

**Consultation Document on the Options for
Addressing Certain Aromatic Azo and Benzidine-
based Substances with Effects of Concern**

**Health Canada
Environment and Climate Change Canada**

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1. Introduction

1.1 Purpose and Scope

The intent of this consultation document is to give interested parties an opportunity to provide input into the selection and development of actions on how to best monitor changes to, and to prevent increases in exposures and/or releases of 105 aromatic azo and benzidine-based substances which have been assessed under the *Canadian Environmental Protection Act, 1999* (CEPA) (Appendix I) as part of the chemicals management plan. These substances, except for one, Disperse Yellow 3¹, do not pose a risk to Canadians or the environment at current levels of exposure; and as a result, have been found to not meet the criteria under section 64 of CEPA. However, they are recognized to have health and ecological effects of concern and future increases in exposures to these substances could lead to potential risk.

This document provides stakeholders with an overview of potential options and an opportunity to provide feedback. Additional consultation opportunities will follow depending on the feedback received on these options and the chosen path forward.

Specific objectives of this consultation document include:

- informing interested parties of the issues and options being considered;
- providing an opportunity for interested parties to contribute feedback on the selection of options outlined in sections 5 and 7 of this consultation document, such as:
 - a voluntary agreement (e.g., sector specific);
 - additions to the Cosmetic Ingredient Hotlist;
 - revisions to maximum permitted levels in natural health products;
 - use of Significant New Activity (SNAc) provisions of CEPA; and/or
 - various information gathering activities; and
- soliciting information from interested parties to fill information gaps described in section 6 of this consultation document, related to:
 - existing chemical supply chain management practices and which substances are subject to these management practices;
 - compliance with regulations in other jurisdictions;

¹ The final screening assessment report concluded that Disperse Yellow 3 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, as defined in paragraph 64(a) of the *Canadian Environmental Protection Act, 1999*.

- level of industry association representation; and/or
- the use of azo disperse dyes not previously surveyed or in quantities below reporting thresholds, with ecological effects of concern in textile dyeing and the formulation of textile dyes.

1.2 Consultation Process

The Government of Canada is committed to providing interested or affected parties with the opportunity to take part in consultations at all stages of the process. Interested parties may provide comments on the proposed options in writing, by mail, fax or email to the contact information provided in section 8 of this consultation document.

Interested parties may include the general public, non-governmental organizations, indigenous organizations, provincial, territorial and other federal government departments, as well as associations, companies and facilities interested or involved in the following activities:

- import, manufacture and/or use of pigments and dyes;
- import, manufacture and/or sale of products available to consumers containing dyes and pigments, such as clothing and apparel, food products, cosmetics, and drugs including natural health products; and/or
- use, formulation, and commerce (including importation, exportation, sale/distribution) of textile dyes or colourants.

2. Background - Chemicals Management Plan

The Chemicals Management Plan (CMP) is a Government of Canada initiative aimed at reducing the risks posed by chemicals to Canadians and their environment. A group of 358 aromatic azo and benzidine-based substances on the Government of Canada's *Domestic Substances List* (DSL) were assessed for risks to human health and the environment under the second phase of the CMP, launched in 2011. Ten draft screening assessments, each followed by a 60-day public comment period, and ten final screening assessments covering all 358 substances have been published since 2013.

Appendix I lists 104 aromatic azo and benzidine-based substances that were not found to meet section 64 of CEPA, but are recognized to have human health and/or ecological effects of concern. The majority of these substances have been assessed either in the second phase of the CMP or earlier in the Challenge initiative (2006-2011).

In addition, Appendix 1 includes one aromatic azo and benzidine-based substance, Disperse Yellow 3 (DY3), CAS RN 2832-40-8, which has been found to meet the criteria

of section 64(a) under CEPA. It is also recognized as having health effects of concern but not meeting the criteria under section 64(c) of CEPA. This consultation document only addresses the human health effects of concern associated with DY3 and does not address the risk management actions to manage the ecological risks associated with DY3. More information on the risk management approach www.ec.gc.ca/ese-ees/default.asp?lang=En&n=0F6111A3-1 for DY3 can be found on the Government of Canada's Chemical Substances website (Canada 2017).

