Risk Management Approach

for

Acetamide, N-[4-[(2-hydroxy-5-methylphenyl)azo]phenyl]-

(Disperse Yellow 3)

Chemical Abstracts Service Registry Number 2832-40-8

Environment and Climate Change Canada

Health Canada

March, 2017

Summary of Proposed Risk Management

This document outlines the proposed risk management action for Disperse Yellow 3 (CAS RN 2832-40-8, and referred throughout this document as "Disperse Yellow 3"), an azo dye.

In particular, the Government of Canada is consideringdeveloping a Notice requiring the preparation and implementation of a pollution prevention plan under section 56 of the *Canadian Environmental Protection Act, 1999* (CEPA) in order to control activities (such as manufacture, import or use) of Disperse Yellow 3 in textile dye formulation and the textile dyeing sector in Canada. Key considerations for the design of the Notice may include use thresholds (e.g., daily, monthly or annual use volumes), operating practices for textile dye formulation and for textile dyeing, and alternatives to the use of Disperse Yellow 3.

Information on the following items should be provided on or before May 10th 2017, to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Users of Disperse Yellow 3 in Canada
- Uses of Disperse Yellow 3 for which there are no known alternatives
- Socio-economic impacts (e.g., Cost of substituting Disperse Yellow 3, reduction of current use thresholds, change of operating practices).

Smaller azo disperse dyes with molar weights below 360 g/mol have been identified to have ecological effects of concern. Therefore, the risk management developed would take into consideration that these substances should be avoided as substitutes to Disperse Yellow 3.

The risk management actions proposed in this Risk Management Approach document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: The above summary outlines the action proposed to manage this substance and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and the Minister of Health (the Ministers) to conduct assessments to determine if substances are toxic to the environment and/or (harmful or dangerous) to human health as set out in section 64 of CEPA[1,2], and if so to manage the associated risks.

As part of the second phase of the Chemicals Management Plan, the Ministers plan to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 500 substances, in 9 substance groupings (Canada 2011a). Disperse Yellow 3, a trade name for the substance with CAS RN 2832-40-8, and referred to throughout this document as "Disperse Yellow 3" is one of 358 substances in the Aromatic Azo and Benzidine-based Substance Grouping assessed as part of the Chemicals Management Plan.Based on its chemical properties and its generally known uses, Disperse Yellow 3 has been classified and assessed both as an azo solvent dye (known as Solvent Yellow 77) and as an azo disperse dye. Its use as a solvent dye has not been identified as a risk to the environment nor human health (Canada 2016c).

During the draft assessment stage, all azo disperse dyes including Disperse Yellow 3 were proposed to meet the criteria under section 64(*a*) of CEPA indicating they are toxic to the environment (Canada 2013). The risk management scope for Azo Disperse Dyes was published on November 2, 2013 and outlined risk management options for all azo disperse dyes as a class, including Disperse Yellow 3. Based on additional information, only Disperse Yellow 3 meets the criteria of section 64. Therefore the scope of this document focuses solely on Disperse Yellow 3.

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[1] Section 64 [of CEPA]: *For the purposes of* [Parts 5 and 6 of CEPA]*, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

- *(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
- *(b) constitute or may constitute a danger to the environment on which life depends; or*
- *(c) constitute or may constitute a danger in Canada to human life or health.*

[2] A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and the use of consumer products. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations* and the *Controlled Products Regulations*, which is part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

2. Issue

2.1 Final Screening Assessment Report Conclusion

Health Canada and Environment and Climate Change Canada conducted joint screening assessments relevant to the evaluation of the subgroups of certain Azo Disperse Dyes and certain Azo Solvent Dyes in Canada (since Disperse Yellow 3, has both azo solvent dye and azo disperse dye applications). A notice summarizing the scientific considerations and conclusion of Disperse Yellow 3 as part of the final Screening Assessment Report of Certain Azo Disperse Dyes was published in the *Canada Gazette*, Part I, on March 11 2017 (Canada 2017a)[3].

Based on the information available regarding the reported uses and exposure concerns of Disperse Yellow 3 in Canada, the final Screening Assessment Report for Certain Azo Disperse Dyes concludes that Disperse Yellow 3 is toxic under section 64 (*a*) of CEPA because it is or may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity (Canada 2017b). Disperse Yellow 3 may persist in water, soil and sediment, but not air and is not likely to bioaccumulate in organisms. It has been determined that Disperse Yellow 3 meets the persistence criteria but does not meet the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA (Canada 2000).

The exposure sources of concern, identified in the final Screening Assessment Report for Certain Azo Disperse Dyes, are based on the release of Disperse Yellow 3 to surface water from textile dye formulation and potential for release from synthetic textile dyeing (disperse dye application) (refer to section 5.2).

2.1.1 Azo Disperse Dye Substances with Ecological and/or Human Health Effects of Concern

The Screening Assessment Report for Certain Azo Disperse Dyes also noted that azo disperse dyes with molar weights below 360 g/mol have demonstrated a higher level of toxicity to aquatic organisms, likely due to their increased

[3] Given the dual application uses of the substance, the screening assessment report of Certain Azo Solvent Dyes includes a summary of the uses and assessment information of Disperse Yellow 3 in the context to its application as a solvent dye, published in *Canada Gazette*, Part 1 on May 28, 2016 (Canada 2016b). Uses of Disperse Yellow 3 in solvent dye applications were not identified as an area of concern in Canada in the final Screening Assessment Report for Certain Solvent Dyes (Canada 2016c). Analysis of other solvent dyes used in solvent dye applications also did not identify any exposures of concern. As such, this document will focus on the use of Disperse Yellow 3 in disperse dye applications.

bioavailability and therefore are substances with ecological effects of concern. Nine substances that were assessed in this subgroup have a molar weight less than 360 g/mol. Disperse Yellow 3 is the only one of these nine substances that has been identified as being in commerce according to a survey conducted under section 71 of CEPA (Canada 2011b) and is the only dye of this assessment that meets the section 64 criteria under CEPA. The other eight substances which had a molar weight below 360 g/mol were not identified as being in commerce in Canada according to recent surveys under section 71 of CEPA and as such, do not meet section 64 criteria under CEPA. Similarly, there are an additional sixteen azo dye substances on the Domestic Substances List (DSL) which could be used in azo disperse dye applications (Annex A) with molar weights below 360 g/mol, that have ecological effects of concern. It is not certain if these additional sixteen substances are in commerce and are being used in disperse dye applications.

