Summary of Public Comments received on Certain Azo Disperse Dyes Screening Assessment and Related Risk Management Scope

Comments on the screening assessment and risk management scope for Certain Azo Disperse Dyes to be addressed as part of the Aromatic Azo and Benzidine-based Substance Grouping initiative were provided by Doubletex, Canadian Vehicle Manufacturers' Association (CVMA), Chemistry Industry Association of Canada (CIAC), Clariant Canada, Color Pigments Manufacturers' Association (CPMA), Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) and Lanxess Inc..

A summary of comments and responses is included below, organized by topic:

Topic	Comment	Response
Methodology	Conservative values for Predicted Environmental Concentration (PEC) in the assessment are from literature review and do not accurately represent current values for industrial wastewater releases.	Current methods for determining PECs relevant to wastewater processing and discharge take into account facility conditions for a wide range of types of mills across Canada.
	Disperse Yellow 7 (CAS No. 6300-37-4) should not be used as read-across for all the 73 azo disperse dyes.	In the final assessment, data from Disperse Yellow 7 is used as read-across for those substances having a molecular weight of less than 360 g/mol, while data from the larger Disperse Blue 79:1 is applied as read-across for substances with a molecular weight greater than or equal to 360 g/mol. The toxicity of this grouping is influenced by the increased bioavailability of smaller substances.
Consultations	An industry wide stakeholder consultation process is required to inform interested parties on how they will be affected by assessment conclusions and related polices.	Following publication of the draft screening assessment and risk management scope document, an information webinar was held with stakeholders of the textile sector. This webinar session included presentations on the proposed conclusions related

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		to Azo Disperse Dyes and the identification of exposures of concern relevant to disperse dye formulation and textile dyeing processes. While the scope of substances found harmful to the environment has narrowed to Disperse Yellow 3 in the Final Screening Assessment for Certain Azo Disperse Dyes, the exposures of concern remain the same. Similar outreach and stakeholder engagement is planned during the 60-day comment period for the risk management approach document for Disperse Yellow 3. The instrument proposed for managing risk is a Pollution Prevention (P2) Planning Notice. Additional consultations with potentially affected stakeholders will be planned to inform the design of the instrument. To participate in this consultation process, please send an expression of interest to: ec.produits-products.ec@canada.ca.
	Better communication on release of publications is required, especially since assessment conclusions for 24 substances in this group were changed.	Timelines and information on release of publications are updated on the Chemical Substances website. Notification letters are also sent to stakeholders upon release of publications. If you wish to be informed of publications as they are published you may subscribe on the Chemical Substances Latest News or submit your email address to eccc.substances.eccc@canada.ca indicating your interest in a substance(s) in order to be added to our stakeholder database.
	Stakeholder consultation and outreach should take place during the data gathering stage or following publication of final screening assessments. This will enable timely input of data and information from the impacted supply	Stakeholder engagement is an ongoing part of the CMP starting with data gathering through to risk management instrument development and engaging stakeholders when draft screening assessments and risk management scope

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	industry and avoid premature conclusion that a substance is harmful.	documents are published. This helps ensure that the final screening assessment and risk management approach are based on the most recent and accurate information available.
	All stakeholders should have transparent and timely access to data that is used to formulate risk assessment conclusions.	Some of the studies that were unpublished when the risk assessment conclusions were being formulated are now published in peer-reviewed journals or are in the process of being published.
Information and data gathering	Effluent Discharge Pollution Prevention Plans for textile mill wet processing should provide Environment Canada with data on nonylphenol and its ethoxylates. The types of on-site wastewater treatment for textile mills should also be identified.	Information from reports submitted under the Pollution Prevention Planning Notice on effluents from textile mills that use wet processing (TMEs) and nonylphenol (NP) and its ethoxylates (NPEs) is available through the Pollution Prevention Planning Database. For further information on the Notice, please see the Final Summary Report (July 2012): Pollution Prevention Planning and Effluents from Textile Mills that use Wet Processing and Nonylphenol and its Ethoxylates. Characteristics of wastewater discharged from textile mills vary across the sector. Research also shows that a large portion of in-commerce disperse dyes remain in wastewater after treatment due to their relatively low sorption capabilities or moderate octanol water partition coefficients. This accounts for the conservative assumption that dyes are not removed during on-site treatment of wastewater from textile mills.
	Apply a weight-of-evidence approach that appropriately accounts for data of differing quality. The assessment emphasizes two unpublished studies limited to a few substances where peer	New data added to the assessment increased weight of evidence and resulted in identification of two distinct subgroups - one for substances less than 360 g/mol and another for those above 360 g/mol. This accounts for other critical aspects such as molecular weight and bioavailability.

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	review status and weight of evidence were not clearly established. There is a concern that this new data has changed decisions that were based on previous assessments from the Challenge initiative for all 24 of the azo disperse dyes.	Some of the data considered in the draft screening assessment for this substance grouping was not available when 24 azo disperse dyes were assessed under the Challenge. Studies in the risk assessment previously identified as unpublished are being published in peer reviewed journals.
Risk Assessment	Only 13 out of 73 azo disperse dyes were assessed as having an import quantity above the reporting threshold of 100kg/yr. Since no exposure is noted for the remaining 60 substances, this entire class of substances should not be concluded as toxic.	In the final assessment, the 73 Azo Disperse Dyes initially included in this subgroup were not found to meet the criteria under Section 64 of the Canadian Environmental Protection Act, 1999 (CEPA); however, azo disperse dyes with molecular weights below 360 g/mol have been flagged as being of potential concern due to their bioavailability. All 13 Azo Disperse Dyes in commerce in Canada have molecular weights greater than 360 g/mol and their current uses are of no concern. Accordingly, the Government of Canada recommends avoiding the use of Azo Disperse dyes with the lower molecular weights. Current uses of the remaining substances are not considered to pose risks that would trigger criteria under CEPA. The use of an additional azo disperse dye (Disperse Yellow 3 (otherwise known as Solvent Yellow 77)) in disperse dye formulation and textile dyeing was evaluated as part of this assessment for ecological concern. This substance has a molecular weight of less than 360 g/mol, and was concluded to meet section 64(*a*). Human health concerns and other uses for this dye were assessed in the Azo Solvent Dyes assessment.
	Alternative dyes are not currently available to industry and using available alternatives could adversely impact product quality.	
	Concerns were raised about listing the 73 substances on Schedule I as a 'group' with no individual substance being 'toxic'. In particular - listing these substances would impact public perceptions and how they are considered in Risk Management discussions and actions under the CMP.	
	Information should be provided on when a risk management plan will be made available and	A Risk Management Approach document for Disperse Yellow 3 was published concurrent to the

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	implemented.	final Screening Assessment Report for this group of substances. The Risk Management Approach outlines proposed risk management actions, and anticipated timelines for development and implementation of risk management measures.
	Outline the steps being taken to ensure all imports of fabric/garments are the subject of a stringent control.	Imports of finished fabric and garment products have not been identified as a concern. The Risk Management Approach for Disperse Yellow outlines the actions to address environmental exposures from certain azo disperse dyes discharged to wastewater from formulation of textile dyes and from synthetic fabric dyeing process.
	Further consideration should be given to determining if the application of the Significant New Activity (SNAc) Provisions is necessary for Azo Disperse Dyes that are no longer in commerce.	The application of the Significant New Activity (SNAc) provisions under CEPA requires that any proposed new manufacture, import or use of the substance be subject to further assessment, and it determines if the new activity requires further risk management consideration. Other approaches may also be considered for gathering information on the use of substances posing a potential risk.