Sixteen substances listed on the DSL which were not evaluated as part of the Aromatic Azo and Benzidine-based Substance Grouping have been identified as having similar properties as substances of potential ecological concern identified in the azo disperse dyes final screening assessment and are also included in Appendix 1 www.ec.gc.ca/ese-ees/default.asp?lang=En&n=E86C5AFA-1.

Appendix I also illustrates in which screening assessment these substances were assessed. All final screening assessment documents and background information related to uses, sources of exposure, hazard information, etc. for the Aromatic Azo and Benzidine-based Substance Grouping can be found on the Government of Canada's Chemical Substances website http://www.chemicalsubstanceschimiques.gc.ca/group/azo_benzidine/package_groupe1/index-eng.php (Canada 2016).

3. Potential Impacts on Human Health and the Environment

3.1 Carcinogenicity

Based on potential for carcinogenicity, 84 of the substances included in this consultation document have been recognized as having health effects of concern due to one or more of the following lines of evidence:

- classification by national or international agencies for carcinogenicity (may be a group classification);
- evidence of carcinogenicity in animal studies and/or human epidemiology, based on the specific substance;
- potential to release one or more of the 22 European Union (EU22) regulated aromatic amines by azo bond cleavage; and/or
- read-across to related substances for which one of the above lines of evidence applies.

3.2 Aquatic Toxicity

Ecological effects of concern have been identified for 25 azo disperse dyes included in this consultation document based on increased bioavailability, characterized by molecular weights below 360 g/mol:

- increased bioavailability results in the ability of a chemical to be absorbed more readily by an organism; and
- low molecular weight azo disperse dyes (< 360 g/mol) are more likely to exhibit effects in aquatic organisms below their limit of solubility under natural environmental conditions.

Four of these 25 substances are also considered to have human health effects of concern and are included in the 84 substances described in section 3.1 of this consultation document.

3.3 Exposure for Canadians

Exposure to Canadians from the 84 azo substances with health effects of concern is currently not expected or is low. However, if exposures to these substances were to increase, particularly from certain products available to consumers such as textiles, clothing and apparel, cosmetics, paints and coatings, food and drugs including natural health products, then potential risks for Canadians could exist.

Results from surveys conducted by the Government of Canada between 2005 and 2011 indicated that the majority of these substances were not manufactured or imported into Canada in quantities above 100 kg per year (EC 2006, EC 2008, EC 2009a, EC 2009b EC 2011). For a limited number of substances that were in commerce, the levels of exposure for Canadians were not determined to be a concern for human health.

Testing of imported and domestic textile and leather products such as children's toys, leather slippers, children's clothing and woollen items was conducted in 2012 for the presence of EU22 aromatic amines. Results of this testing did not identify EU22 aromatic amines in textile and leather products at levels that would be harmful to human health (Health Canada 2013).

3.4 Environmental Exposure

Environmental exposure to the azo disperse dyes with ecological effects of concern included in this consultation document is believed to be low based on known current uses in Canada. However, if environmental releases of these substances were to increase in industrial effluents from the formulation of textile dyes/colourants or from the dyeing of synthetic fibres, such as polyester, polyester blends, nylon and acrylics, as

well as the dyeing process for cellulose acetate (ETAD 1995; Bardi and Marzona 2010), then potential risks for the Canadian environment could exist. Other potential activities with these substances, assessed as part of the certain azo solvent dyes screening assessment, are not considered to be of concern.

Results from surveys conducted by the Government of Canada on 9 of the 25 azo disperse dyes with ecological effects of concern between 2005 and 2011 indicated that none were found to be used in and/or imported for the dye formulation or textile dyeing sectors in Canada above 100 kg per year (EC 2006, EC 2008, EC 2009a, EC 2011).

Sixteen of the 25 azo disperse dyes in this consultation document were not included in the Aromatic Azo and Benzidine-based Substance Grouping screening assessments, but they are similar in terms of size and chemical structure to the substances in the azo disperse dyes screening assessment which were identified as having ecological effects of concern. Current information related to the manufacture, use or import of these substances in Canada is unknown.