In addition, although a risk to human health has not been identified at current levels of exposure; three Azo Disperse Dyes (including Disperse Yellow 3) are recognized as substances with human health effects of concern due to potential carcinogenicity.

A consultation document outlines potential options on how to best monitor changes to and prevent increases in exposures and/or releases of these and other aromatic azo and benzidine-based substances with ecological and/or human health effects of concern and requests input from stakeholders on these options (Canada 2017a).

Refer to the Screening Assessment Report for further information on Certain Azo Disperse Dyes which includes the assessment conclusion for Disperse Yellow 3, and the Screening Assessment Report for Certain Azo Solvent Dyes which includes additional assessment information on Disperse Yellow 3..

2.2 Recommendation under CEPA

Based on the findings of the ecological assessment in the final screening assessment conducted as per CEPA, the Ministers recommend that Disperse Yellow 3 be added to the List of Toxic Substances in Schedule 1 of the Act[4].

The Ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft Screening Assessment Report for Certain Azo Disperse Dyes and Risk Management Scope document, by analysing additional data and studies provided by stakeholders. The proposed ecological conclusion at the draft assessment stage that all azo disperse dyes may be harmful to the environment has changed because new data suggests that only smaller azo disperse dyes have ecological effects of concern. The result is a significantly narrower scope of the final Screening Assessment conclusion, where only a single Azo Disperse Dye, Disperse Yellow 3, is concluded to meet section 64 (*a*) criteria. As the Ministers finalize the recommendation to add Disperse Yellow 3 to Schedule 1, risk management instruments must be proposed and finalized within a set period of time, as outlined in sections 91 and 92 of CEPA (refer to section 8 for targeted publication dates applicable to Disperse Yellow 3).

2.3 Public Comment Period on the Risk Management Scope

The Risk Management Scope document for Azo Disperse Dyes (including CAS 2832-40-8), which summarized the proposed risk management actions under consideration at that time for all azo disperse dyes, was published on November 2, 2013. Industry and other interested stakeholders were invited to submit comments on the Risk Management Scope document during a 60-day comment period. Comments received on the Risk Management Scope document were taken into consideration in the development of this document. A summary of responses to public comments received is available.

3. Proposed Risk Management

[4] When a substance is found to meet one or more of the criteria under section 64 of CEPA, the Ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

3.1 Proposed Environmental Objective

Proposed environmental objectives are quantitative or qualitative statements of what should be achieved to address environmental concerns.

For this substance, the proposed objective is focused on addressing the releases to water from textile dye formulation and synthetic textile dyeing outlined in section 5 of this document. As such, the proposed environmental objective for Disperse Yellow 3 is to reduce concentrations found in the aquatic environment to levels below the predicted no-effect concentration of 0.0023 mg/L.

3.2 Proposed Risk Management Objective and Proposed Action

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objective for Disperse Yellow 3 is to limit its domestic release to water in effluents from domestic textile dye formulation and where appropriate, textile mill dyeing, to protect the aquatic environment as set out in the environmental objective.

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed risk management action being considered for Disperse Yellow 3 is to develop a Notice requiring the preparation and implementation of a pollution prevention plan under Section 56 of CEPA in order to control domestic activities (such as manufacture, import or use) of Disperse Yellow 3 in the textile dye formulation and the textile dyeing sector. Key considerations for the design of the Notice may include use thresholds (e.g., daily, monthly or annual use volumes), release concentrations, operating practices for textile dye formulation and for textile dyeing, and alternatives to the use of Disperse Yellow 3.

In addition, the Government of Canada will consider data obtained from the CMP Monitoring and Surveillance program on Disperse Yellow 3 in order to establish a baseline environmental presence and to measure the effectiveness of the instrument in meeting risk management and environmental objectives.

Following the publication of this Risk Management Approach document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process[5]. The risk

[5] The proposed risk management regulation(s), instrument(s) or tool(s) are selected using a thorough, consistent and efficient approach and take into consideration available information in line with the

management options outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

3.2.1 Other Azo Disperse Dyes with Ecological Effects of Concern

As smaller azo disperse dyes with molar weights below 360 g/mol have demonstrated a higher level of toxicity to aquatic organisms, likely due to increased bioavailability, their presence in the aquatic environment would be of concern. Therefore, development of risk management will take into consideration that these substances should be avoided as substitutes to Disperse Yellow 3. A preliminary non-exhaustive list of azo disperse dyes on the *Domestic Substances List* with molar weights below 360 g/mol is provided in Annex A for information. Of the identified dyes, eight substances have not been identified to be currently in commerce within Canada, one is used as a solvent dye, and current use patterns for the remainder are not known. Please refer to Section 2.1.1, for information on exploration of options to monitor changes in use profiles of these and other substances.

3.3 Risk Management Information Gaps

In order to make informed decisions on proposed risk management, more information is requested on the following:

- Users of Disperse Yellow 3 in Canada
- Textile Dyeing uses of Disperse Yellow 3 for which there are no known alternatives, and
- Socio-economic impacts associated with the risk management option presented (e.g. Cost of substituting Disperse Yellow 3, reduction of current use thresholds, change of operating practices).

4. Background

Government of Canada's Cabinet Directive on Regulatory Management (TBS 2012a) and Red Tape Reduction Action Plan (TBS 2012b). Of note, the Government of Canada has introduced the "One-for-One" Rule and the Small Business Lens (TBS 2012b). The "One-for-One" Rule and the Small Business Lens apply only to regulations. Depending on the risk management instrument(s) selected for these substances, the "One-for-One" Rule and/or the Small Business Lens may apply.

The One-for-One Rule is designed to control the overall administrative burden on Canadian business. The Rule will reduce administrative burden in two ways: first, by removing an existing regulation if a new regulation introduces administrative burden and second, when a new regulation or amendment increases administrative burden, that an equal amount of administrative burden is reduced from an existing regulation.

The purpose of introducing a Small Business Lens is to ensure that the specific needs of small businesses are considered and that the least burdensome but most effective approach to addressing these needs is identified.

4.1 Azo Disperse Dyes

Dyes may be classified according to chemical structure (e.g. azo dyes, anthraquinone dyes) and/or by their usage or application method; very often, both terminologies are used. Classification by usage or application is the principal system adopted by the Colour Index International. In some cases, the same essential colourant is present in more than one application category, for example, a disperse dye can be applied as a solvent dye (Colour Index 2017); this case applies to Disperse Yellow 3.

