

Summary of the Main Public Comments Received on the Notice of Intent for the Aromatic Azo- and Benzidine-based Substances Class Approach

Formal comments made during the 60-day public comment period that took place from June 5, 2010 to August 4, 2010 on the Notice of intent to assess, and to manage where necessary, the aromatic azo- and benzidine-based substances as part of the Chemicals Management Plan under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), were provided by:

- the Assembly of First Nations;
- Canadian Cosmetic, Toiletry and Fragrance Association;
- Canadian Paint and Coating Association (CPCA);
- Canadian Vehicle Manufacturers Association;
- Chemical Sensitivities Manitoba; Color Pigments Manufacturers Association Inc. (CPMA)
- Clariant (Canada) Inc.;
- Colorama Dying and Finishing Inc.;
- Crooked Creek Conservancy Society of Athabasca; Dominion Colour Corporation;
- Dow Chemical Canada ULC;
- the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) North America;
- International Association of Color Manufacturers;
- International Institute of Concern for Public Health (IICPH);
- Michelin North America (Canada) Inc.;
- PGI/Difco Tissus de Performance Inc.;
- Shaw; StarChem Inc.;
- Tri-Textco Inc.;
- a Member of Parliament;
- Learning Disabilities Association of Canada;
- Municipalité de Magog;
- Canadian Environmental Law Association;
- the Food and Consumer Products Manufacturers of Canada;
- and private citizens.

The main comments received are summarized below with responses from the Government of Canada.

Summarized Main Comment	Response
What is a class approach in the context of this Notice of intent and how will individual substances be	Addressing substances as a class allows for more comprehensive and consistent science-based approaches and decisions in the assessment and management processes, particularly for data poor

<p>considered within the class?</p>	<p>substances. Using this approach means that substances that are structurally similar, as an example, are addressed simultaneously, allowing for better information gathering and use of read-across techniques. However, this does not necessarily mean there would be one conclusion drawn for the entire class, as there could be important differences among the substances. A class may be divided into one or more subgroups. These subgroups will cluster substances based on similar physical-chemical properties, chemical structures, uses, and component aromatic amines or benzidine congeners.</p> <p>The aromatic azo- and benzidine-based substances allow for a class approach because many of them share common structural features that may result in similar physical, chemical and toxicological properties or degradation pathways as well as similar anticipated uses which could result in similar exposures. Therefore, data collection and analysis for subgroups of these substances would be more efficient when completed together.</p> <p>Within these groupings, individual hazard and exposure characterizations can be considered, depending on data availability, and relative toxicity may be defined. Various methods would be used to obtain information for these substances on types of uses and volumes imported and manufactured. Unpublished data or studies which could help inform the risk assessment process (e.g. data on toxicity, metabolism, degradation, physical-chemical data, migration from products, etc.) will also be sought.</p> <p>Risk management actions, if deemed appropriate, would likely vary by subgroup as well, based on consideration of relevant information on use patterns and exposures.</p>
<p>Why are aromatic azo- and benzidine-based substances being targeted first after the Challenge?</p>	<p>The plan to address this class of substances was based on several factors. As some aromatic azo- and benzidine-based substances were being assessed individually in the Challenge, it was found that:</p> <ol style="list-style-type: none"> 1. There is a large number of similar chemicals outside of the Challenge (e.g., priorities remaining to be addressed under the CMP). 2. Assessing substances of this nature in the Challenge one by one identified some limitations since many substances in this class are data poor.

	<p>3. Some substances within this class have been identified by other jurisdictions as a concern due to the potential cleavage of the azo bonds that can lead to the release of aromatic amines known or likely to be carcinogenic or genotoxic. Therefore, the concern expressed by other jurisdictions can be more comprehensively and consistently addressed for the relevant prioritized substances by applying a class approach as opposed to a substance by substance approach.</p> <p>4. Addressing similar substances (e.g. common properties or uses) together would allow for more robust risk assessment and potential efficiencies in managing these substances, where required, for both affected stakeholders and the Government of Canada.</p>
<p>What substances are included in the class, how were they selected, and why are the related Challenge substances included?</p>	<p>Relevant aromatic azo- and benzidine-based substances that were prioritized for action through the Categorization exercise would be considered in this class assessment. A draft list of approximately 350 substances which may be addressed is available here.</p> <p>This approach would include a number of the aromatic azo- and benzidine-based substances that were assessed in the Challenge. It is anticipated that information previously gathered for the risk assessment of these Challenge substances as well as information on other relevant substances would help the class assessment. As noted above, use of a class approach rather than individual assessments would allow for a more efficient and informed assessment. While assessments for affected Challenge substances are being published within Challenge timelines, these assessments would later be updated if subsequent evaluation of these substances based on a more comprehensive body of information as part of a larger subgroup supports a different outcome.</p> <p>The scope of the class assessment approach would involve three broad groups of substances as indicated in the Notice of intent of June 5, 2010. These are listed below. The Government of Canada would further subgroup these substances in order to draw appropriate conclusions.</p> <ul style="list-style-type: none"> • "Aromatic azo substances which may break down to certain aromatic amines": The European Union has identified specific aromatic amines of concern due to