4. Existing Risk Management

4.1 Canadian Risk Management Context

Some of the 84 substances with human health effects of concern are addressed by existing Acts and Regulations in Canada for particular uses and applications, such as in drugs including natural health products, cosmetics and/or as food additive colouring agents. In addition, some of the substances have been subject to SNAC provisions as a result of other CMP initiatives (i.e., the Challenge initiative, 145 Persistent, Bioaccumulative and Inherently Toxic substances assessment).

No risk management is currently in place in Canada to address the 25 azo disperse dyes with ecological effects of concern; however, six of these substances are subject to SNAC provisions.

4.1.1 Drugs including Natural Health Products

Drug colourants are regulated under Part C, Division 1 of the *Food and Drug Regulations* in Canada. If a colourant is not listed in the regulations, then it is not permitted in drugs.

Out of the 84 substances with health effects of concern, only Pigment Red 4 is an approved colouring agent permitted for internal and external use in drugs.

Pigment Red 4 is listed in the Natural Health Products Ingredients Database with a non-medicinal role for use in natural health products as a colour additive, up to 1.0 mg per day in oral products unless additional evidence for safety is submitted (NHPID 2016). It

is listed in the Licensed Natural Health Products Database as being present in currently licensed natural health products (LNHPD 2016).

4.1.2 Cosmetics

Colourants used in cosmetic products are subject to the provisions of the *Food and Drugs Act* and its *Cosmetic Regulations* and administrative requirements such as the Cosmetic Ingredient Hotlist (Health Canada 2015).

While the majority of the 84 substances with health effects of concern are not listed on the Cosmetic Ingredient Hotlist, 10 have been identified as having the potential to release a substance managed by the Hotlist (Appendix I).

In Canada, face paints are considered cosmetics.

4.1.3 Food Additive Colouring Agents

Food colouring agents are regulated as food additives under the *Food and Drug Regulations*. Colouring agents that are permitted for use in food are listed in the *List of Permitted Colouring Agents* incorporated by reference in the *Marketing Authorization for Food Additives that May be Used As Colouring Agents*, issued under the authority of the *Food and Drugs Act*. None of the 84 substances with health effects of concern have been approved for use as food additive colours for foods sold in Canada.

The Canadian Food Inspection Agency (CFIA)'s compliance activities aim to prevent the sale of foods in Canada that are non-compliant with the regulations. Since 2009, the CFIA has been conducting annual targeted surveys on food colours, including colours that are not permitted for use in Canada. These surveys include the sampling and analysis of a wide variety of foods. Substances included in this consultation document which are subject to CFIA monitoring are listed in Appendix I.

Any food products that are found to be non-compliant with food additive provisions are assessed by Health Canada. The type of enforcement action taken by the CFIA is determined in part by the results of Health Canada's risk assessment. For example, one of the actions may include a public recall of the food product.

4.1.4 Significant New Activity

The Significant New Activity (SNAC) provisions of CEPA trigger an obligation for a person to provide the Government of Canada with information specified in the notice about a substance when proposing its use, import or manufacture for an activity described in the notice. If risks are identified, the Government of Canada may impose risk management actions.

To date, the SNAc provisions have been applied to 67 aromatic azo and benzidine-based substances on the Government of Canada's DSL. Sixty-five of these substances have been re-assessed based on ecological considerations under the current Aromatic Azo and Benzidine-based Substance Grouping, with 51 no longer identified to have human health or ecological effects of concern. As such, the SNAc requirements for the 51 substances have been, or are in the process of being, rescinded.

For the remaining 16 aromatic azo and benzidine-based substances with SNAc requirements currently in place, risk assessments continue to identify human health and or ecological effects of concern; therefore, the SNAc requirements will be re-evaluated once the overall approach for tracking these substances has been confirmed.

Appendix II provides a list of all substances included in the Aromatic Azo and Benzidine-based Substance Grouping to which the SNAc provisions have been applied, including a list of any relevant publications. More information on SNAc requirements can be found on the Government of Canada's CEPA Environmental Registry <https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=9EFCCB36-1> (EC 2016).