The disperse dye class refers to substantially water-insoluble, nonionic dyes used for application to hydrophobic fibres from aqueous dispersion. Disperse dyes are primarily used for the dyeing of polyester, polyester blends, nylon (polyamide), cellulose fibres (acetate and triacetate) and acrylics (ETAD 1995; Bardi and Marzona 2010). The solvent dye class refers to dyes that are water insoluble, but soluble in solvents that do not contain polar solubilizing groups such as sulfonic acid, carboxylic acid or quaternary ammonium. Solvent dyes are used for colouring plastics, gasoline, oils and waxes.

Azo disperse dyes refer to dyes that contain one or more azo bonds (i.e. two nitrogen atoms joined by a double bond) that are used as disperse dyes and represent the largest group of disperse dyes, accounting for more than 50% of the total commercialized disperse dyes in the world (Koh 2011, Wiley 2003). Polyester fibres are almost exclusively coloured with disperse dyes (Wiley 2003). Historically, disperse dyes were first used to dye cellulose acetate. Since 1950, the production of disperse dyes has increased sharply, closely following the worldwide production of synthetic fibres, especially polyester, which has grown steadily (Wiley 2003). Disperse dyes have been and are still being used for a significant segment of the nylon textile business (Aspland 1993). Cellulose and polyester fibres account for 78% of world textile consumption, which is steadily increasing worldwide. Disperse dyes have the largest market share of all textile dyes and accounted for 28% of the world textile dye market in 1998 (Wiley 2003).

Azo disperse dyes generally have good lightfastness (the ability of a colour to resist fading when exposed to light), while fastness to washing (resistance of colour to fading when the textile is washed) depends mostly on the fibre used. In particular, for polyamide and acrylic fibres, azo disperse dyes are mainly used for pastel shades. Azo disperse dyes are available in powder or liquid form. Powder forms contain 40–60% dispersing agents and liquid forms contain 10–30% dispersing agents (FINTEX, 2008).

4.2 Current Use and Identified Sector of Disperse Yellow 3

Disperse Yellow 3 was reported to be used as an azo disperse dye in the Canadian textile sector (Canada 2009a). The Domestic Substances List Inventory Update reported for the 2008 year that Disperse Yellow 3 was imported in a range of 100-1000 kg as an azo disperse dye in the Canadian textile sector. Additional uses, including solvent dye applications, from other sectors were not identified.

5. Exposure Sources and Identified Risks

Uses of Disperse Yellow 3 identified in Canada include textile dye formulation and textile dyeing. Because no other uses have been identified as occurring in Canada, including solvent dye applications, the description of exposure sources and identified risks focuses on these two activities.

5.1 Formulation of Disperse Yellow 3

Disperse dyes do not dissolve in water readily and the substances are often in the form of crystals of varying sizes. These properties make it difficult to uniformly distribute the dyes in water and can result in uneven dyeing. In order to improve the dyeing process, the disperse dye is finely ground, usually in the presence of another substance acting as a dispersing agent, and then sold as a paste or spray dried and sold as a powder. Generally, the dispersing agents have specific chemical properties (anionic, polymeric compounds and include formaldehyde), which facilitates milling by preventing agglomeration of the dye particles (Koh 2011).

In response to an information request by Environment and Climate Change Canada, one importer of Disperse Yellow 3 indicated that a dispersing agent is added to the imported dye before it is sold to customers who use the product in textile dyeing. The Screening Assessment Report for Certain Azo Disperse Dyes indicates that during this formulation process, there is the potential for releases to water of Disperse Yellow 3 (which is used as a disperse dye in this application) from the wastewater generated through equipment cleaning, and that these releases have the potential to cause harm to aquatic organisms (Canada 2017c). As a result, risk management will be considered for the formulation of Disperse Yellow 3 (i.e. the process of milling/grinding the disperse dye with dispersing agents and the subsequent wastewater generated through the cleaning of the equipment used in this process).

5.2 Using Disperse Yellow 3 in Textile Dyeing

The final screening assessment report indicates that there is potential for environmental releases of Disperse Yellow 3 that result from textile dyeing to cause adverse effects on aquatic organisms in the environment. Aquatic exposure analysis for the textile dyeing scenario was conducted using probabilistic methods. The likelihood of Predicted Environmental Concentrations (PEC) from textile dyeing operations exceeding the Predicted No Effects Concentration (PNEC) for Azo Disperse Dyes with a molar weight below 360 g/mol was found to be high (55%) (Canada 2017c). As a result, risk management will be considered for this life cycle stage (i.e. textile dyeing).

In textile mills, there are two principal processes that contribute to the release of dyes to the environment: the cleaning of the dye tank following the preparation of the dye bath, and draining of the dye bath after the dyeing process is complete (FINTEX 2008). During a typical dyeing process, the dye bath is prepared, which involves the addition of the dye and a dispersing agent to the dyebath (Koh 2011). The dye is weighed precisely and mixed in a quantity of hot water, which varies from a volume of 400 litres for small machines to a volume of 16 000 litres for machines with larger capacities. Occasionally, errors are made during the preparation of the dye recipe that result in the release of the dye bath contents, including the dye, to the publically-owned sewer system. Once the homogeneous mixture is completely dissolved, the contents of the dye bath are transferred to the dyeing machine to begin the dyeing process, and the tank is cleaned with water in order to prepare it for the next dyeing cycle. This step results in the release of dyes in the textile mill effluent, which is discharged to sewer. In textile mills, of the total disperse dye that may be released by a mill, approximately 90% originates from the draining of the dye bath following the dyeing process, containing the remaining dye which has not been absorbed onto the fibre. This value has been estimated from observations made of the dyeing processes at several Canadian textile mills (FINTEX 2008).

5.3 Exposure of Concern in Canada

The exposure of concern for Disperse Yellow 3 is associated with its release to surface water. The aquatic exposure was estimated based on estimated quantities released from industrial facilities to receiving waters via wastewater treatment systems as described in Appendix E of the Screening Assessment Report for Certain Azo Disperse Dyes (Canada 2017c).

For textile dye formulation, calculations were based on information provided by real-time use of the substance based on four or fewer facilities. The daily use quantity of Disperse Yellow 3 was 440 kg/day and the quantity released to wastewater determined to be 3.57 kg/day. The resulting effluent would be released to the factory sewer for further off-site treatment in the publicly-owned wastewater facility (assuming secondary wastewater treatment as a best case

scenario). The resulting predicted environmental concentration in the receiving waters was calculated to be 0.011 mg/L given the local parameters of both the on-site and off-site wastewater treatment facilities. Please see the Screening Assessment Report, Appendix E for detailed calculations and assumptions.