	<p>their carcinogenicity or genotoxicity. In substances where an amine is linked with an azo bond, there may be concern of release of the aromatic amine. In the list of substances identified through Categorization, other azo-linked substances with aromatic amine substructures not specifically identified by the EU would also be included in this class assessment approach.</p> <ul style="list-style-type: none"> • "Substances Which May Break Down to Certain Benzidines": Additionally, since there is generally more information regarding the toxicity of benzidine and benzidine congeners, substances identified during Categorization with substructures corresponding to those components, with or without azo linkage (e.g., amide linkage) are included. While it is recognized there is uncertainty as to whether the benzidine or benzidine congeners could be released from these non-azo linkages, the Government of Canada plans to address these substances through this class approach. • "Corresponding Aromatic Amines or Benzidines": Finally, the component aromatic amines included in the structures of these substances, which could be released from azo cleavage, were also considered to be part of the class.
<p>How will differences between dyes and pigments be addressed in this approach? Will a single conclusion be applied to all structurally related substances although there may be other important differences?</p>	<p>It is recognized that there may be differences and similarities across the class of substances to be addressed which could impact potential risk to human health or the environment (e.g., physical-chemical properties, applications, etc.). All identified relevant information would be taken into consideration in development of approaches to assessment (e.g., in further sub-grouping or in hazard characterizations). The nature of the information will likely impact the extent of extrapolation of a conclusion across a sub-group of structurally related compounds.</p>
<p>The large number of substances being surveyed and potential regulation on some of these substances will have major impacts on some industries; therefore, it is suggested that the effort focus only on substances currently sold</p>	<p>Based on information identified to date, most of the substances included in this class approach appear to be used or have been used historically in a variety of sectors as pigments or dyes. This includes consumer products such as personal care products, textiles (e.g. clothing, footwear, bedding), pharmaceuticals, children's items and toys, food, food packaging, and plastics among others. Further data collection initiatives would help to identify other possible uses</p>

<p>or used in Canada.</p>	<p>as well as which of these substances are in Canadian marketplace.</p> <p>Finished products imported from other countries may contain these substances and potentially contribute to exposure in Canada. Although the use of these substances is currently being controlled in some countries it is not controlled in all countries; therefore, it is often difficult to determine the potential that imported products contain substances of this nature. Cooperative exchange of information between importers and their suppliers would be of great value in identifying exposure sources of these substances in Canada.</p> <p>International action on some of these substances over the last several years has focused on azocolourants that may break down to specific aromatic amines of known concern. It is recognized that these international actions may have had an impact on the azodye, textile, and cosmetic markets.</p>
<p>The European Union list of 22 aromatic amines (EU 22 AAs) relates to dyes that are typically no longer in commerce in Canada.</p>	<p>Recent data gathering initiatives have revealed that some of the substances related to the European Union "Azocolourant and Azodye" restriction in the REACH Regulation (EC) No. 1907/2006 are in commerce in Canada.</p> <p>Recent compliance testing data from European member states indicate that the dyes containing the EU 22 AAs are still found in imported consumer products (e.g. clothing, leather products, toys, etc.). This demonstrates that these restricted substances are in commerce, even in jurisdictions that have legislation in place to control exposure to these substances.</p>
<p>Does this Notice of intent indicate that the Government of Canada is proposing to regulate these 350 substances?</p>	<p>No. The Notice indicates that the Government of Canada plans to address these substances by initiating data collection and risk assessment activities. It does not indicate that the Government of Canada plans to regulate these substances at this time.</p> <p>If it is determined that some of these substances are considered to be harmful to human health or the environment, then management action would be considered where appropriate.</p> <p>Similar to the Challenge, there would be consultations with stakeholders regarding any proposed risk management activities for groups of</p>

	<p>substances or individual substances. In addition, we would continue with public comment periods on any risk management documents.</p>
<p>Although there is commercial interest in some of these substances, the reporting threshold levels may result in some industries being involved by a "stakeholder interest" level only.</p>	<p>The reporting threshold for any upcoming Section 71 survey Notices pertaining to these would be based on data needs and knowledge of the current marketplace in respect of these substances.</p> <p>Information submitted by stakeholders on a voluntary basis, such as through stakeholder interest forms, is highly encouraged to inform risk assessment and management decisions. Therefore, we encourage stakeholders to submit information pertaining to these substances even in cases where a section 71 trigger has not been exceeded.</p>
<p>The public comment period on the Notice was too short, given the large number of substances involved.</p>	<p>The Notice of intent to address the aromatic azo- and benzidine-based substances was published to solicit comments on how to address these substances using a class approach. Discussion with interested stakeholders would continue throughout the data collection, risk assessment and if appropriate, risk management process.</p> <p>Comments received in response to publication of the Notice of intent are being considered and there will be more opportunities to provide comments at later stages. The submission of information that could aid in the assessment and potential management of these substances is always appreciated.</p>