4.1.5 Other Risk Management Measures in Canada

British Columbia, Québec, Ontario and New Brunswick have guidelines and standards that target the textile sector and/or industrial discharges to water (Nagpal *et al.* 2006; MDDEP 2008a, 2008b, 2009; OMOE 2007; NB 1982). These initiatives are not specific to aromatic azo and benzidine-based substances, although they focus on general effluent discharge parameters, such as colour.

Nationally, the *Wastewater Systems Effluent Regulations (2012)* established under the *Fisheries Act* include mandatory minimum effluent quality standards that can be achieved through secondary wastewater treatment. Secondary and more advanced treatments have been known to optimize removal rates of textile dyes from wastewater effluents (Canada 2012).

4.2 International Risk Management Context

Some of the substances with health effects of concern are also addressed in other jurisdictions through regulatory and other activities, particularly for use in textile and clothing applications but also in areas such as drugs, cosmetics and food colours. However, there are no regulatory initiatives in place for substances with ecological effects of concern in other jurisdictions at the moment. Below is a summary of relevant international activities.

4.2.1 Textiles and Clothing

European Union REACH Regulation (EC) No. 1907/2006 Annex XVII

The European Union (EU) member states have imposed restrictions that apply to azo dyes that, by reductive cleavage of one or more azo groups, may release one or more of the EU22 listed in Appendix 8 of the European Commission Regulation (EC) 552/2009, in concentrations that exceed 30 parts per million (ppm) in the finished articles (or their parts), such as textile and leather articles that may come into direct and prolonged contact with the human skin or oral cavity or in the dyed parts thereof (EU 2009a).

The National Standard of the People's Republic of China GB 18401-2010 (textiles) and GB 20400-2006 (leather)

These national standards of the People's Republic of China take a similar approach to the European Union REACH Regulation (EC) No. 1907/2006, applying restriction to 24 aromatic amines, with a limit of 20 ppm for textile articles and 30 ppm for leather articles (China 2010).

Australian Competition and Consumer Commission

The Australian Competition and Consumer Commission is considering regulatory and non-regulatory options to limit consumer exposure to hazardous azo dyes in certain clothing, textiles and leather goods. Individual substances have not been identified and publication of the consultation paper on the subject does not create a new law or regulation (Australia 2015).

4.2.2 Food Additive Colouring Agents

European Union

Permitted food additive colours are listed in Council Directive 94/36/EC in Europe (EU 1994). None of the 84 substances with health effects of concern have been approved for use as food additive colours in the EU.

United States Food and Drug Administration

Under the *Federal Food, Drug and Cosmetic Act*, Chapter VII, section 721, colour additives are subject to United States Food and Drug Administration (US FDA) approval before they may be used in food. The *Colour Additive Status List* provides information concerning colour additives in food (US FDA 2015). None of the 84 substances with health effects of concern have been approved for use as food additive colours in the United States (US).

4.2.3 Drugs including Natural Health Products

European Union

Only the colouring matters listed in Annex I to Directive 94/36/EC (Colours which may be used in foods) may be used to colour medicinal products. None of the 84 substances with health effects of concern are listed in Annex I (EU 2015a). Conversely to the *Food and Drug Regulations* of Canada, Pigment Red 4 is not permitted for use in drugs in the EU (EU 2015a).

United States Food and Drug Administration

Under the *Federal Food, Drug and Cosmetic Act*, Chapter VII, section 721, colour additives are subject to US FDA approval before they may be used in drugs. The *Colour Additive Status List* provides information concerning colour additives in drugs (US FDA 2015). Similar to Canada, Pigment Red 4 is allowed for use in ingested drugs, other than mouthwashes and dentifrices, if taken continuously for < 1 year (at most 1.7 mg per day); ingested drugs if taken continuously for > 1 year (at most 1.0 mg per day); and external drugs in the US (US FDA 2015).

4.2.4 Cosmetics

European Union

Regulation (EC) No 1223/2009 establishes rules to be complied with by any cosmetic products made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health (EU 2009b). For example, substances classified as carcinogenic, mutagenic or toxic for reproduction are not permitted to be used in cosmetic products (EU 2015b).

While Pigment Red 4 is allowed for use in cosmetics at a maximum concentration of 3% in the EU, it is prohibited for use in hair dye products (EU 2013).