For textile dyeing, calculations using a probabilistic approach were conducted based on available information associated with the use of 14 Azo Disperse Dyes (including Disperse Yellow 3). The daily use quantity for these substances at each textile dyeing facility was determined based on literature data or facility-supplied data. Among 38 textile dyeing facilities, one facility in Ontario provided its daily use quantity as being below 15 kg (2013 emails from textile mill to Environment and Climate Change Canada; unreferenced). For the other 37 facilities, the daily use quantity remained unknown and was therefore assumed as 36 kg/day based on literature data (US EPA 1994; Cai et al. 1999).

Quantities released to wastewater were determined to be 1.80 kg/day for the one Ontario facility and estimated to be 4.32 kg/day for the other 37 facilities. Many textile dyeing facilities were known to have on-site wastewater treatment, but the type of treatment was unknown. As a conservative approximation, it was assumed that Azo Disperse Dyes were released to the sewer system without being removed by on-site wastewater treatment. The effluent would be released to the factory sewer for further off site treatment in the publicly-owned wastewater facility (assuming secondary wastewater treatment as a best case) resulting in releases to receiving waters ranging from 1.2×10^{-4} to 0.11 mg/L as predicted environmental concentrations from the selected representative facilities chosen. These concentrations also did not necessarily reflect the actual level of exposure, because facility-specific data were unavailable for textile dyeing and could not be used in the calculations, except for the one textile dyeing facility in Ontario. Nevertheless, the estimated aquatic PECs were indicative of a conservative level of exposure for the industrial use of 13 Azo Disperse Dyes in this subgroup and Disperse Yellow 3.

5.4 Identified Risks

Azo disperse dyes generally have very low water solubilities (nanograms to micrograms per litre) but have higher solubilities in octanol. Given their import and use in Canada, potential releases to the aquatic environment and to the terrestrial environment (via wastewater treatment sludge) have been estimated. Azo disperse dyes are not volatile and are likely to eventually deposit in sediment if released to water, but they may still be present in the water column at low concentrations. If released to soil, they are expected to remain there.

The bioavailability of most of these substances is expected to be low based on their low solubilities in water and slow uptake due to their molar weights (most above 360 g/mol) and large cross-sectional diameters. Disperse Yellow 3 has a

molar weight of 269 g/mol, suggesting the substance would likely be more bioavailable to aquatic organisms than higher molar weight azo disperse dyes if the substance was released to water from the textile dye formulation and synthetic textile dyeing process.

For Disperse Yellow 3, the predicted no-effect concentration (PNEC) was calculated as 0.0023 mg/L based on the read-across of an acute toxicity data for Solvent Yellow 1 (CAS RN 60-09-3, 96-hour LC50). The aquatic Predicted Environmental Concentration (PEC) from a site specific textile formulation scenario was estimated as 0.011 mg/L and ranged with an estimated concentration from 1.2×10^{-4} to 0.11 mg/L from 38 textile facilities for the textile dyeing scenario. The outcome of the risk quotient analysis was 4.7 (formulation) and ranged from 0.05 to 43.1 (dyeing), respectively, suggesting a concern to aquatic organisms.

Considering all available lines of evidence presented in the Screening Assessment for Certain Azo Disperse Dyes and in the Screening Assessment for Azo Solvent Dyes (in which this substance was referred to as Solvent Yellow 77), it is concluded that CAS RN 2832-40-8 meets the criteria under paragraph 64*(a)* of CEPA as it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

As discussed in Section 4.1 (Background-Azo Disperse Dyes), polyester fibres are almost exclusively coloured with disperse dyes, and azo disperse dyes are the most used class of disperse dyes, accounting for more than 50% of the total commercialized disperse dyes in the world.

Other types of disperse dyes include anthraquinone dyes, which account for about 25% of disperse dyes, and the remainder include nitroarylamino, coumarin, quinophthalone, methine, naphthalimide, naphthoquinone, naphthostyryl, formazan, benzodifuranone and nitro disperse dyes (Koh 2011, Wiley 2003). Azo disperse dyes are currently employed to create almost the entire range of shades; anthraquinone derivatives are used for red, violet, blue and turquoise. The remaining dye classes are used mainly to produce yellow shades (Wiley 2003).

Azo dyes represent the largest group of disperse dyes for two reasons: the ease with which a large number of molecular combinations can be generated, which

results in a large variety of dyes, and the relatively simple process by which the dyes can be produced. With this class of dyes, manufacturers can respond much more easily to customers' and end users' requests for special shades and fastness characteristics (Wiley 2003). By virtue of their simplicity, and the ease of manufacture, unlike other types of dyes such as anthraquinone dyes, the cost of manufacturing azo dyes is comparatively lower than the expensive anthraquinone dyes (Koh 2011).

Of note based on evidence reported in the Screening Assessment Report of Certain Azo Disperse Dyes, azo disperse dyes of molar weights above the 360 g/mol threshold are likely less bioavailable to aquatic organisms.

Anthraquinone disperse dyes produce bright dyeing of excellent light fastness and cause no dye stability problems during dyeing. Simple anthraquinone disperse dyes can be used for the colouration of cellulose acetate, although of limited colour range and of moderate fastness. Although anthraquinone disperse dyes have many advantages such as bright shades, high light fastness, good stability in dyeing, and excellent levelling, serious economic drawbacks ensure the continuing displacement of these dyes by other types (Koh 2011). A serious drawback of anthraquinone dyes is their poor dyeing strength (the ability of a dye to change the colour of a material), which is the reason why disperse anthraquinone dyes have been increasingly displaced by azo disperse dyes. In addition, several anthraquinone disperse dyes have been assessed under the Challenge initiative in which some have since then been subject to the Significant New Activity Provisions (SNAc) under CEPA. The Government of Canada also plans to address those anthraquinone disperse dyes that have been identified as remaining priorities under the CMP (Canada 2016a).

6.2 Socio-economic and Technical Considerations

6.2.1 Overview of Canadian Textile Sector

Textile manufacturing is one of Canada's oldest and most diverse industries. Textiles can be found in a wide range of forms for many different types of industries including the clothing, transportation, health (medical), agriculture, civil engineering, packaging, protection (individual, environmental) and building industries. According to the CTT Group, Canadian textile companies are classified by five sectors; apparel, carpets, home furnishings, technical textiles (TUT) and other value-added textiles (OVAT) (CTT Group 2007).

