council on the cumulative assessment of phthalates (see <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12528>); and

iii) the National Academy of Sciences Report on Toxicology Testing in the 21st Century, upon which the above-noted new strategic direction for pesticides is based (see <http://www.epa.gov/pesticides/science/testing-assessment.html>).

## Concluding Remarks

Our comments above outline a number of elements our organizations expect in the risk assessments to be conducted on the 350 aromatic azo-or benzidine-based substances. We hope the government will provide careful consideration of these elements to enhance the quality of the assessments. In particular, the Notice of Intent provides consideration of a class approach on these substances. It was noted that our organizations advocated for the class approach for substances demonstrating similar modes of action over the years. However, such an approach would be supported with clear commitments to apply the precautionary principle in the absence of toxicity data or uncertain data. That is, the presence of low toxicity data for one substance should not be taken to assume the all substances in the class have low toxicity. In these situations, the public has high expectation that the precautionary principle will be applied in the decision making process.

In closing, before conducting the assessments on the 350 substances, we strongly urge the government to establish a public dialogue that would focus on the type of assessment that should be undertaken on these substances rather than simply relying on the comments received through this 60-day comment period to inform them of the process.

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