United States Food and Drug Administration

Under the *Federal Food, Drug and Cosmetic Act*, Chapter VII, section 721, colour additives are subject to US FDA approval (except coal tar hair dyes) before they may be used in cosmetics. The *Colour Additive Status List* provides information concerning colour additives in cosmetics in the US. While Pigment Red 4 is allowed for use in externally-applied cosmetics in the US, it is restricted at a maximum concentration of 3% in lip products (US FDA 2015).

4.2.5 Arts and Crafts materials

United States Consumer Product Safety Commission

US federal law requires that all art materials offered for sale to consumers of all ages in the US undergo a toxicological review of the complete formulation of each product to determine the product's potential for producing adverse chronic health effects. Also, art materials must be properly labelled for acute and chronic hazards, as required by the *Labeling of Hazardous Art Materials Act* and the *Federal Hazardous substances Act*, respectively (US 2015).

European Union

European Standard EN71-7 (Safety of Toys, Part 7: Finger paints – requirements and test methods) specifies requirements for the substances and materials used in finger paints (CEN 2017).

4.3 Existing Information Gathering and Monitoring Activities in Canada

None of the 84 substances with human health effects of concern or the 25 substances with ecological effects of concern is currently subject to environmental monitoring.

One of the 25 substances with ecological effects of concern (Solvent Yellow 14/Disperse Yellow 97) is currently subject to National Pollutant Release Inventory (NPRI) reporting requirements, with a reporting threshold of 10 tonnes MPO (manufactured, processed, or otherwise used). However, there has been no reporting of substance releases.

5. Proposed Options under Consideration

Given the numerous substances with effects of concern and potential sources of exposure, various options can be considered to address future increases in exposure. These may include actions that are preventive in nature or actions focused on additional information gathering to inform assessment and risk management. These options are described below.

5.1 Preventive Actions

5.1.1 Voluntary Agreement

Recognizing the results of these most recent screening assessments and actions that exist in other jurisdictions, the intent of this option is to formalize an agreement with implicated parties to limit the sale of products available to consumers that may contain or release these substances, in applications that would result in increased general population exposure.

With increasing globalized markets, industry has already recognized regulatory actions on clothing and apparel for example, in other jurisdictions such as the EU and China, and has adapted to comply with these markets over the years. This is evident in industry tools and best practices such as restricted substance lists, which summarize substances to avoid subject to regulatory and non-regulatory controls internationally. Restricted substance lists are promoted by industry associations such as the American Apparel and Footwear Association to its members (AAFA 2015).

Another example would be the Ecological and Toxicological Association of Organic Dyes and Pigments Manufacturers (ETAD) which promotes a Code of Ethics (ETAD 2017). The Code of Ethics is the key policy of the association and describes the implementation of their aim to manufacture, sell and use synthetic organic colorants so that any possible negative effect on health and the environment is minimized. For example, all ETAD member companies shall comply with all applicable laws and regulatory requirements dealing with the safety and the environmental impact of synthetic organic colorants (ETAD 2017).

This type of agreement could be used to address each of the substances with health effects of concern, as a comprehensive option to address potential increases in general population exposure. While the majority of the substances with health effects of concern have lines of evidence linked to the potential release of an EU22 aromatic amine or are EU22 aromatic amines themselves, substances linked to the other lines of evidence (e.g., carcinogenicity classifications, read-across, evidence of carcinogenicity in studies) could also be considered.

5.1.2 Options for Cosmetics

The Cosmetic Ingredient Hotlist is an administrative tool that helps industry satisfy the requirements for the sale of a cosmetic, by providing a list of substances that are considered as restricted or prohibited in cosmetics. Substances on the Hotlist may contravene the general prohibition found in section 16 of the *Food and Drugs Act* or a section of the *Cosmetic Regulations*. The Hotlist is reviewed and updated as new scientific data becomes available and serves to keep the cosmetic industry aware of new substances that Health Canada considers inappropriate for cosmetic use, or which require hazard labelling. The final screening assessment no longer identifies a risk to human health from cosmetics currently on the market containing Pigment Red 4. However, the Cosmetic Ingredient Hotlist may be considered an option for certain azo substances with health effects of concern, predicted to have the highest potential to pose a risk via cosmetic exposure, such as Pigment Red 4.