6.2.2 Socio-economic Considerations

Approximately 92% of textile mills in Canada are micro (less than 5 employees) or small (5 to 99 employees) businesses (Industry Canada 2012). According to the Textiles Human Resources Council (THRC 2010), 64% of firms have fewer

than 10 employees. As a sub-sector of the textile industry, textile mills have traditionally been categorized according to manufacturing processes. According to the evaluation of the Canadian textile industry, six major categories of wet processing mills were identified based on mill operations and finished textile products. The categories identified were: knit fabric finishing mills, woven fabric finishing mills, wool finishing mills, carpet finishing mills, stock/yarn finishing mills and non-woven fabric finishing mills (Environment and Climate Change Canada and Health Canada 2001). Textile mills are part of a relatively small sector that, in 2010, constituted 0.05% of the Canadian Gross Domestic Product (Industry Canada 2011 and Statistics Canada 2011). The Canadian textile industry is mainly concentrated in Quebec and Ontario (Environment and Climate Change Canada 2005).

The Canadian textile industry has experienced considerable change over the past decade. Though much of its structure has endured, increased global competition from developing countries has compelled firms to redefine their competitive strategies. Industry leaders have recognized that to move forward and continue to succeed, they must move away from primary, commodity-type textiles and focus on technological, specialized, high-end or value-added products and expand their markets. Over the past 20 years, there has been a significant decline in the number of textile firms in Canada. The decrease was due in part to dollar-parity, the abolition of import quotas combined with the U.S.'s establishment of new trade regulations, and reduced control over products entering Canada. These changes decreased the competitiveness of the Canadian textile industry, particularly in mass markets (CTT Group 2008).

These socio-economic factors have been considered in the selection and will be considered in the development of the risk management instrument.

6.2.3 Technical Considerations

To minimize environmental releases from textile mills, pollution prevention techniques or various types of effluent treatment could be used. Pollution prevention techniques could include substitution, automatic distribution of colourants to the dyeing facility, automatic weighing of colourants, employee training, and management of stocks and wastes (FINTEX 2008).

Industrial wastewater treatment systems in Canadian textile mills generally only have pre-treatment, which consists of a fibre removal system, an equalization basin, a pH measurement and control system, and a flow measurement chamber. Further treatment of the effluent takes place at publically- owned wastewater treatment facilities. No Canadian textile mills are known to have a process in place to remove colour from their effluent. Treatment systems that are found in textile mills (outside of Canada) generally consist of primary treatment to remove suspended material, secondary treatment that comprises a biological

process to remove organic material from the effluent, and tertiary membrane separation to allow for re-use of process water. These types of treatment systems are typically found in Italy, Germany, India and Mexico, where water is recycled due to its high cost (FINTEX 2008).

Dyes can be removed from effluent via several mechanisms such as secondary treatment, adsorption on activated carbon, chemical treatment with a flocculating agent, and chemical oxidation. Secondary treatment with activated sludge usually removes only a moderate amount (10–20%) of the dye. Removal of the dye by adsorption on activated carbon is very effective in removing low concentrations of soluble chemicals, including dyes; however, its main drawback is its limited capacity. Consequently, activated carbon is best for removing colour from low volumes of dilute effluent. Chemical treatment of the effluent with a flocculating agent is generally the most efficient and robust way to remove dyes from larger volume effluents. The process involves adding a flocculating agent, such as ferric (Fe^{3+}) or aluminum (Al^{3+}) ions to the effluent, which induces flocculation. A coagulant may also be added to assist the process. The final product is a concentrated sludge that can be separated from the effluent using physical processes. Chemical oxidation is a procedure that uses strong oxidizing agents such as ozone, hydrogen peroxide, chlorine or potassium permanganate to force degradation of organic molecules. At present, treatment by chemical oxidation remains very expensive and is of limited scale (Wiley 2003).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context- Textile Mill Effluents

There are several existing federal and provincial risk management actions that have focused on the textile sector, specifically, and in absence of measures specified pertaining to the textile sector, general industrial effluent standards have applied.

- The Minister of the Environment published a *Notice requiring the preparation and implementation of pollution prevention plans in respect of effluents from textile mills that use wet processing (TMEs) and nonylphenol (NP) and its ethoxylates (NPEs)* in 2004 (*Canada*, 2004). Wet processing textile mills subject to the Notice were required to prepare and implement a pollution prevention plan that took into consideration reducing the toxicity of TMEs to a level equivalent to or less than 13% IC_{50} (50% inhibiting concentration) by 2009 (Note: the Notice ended in 2009). The *Final Summary Report: Pollution Prevention Planning and Effluents from Textile Mills that use Wet Processing and Nonylphenol and its Ethoxylates (NP-NPEs)* was published in July of 2012 and outlines progress achieved

(Environment and Climate Change Canada 2012). The report suggests that risk management actions taken to reduce environmental releases of other substances that may be contributing to TME toxicity, such as phosphates, solvents and dyes (e.g., azo disperse dyes), may help to further reduce TME toxicity. The Notice has largely been successful. The risk management objective for NP-NPEs was surpassed and although the risk management objective for TMEs was not fully achieved, it was met or partially met by 92% of mills. Approximately 85% of mills subject to the Notice were engaged in dyeing activities.

Several provinces have guidelines and standards for industrial releases to water. The following provinces have guidelines, standards and regulatory measures that focus on substances released by textile industries but these are not specific to textile dye substances:

- British Columbia: Working guidelines include standards for colour that are specific to textile and tanning operations (Nagpal *et al*., 2006)
- Québec: The Province of Québec has developed best practices guidance documents for certain non-regulated industries to develop effluent discharge objectives for their industrial effluents and guidelines for self-monitoring of effluents (MDDEP 2008a, 2008b, 2009).
- New Brunswick: The Province of New Brunswick has established effluent criteria based on point of discharge. One of the three overarching criteria is that effluents must not impart colour to the waterway into which discharge occurs (New Brunswick, 1982)

Additionally, the *Wastewater Systems Effluent Regulations (Canada 2012)* established under the *Fisheries Act* are in force. These Regulations include mandatory minimum effluent quality standards that can be achieved through secondary wastewater treatment which in turn, optimizes removal rates of textile dyes from municipal wastewater effluents.

7.2 Related International Risk Management Context

Risk management measures implemented in other jurisdictions are listed below to provide an indication of how the textile sector has been regulated globally in the context of Disperse Yellow 3. Any regulatory action on Disperse Yellow 3 has targeted textile products for human health concerns, not the textile formulating and dyeing processes which result in environmental releases of the substances. Additional risk management of Azo dyes and Azo Disperse Dyes can be found in Annex B for reference.

Azo Disperse Dyes Including Disperse Yellow 3

European Union

- The authoritative German Federal Institute for Risk Assessment strongly advises not to use certain sensitizing disperse dyes, including Disperse Yellow 3 (Germany 2012).
- The Swedish Chemicals Agency has been assigned by the Swedish government to further develop the idea of a coherent piece of EU legislation on hazardous chemicals in textiles including disperse dyes. The Swedish Chemical Agency's overall recommendation is to regulate hazardous chemicals in textiles in the Regulation (EU) No. 1007/2011 of the European Parliament and of the Council of 27 September 2011 (KEMI 2013).

United States

- California's Office of Environmental Health Hazard Assessment has added C.I. Disperse Yellow 3 (CAS No. 2832-40-8) to the list of chemicals known to the State to cause cancer for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, Health and Safety Code section 25249.5 et seq.) (California 2013).

Indonesia

- The Indonesian National Standard (SNI 7616:2010) has prohibited the use of azo dyes in clothing for babies and children, and this regulation became effective on February 6, 2013 (Indonesia 2013).

8. Next Steps

8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Approach or other information that would help to inform decision-making (such as outlined in sections 3.2 or 3.3). Please submit additional information and comments prior to May 10th, 2017.

Comments and information submissions on the Risk Management Approach should be submitted to the address provided below:

Environment and Climate Change Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-800-567-1999 | 819- 938-3232
Fax: 819-938-3231
Email: ec.substances.ec@gc.ca

Companies who have a business interest in Disperse Yellow 3 are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding Disperse Yellow 3 and may be contacted for further information.

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the specific risk management instrument(s), where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the development of the instrument(s). Additional consultation will also take place as the instrument(s) are developed.

8.2 Timing of Actions

Electronic consultation on the Risk Management Approach: March 11, 2017 to May 10, 2017.

Submission of additional studies or information on Disperse Yellow 3: on or before May 10, 2017.

Publication of responses to public comments on the Risk Management Approach document: On or before March 11, 2019.

Publication of the proposed instrument, if required: On or before March 11, 2019

Consultation on the proposed instrument, if required: 60-day public comment period starting upon publication of proposed instrument

Publication of the final instrument, if required: On or before September 11, 2020

9. References

Aspland J.R. 1993. Chapter 9: The Structure and Properties of Disperse Dyes And Related Topics. Textile Chemist & Colorist; January 1993, Vol. 25 Issue 1, p21.

Bardi L, Marzona M. 2010. Factors affecting the complete mineralization of azo dyes. In: Erkurt HA, editor. Biodegradation of azo dyes. (The Handbook of Environmental Chemistry, vol. 9). Berlin (DE): Springer-Verlag. p. 195–210.
Cai Y, Pailthorpe MT, David CK. 1999. A new method for improving the dyeability of cotton with reactive dyes. Textile Res J 69:440–446.

California 2013. http://oehha.ca.gov/prop65/CRNR_notices/list_changes/020813list.html

Canada. 1999. *Canadian Environmental Protection Act, 1999*. S.C., 1999, ch. 33. Canada Gazette. Part III. vol. 22, no. 3. Ottawa: Queen's Printer. Available from: http://www.gazette.gc.ca/archives/p3/1999/index-eng.html

Canada. 2000. *Canadian Environmental Protection Act, 1999: Persistence and Bioaccumulation Regulations,* P.C. 2000-348, 23 March 2000, SOR/2000-107. Available from: http://publications.gc.ca/gazette/archives/p2/2000/2000-03-29/pdf/g2-13407.pdf

Canada 2004. *Notice requiring the preparation and implementation of pollution prevention plans in respect of effluents from textile mills that use wet processing (TMEs) and nonylphenol (NP) and its ethoxylates (NPEs)*. Canada Gazette, Part I, vol.138, no. 49, p. 3522. http://www.canadagazette.gc.ca/archives/p1/2004/index-eng.html

Canada, Dept. of the Environment. 2009a. *Canadian Environmental Protection Act, 1999: Notice with respect to certain inanimate substances (chemicals) on the Domestic Substances List*. Canada Gazette, vol. 143, no. 40. Available from: www.gazette.gc.ca/rp-pr/p1/2009/2009-10-03/html/notice-avis-eng.html#d101

Canada. 2011a. Dept. of the Environment and Dept. of Health. *Canadian Environmental Protection Act, 1999: Announcement of planned actions to assess and manage, where appropriate, the risks posed by certain substances to the health of Canadians and the environment.* Canada Gazette, Part I, vol. 145, no. 41, p. 3125-3129. Available from: www.gazette.gc.ca/rp-pr/p1/2011/2011-10-08/html/notice-avis-eng.html#d127

Canada, Dept. of the Environment. 2011b. *Canadian Environmental Protection Act, 1999*: *Notice with respect to certain aromatic amines and aromatic azo- and benzidine-based substances*. Canada Gazette, Part I, vol. 145, no. 51, supplement. Available from: www.gazette.gc.ca/rp-pr/p1/2011/2011-12-17/pdf/g1-14551.pdf

Canada. 2012. *Wastewater Systems Effluent Regulations.* Canada Gazette, Part II, vol. 146, no.15, p. 1636-1727. Available from: www.gazette.gc.ca/rp-pr/p2/2012/2012-07-18/html/sor-dors139-eng.html

Canada. 2013. Dept. of the Environment, Dept. of Health. *Publication after screening assessment of azo disperse dyes specified on the* Domestic Substances List *(paragraphs 68(*b*) and (*c*) and subsection 77(1) of the* Canadian Environmental Protection Act, 1999*)*. Canada Gazette, Part I, vol. 147, no. 44, p. [2479-2487]. Available from: http://www.gazette.gc.ca/rp-pr/p1/2013/2013-11-02/pdf/g1-14744.pdf

Canada. 2016a. Dept. of the Environment, Dept. of Health. List of Substances in the next phase of the Chemicals Management Plan (CMP) and Two-year Rolling Risk Assessment Publication Plan. Available from: http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2A33EEC9-1