For those with less certainty on the potential to pose a risk, but with information indicating potential use in cosmetic products, monitoring for shifts in Canadian cosmetic

products may be more appropriate for substances such as Solvent Red 1, Oil Orange SS/Solvent Orange 2, Pigment Red 53:1, Ponceau MX, Phenazopyridine Hydrochloride and Basic Orange 2.

5.1.3 Options for Natural Health Products

While exposure to Pigment Red 4 from use in oral natural health products did not indicate a high concern for risk to human health, the health effects of Pigment Red 4, including potential carcinogenicity, are recognized. As a result, consideration will be given to:

- obtaining the actual concentration or quantity of Pigment Red 4 present in currently licensed oral natural health products; and
- revising the maximum permitted limit of 1.0 mg/day for Pigment Red 4 outlined in the Natural Health Products Ingredients Database (NHPID 2016), to be expressed in mg/kg-bw per day, to account for potential daily exposure for adolescents and children.

5.2 Information Gathering and Monitoring

Additional options to the proposed preventive actions described in section 5.1 of this consultation document include various mechanisms as described below, to monitor for shifts in use to address potential increases in exposure to the environment and general population. The *Approach for Identification of Chemicals and Polymers as Risk Assessment Priorities Under Part 5 of the Canadian Environmental Protection Act, 1999* describes how Health Canada and Environment and Climate Change Canada keep current with new information, and the considerations applied when identifying priorities for risk assessment (EC 2014). Under the CMP, new information will continue to be sought and developments relevant to the prioritization of substances for risk assessment will continue to be tracked. Some of the information gathering activities listed below can serve to inform the acquisition phase of the approach mentioned above.

5.2.1 Significant New Activity Requirements (SNAc)

Health Canada may consider the application of the SNAc provisions, to enable the Government of Canada to evaluate potential risks prior to the start of new domestic activities, such as the import and use of substances with health effects of concern.

Environment and Climate Change Canada is also considering the application of the SNAc provisions for the 25 azo disperse dyes with effects of ecological concern, to enable the Government of Canada to evaluate and manage potential risks prior to the start of new activities.

Given their high hazard profile, it is anticipated that use of these 25 substances in the textile dye formulation and dyeing sectors in Canada would likely pose a risk to the environment and require risk management in a fashion consistent with the approach that will be taken for DY3.

Commercial activity above the reporting threshold of 100 kg/year has not been reported in previous Notices issued under section 71 of CEPA for 9 of these substances (EC 2006, EC 2008, EC 2009a, EC 2011). However, there is no current information on use patterns of the remaining 16. One of the purposes of this consultation document is to seek stakeholder input on the commercial status of the 25 azo disperse dyes with ecological effects of concern, in order to ensure that any existing or potential activities would be considered in the development of the SNAc Notice of Intent. If any of the 25 azo disperse dyes are identified in commerce in Canada, further risk assessments may be required.

5.2.2 Inventory Update under CEPA (IU)

Certain substances with health effects of concern may be considered for nomination to the IU. The DSL was first compiled in the early-1990s to identify substances that were in commerce in Canada between 1984 and 1986. At the time of compilation, basic information such as substance quantities, uses and industry sectors involved were collected. The Government of Canada recognizes the benefits of maintaining an up-to-date inventory of substances in commerce. Work to update information on substances on the DSL, undertaken under the CMP, is addressed in phases. Each update does not include all substances on the DSL. Instead, subsets of substances of interest are surveyed based on consultations with stakeholders.

5.2.3 National Pollutant Release Inventory (NPRI)

The NPRI is Canada's legislated, publicly-accessible inventory of pollutant releases (to air, water and land), disposals and transfers for recycling. It comprises information reported by facilities to Environment and Climate Change Canada under CEPA.

5.2.4 Voluntary Surveys

Occasional voluntary surveys or questionnaires can be sent to interested parties to help identify shifts in market status of substances. Questions could be focused on products available to consumers that would result in increased general population exposure.