Canada. 2016b. Dept. of the Environment and Dept. of Health. *Canadian Environmental Protection Act, 1999: Publication of final decision after screening assessment of 22 azo solvent dyes specified on the* Domestic Substances List *(paragraphs 68(*b*) and (*c*) or subsection 77(6) of the* Canadian Environmental Protection Act, 1999*).* Canada Gazette, Part I, vol. 150, no. 22, p. [1674-1681]. Available from: http://www.gazette.gc.ca/rp-pr/p1/2016/2016-05-28/html/notice-avis-eng.php#nb1

Canada. 2016c. Dept. of the Environment, Dept. of Health. Screening Assessment for Certain Azo Solvent Dyes. Available from: http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=AB88B1AB-1

Canada. 2017a. Dept. of the Environment, Dept. of Health. Consultation Document on the Options for Addressing Certain Aromatic Azo and Benzidine-Based Substances with Effects of Concern. Available from: http://www.ec.gc.ca/ese-ees/default.asp?lang=Fr&n=B6C9B722-1

Canada. 2017b. Dept. of the Environment and Dept. of Health. *Canadian Environmental Protection Act, 1999: Notice with respect to certain Azo Disperse Dyes substances.* Canada Gazette, Part I, vol. 151, no. 10, p. 1086 to 1101. Available from: http://gazette.gc.ca/rp-pr/p1/2017/2017-03-11/html/notice-avis-eng.php#na1

Canada. 2017c. Dept. of the Environment, Dept. of Health. Screening Assessment of Certain Azo Disperse Dyes. Available from: http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=E86C5AFA-1

Chequer et al. 2013. Eco-Friendly Textile Dyeing and Finishing. Chapter 6: Textile Dyes: Dyeing Process and Environmental Impact. 2013. Available from: www.intechopen.com/books/eco-friendly-textile-dyeing-and-finishing/textile-dyes-dyeing-process-and-environmental-impact

China. 2010. National General Safety Technical Code for Textile Products, draft version. General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardisation Administration of the People's Republic of China. Available from: http://members.wto.org/crnattachments/2010/tbt/chn/10_0909_00_et.pdf

Colour Index 2017. Definition of a Colour Index™ Generic Name. January 2017. http://www.colour-index.com/colour-index-generic-name

CTT Group, 2007: Vermeersch and Mlynarek, "Detailed survey of TUT and VAT companies in Canada", CTT Group, March, 2007

CTT Group, 2008: Centre for Textile Technologies (CTT). Technology Roadmap; for the Canadian textile industry. 2008.

Environment and Climate Change Canada and Health Canada, 2001: Environment and Climate Change Canada and Health Canada 2001b. Priority Substances List Assessment Report. Textile Mill Effluents. Available from: www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl2-lsp2/textile_effluents/index-eng.php

Environment and Climate Change Canada 2005. Risk Management Strategy in Respect of Effluents from Textile Mills that Use Wet Processing (TMEs) and Nonylphenol (NP) and its Ethoxylates (NPEs) Under CEPA (revised 2005). Available from: http://publications.gc.ca/collections/collection_2014/ec/En14-167-2005-eng.pdf

Environment and Climate Change Canada 2012. Final Summary Report: Pollution Prevention Planning and Effluents from Textile Mills that use Wet Processing and Nonylphenol and its Ethoxylates. www.ec.gc.ca/planp2-p2plan/default.asp?lang=En&n=6D9BA45F

[ETAD] Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers. 1995. Health and environmental information on dyes used in Canada. An overview to assist in the implementation of the New Substances Notification Regulation under the Canadian Environmental Protection Act. Report prepared by the ETAD Canadian affiliates, Dayan J, Trebits H, consultants. July 21, 1995.

[EU] European Union. 2009a. Commission Regulation (EC) No. 552/2009 of 22 June 2009 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII [Internet]. Off J Eur Union L 164:7–31. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:en:PDF

[EU] European Union. 2009b. Commission Decision of 9 July 2009 establishing the ecological criteria for the award of the Community Ecolabel for bed mattresses [Internet]. Off J Eur Union L 203: 65-80. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:203:0065:0080:EN:PDF

FINTEX 2008. Étude technique sur certaines substances du défi en vertu du plan de gestion des produits chimiques, d'intérêt et présentes dans l'industrie textile. Phase II, Rapport final. Soumis à Environnement Canada par FINTEX méchanique et procédés inc, Octobre 2008.

Germany 2012. Available from:
http://www.oecd.org/internet/consumer/50195102.pdf

India. 1997. Prohibition on the handling of azodyes [Internet]. Regd. No. D.L.-33004/97, Annexure-10. The Gazette of India: Extraordinary, Part II, Section 3, Sub-section (ii). New Delhi (IN): Government of India, Ministry of Environment and Forests. Available from:
http://cibrc.nic.in/Anex%2010.pdf

Indonesia 2013. SGS Indonesia Accredited For Azo Dye Testing For The Indonesian National Standard (SNI). www.sgs.com/en/Our-Company/News-and-Media-Center/News-and-Press-Releases/2013/02/SGS-Indonesia-Accredited-for-Azo-Dye-Testing-for-the-Indonesian-National-Standard-SNI.aspx

Industry Canada, 2012: Canadian Industry Statistics (CIS): Textile Mills (NAICS 313): Establishments),https://www.ic.gc.ca/app/scr/sbms/sbb/cis/establishments.html?code=313&lang=eng

Japan 2016. Outline of the partial revision of "the Cabinet Order specifying the substances under Paragraph (2) of Article 2 of the Act on Control of Household Products Containing Harmful Substances", and "the Ordinance for enforcement of the Act on Control of Household Products Containing Harmful Substances". Available from:
https://members.wto.org/crnattachments/2014/TBT/JPN/14_5511_00_e.pdf and http://www.mts-global.com/en/technical_update/CPIE-009-16.html

KEMI 2013. Hazardous chemicals in textiles – report of a government assignment Available from:
https://www.kemi.se/global/rapporter/2013/rapport-3-13-textiles.pdf

Koh, 2011. Textile Dyeing. Chapter 10, Dyeing with Disperse Dyes. Jonseok Koh. December 2011.Available from: www.intechopen.com/books/textile-dyeing/dyeing-with-disperse-dyes

Ministère de Developpement durable, Environnement et Parcs 2008a. Lignes directrices pour l'utilisation des objectifs environnementaux de rejet relatifs aux rejets industriels dans le milieu aquatique. Available from : http://www.mddelcc.gouv.qc.ca/eau/eaux-usees/industrielles-en.htm

Ministère de Developpement durable, Environnement et Parcs 2008b. Guide d'information sur l'utilisation des objectifs environnementaux de rejet relatifs aux rejets industriels dans le milieu aquatique. Available from : http://www.mddelcc.gouv.qc.ca/eau/eaux-usees/industrielles-en.htm

Ministère de Developpement durable, Environnement et Parcs 2009. Lignes directrices pour l'élaboration d'un programme d'autosurveillance des effluents industriels des secteurs non réglementés. Available from : http://www.mddelcc.gouv.qc.ca/eau/eaux-usees/industrielles-en.htm

Nagpal, N.K., Pommen, L.W., and Swain, L.G. 2006. A Compendium of Working Water Quality Guidelines for British Columbia. Science and Information Branch, British Columbia Ministry of Environment, Victoria, B.C. 35p. Available at: http://www.env.gov.bc.ca/wat/wq/BCguidelines/working.html

New Brunswick, Department of Environment and Local Government 1982. *Clean Environment Act. Water Quality Regulations.* O.C. 82-588. 6 August, 1982. Regulation 82-126. Available from: http://laws.gnb.ca/en/showdoc/cr/82-126

Statistics Canada, 2011: Real Gross Domestic Product, expenditure-based, by province and territory. www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/econ50-eng.htm

[TBS] Treasury Board of Canada Secretariat. 2012a. Cabinet Directive on Regulatory Management. Available from: http://www.tbs-sct.gc.ca/hgw-cgf/priorities-priorites/rtrap-parfa/guides/cdrm-dcgr-eng.asp

[TBS] Treasury Board of Canada Secretariat. 2012b. Red Tape Reduction Action Plan. Available from: www.tbs-sct.gc.ca/rtrap-parfa/rtrapr-rparfa-eng.asp

THRC, 2010: Textiles Human Resource Council. Canadian textile industry labour market information and the needs assessment. 2010.

[US EPA] US Environmental Protection Agency. 1994. Generic scenario—fabric finishing. Washington (DC): US EPA, Chemical Engineering Branch.

Wiley-VCH, 2003. Industrial Dyes: Chemistry, Properties, Applications. Edited by Klaus Hunger. pp 134–135, 339, 396, 634

ANNEX A. Preliminary Non-Exhaustive List of Azo Disperse Dyes on the *Domestic Substances List* with Molar Weights below 360 g/mol

The table below is a compilation of the Azo Disperse Dyes on the *Domestic Substances List* (DSL) that have a molar weight below 360 g/mol (substances with ecological effects of concern). Further exploration of the DSL may lead to identification of additional azo dyes that are below 360g/mol and which could be used as azo disperse dyes. In addition, there are azo disperse dye substances meeting the molar weight criteria that are new to Canada (not shown).

Table 1. Azo Disperse Dyes on the *Domestic Substances List* with molar weights below 360 g/mol

CAS RN	C.I. Name	Molar weight (g/mol)	Assessed under Subgrouping/ Initiative
2832-40-8	Disperse Yellow 3[ab]	269	Azo Disperse Dyes/ Azo Solvent Dyes
6250-23-3	Disperse Yellow 23[b]	302	Azo Disperse Dyes
65122-05-6	n/a[b]	306	Azo Disperse Dyes
6300-37-4	Disperse Yellow 7[b]	316	Azo Disperse Dyes
21811-64-3	Disperse Yellow 68	318	Azo Disperse Dyes
27184-69-6	n/a	346	Azo Disperse Dyes
6657-00-7	n/a	346	Azo Disperse Dyes
69472-19-1	Disperse Orange 33	351	Azo Disperse Dyes
6253-10-7	Disperse Orange 13	352	Azo Disperse Dyes
842-07-9	Solvent Yellow 14/ Disperse Yellow 97[b]	248	Azo Solvent Dyes
730-40-5	Disperse Orange 3	242	Not Assessed
6054-48-4	Disperse Black 1	262	Not Assessed
4314-14-1	Disperse Yellow 16	278	Not Assessed
12222-69-4/ 20721-50-0	Disperse Black 9	300	Not Assessed
31464-38-7	Disperse Orange 25:1	309	Not Assessed
2872-52-8	Disperse Red 1	314	Not Assessed
2581-69-3	Disperse Orange 1	318	Not Assessed
43047-20-7	Disperse Orange 138	321	Not Assessed
31482-56-1	Disperse Orange 25/Disperse Orange 36	323	Not Assessed
6439-53-8	Disperse Yellow 5	324	Not Assessed
2734-52-3	Disperse Red 19	330	Not Assessed
83249-52-9	Disperse Yellow 241	337	Not Assessed
3179-89-3	Disperse Red 17	345	Not Assessed
16889-10-4	Disperse Red 73	348	Not Assessed
3180-81-2	Disperse Red 13	349	Not Assessed
40880-51-1	Disperse Red 50	358	Not Assessed

[a] Meets one or more criteria under section 64 of CEPA
[b] Substance with both ecological and human health effects of concern

ANNEX B. List of International Risk Management for Azo Disperse Dyes-related to Disperse Yellow 3 and includes Azo Disperse Dyes with Ecological Effects of Concern

Azo Disperse Dyes

European Union

- Six of the Azo Disperse Dyes have the potential to break down into aromatic amines listed in the Commission Regulation (EC) No. 552-2009 of 22 June 2009 amending Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (EU 2009a).
- Disperse Brown 1 is listed as a potentially sensitizing dye that shall not be used in the EU COMMISSION DECISION of 9 July 2009 establishing the ecological criteria for the award of the Community Ecolabel for bed mattresses and for textile products (EU 2009b).

India

- Disperse Yellow 23, Disperse Yellow 7, Disperse Yellow 56, Disperse Orange 149 and Disperse Red 151 are included in India's prohibition on the handling of 70 azo dyes (India 1997).

China

- China's GB 18401-2010 National Safety Technical Code for Textile Products has added 4-aminoazobenzene to its list of 24 forbidden carcinogenic arylamines (China 2010). Disperse Yellow 23, Disperse Yellow 7, CAS RN 58104-55-5 and Disperse Red 151 may decompose into 4-aminoazobenzene.

Japan

- Japan's Ministry of Health, Labor and Welfare has officially enacted an amendment to designate azo compounds as harmful substances under the "Act on Control of Household Products Containing Harmful Substances." According to the amended ordinance, 24 listed aromatic amines will be restricted with a threshold limit of less than 30 mg/kg when tested with a gas chromatograph mass spectrometer. (Japan 2016).