5.2.5 Monitoring of International Activities

This information gathering activity is meant to capture shifts in use, regulatory and/or risk assessment developments or product recalls taking place in other jurisdictions. Relevant information may be acquired through Canada's many interactions with

domestic and international partners, as well as with various stakeholders including industry associations. Through participation in a variety of international activities and relationships with other national regulators, representatives of Environment and Climate Change Canada and Health Canada obtain and share information on issues, concerns and regulatory initiatives relating to specific substances. Environment and Climate Change Canada and Health Canada also monitor publicly-available information sources that relate to data collection, risk assessment and risk management initiatives undertaken on substances by other agencies.

5.2.6 Reviewing Internal Databases and Monitoring

Health Canada has existing information gathering tools in place such as Cosmetic Notification Forms. This tool can be leveraged by periodically reviewing and looking for shifts in use, types of products or concentrations.

6. Data Needs

Data needs and uncertainties exist on the topics identified below, as those topics are typically outside the scope of previous and existing information gathering activities, both in terms of nature of questions and reporting threshold requirements. In addition, current use information is not available for certain substances with ecological effects of concern. In order to make informed decisions on proposed future actions, the information below is being requested to fill data needs and uncertainties related to establishing preventative measures or information gathering.

- What chemical supply chain management practices (e.g., restricted substance lists, product testing, or supplier agreements) are in place to avoid the use of aromatic azo and benzidine-based substances with effects of concern, for example those subject to textile and leather article regulations in other jurisdictions?
- Which aromatic azo and benzidine-based substances are subject to the above supply chain management practices?
- Are any of the 25 azo disperse dyes identified as having ecological effects of concern (Appendix I) currently, or planned to be, used, manufactured or imported in the dye formulation and/or textile dyeing sectors in Canada? If so, in what quantities?
- Are any azo disperse dyes with a molecular weight less than 360 g/mol, but which are not identified in Appendix I, currently, or planned to be, used, manufactured or imported in the dye formulation and/or textile dyeing sectors in Canada? If so, in what quantities?
- Provide specific examples of best management practices, or any other considerations, that highlight advantages or challenges with any of the approaches identified in this paper.

7. Summary of Preferred Options

While this document provides an overview of potential options for addressing certain aromatic azo and benzidine-based substances with effects of concern, the following options represent the Government of Canada's current preferred approach.

Neither of the options proposed below will preclude additional actions under consideration, to prevent exposure from increasing on a case by case basis for certain substances. For example, actions on Pigment Red 4 in relation to cosmetics and natural health products may still be considered.

7.1 Significant New Activity Provisions

Given their hazard profile, aromatic azo and benzidine-based substances with ecological effects of concern and certain substances with health effects of concern may be proposed, or may continue to be subject to SNAc provisions in order to enable the Government of Canada to assess the potential risks associated with a new activity before the new activity is undertaken.

7.2 Voluntary Agreement Combined with Future Information Gathering for Performance Measurement

A voluntary agreement could be used as a comprehensive approach to address substances with health effects of concern by reducing the potential for increases in future exposures so that exposures remain below levels that pose a risk to human health.

A manner in which to measure the effectiveness of this option could be to propose future information gathering activities, to monitor whether uses or products that could lead to general population exposure have changed.

8. Public Comment Period

Interested parties are invited to submit comments during the 60-day public comment period on the content of this consultation document or other information that would help to inform decision-making about future actions.

Please submit additional information and comments prior to May 10, 2017 to the Substances Management Information Line:

Telephone: 1-800-567-1999 (in Canada) or 819-938-3232

Fax: 819-938-3231

Email: eccc.substances.eccc@canada.ca

Companies who have a business interest in these aromatic azo and benzidine-based substances with effects of concern are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding these substances and may be contacted for further information.

Following the public comment period on the consultation document, the Government of Canada will initiate the development of specific action(s), where necessary. Comments received on the consultation document will be taken into consideration in the selection or development of these action(s). Consultation will also take place as action(s) are developed.

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Appendix I: Aromatic azo and benzidine-based substances with effects of concern

CAS RN	C.I. name	Assessed under CMP initiative	Effects of concern	Existing action
<i>Benzidine-based Dyes and Related Substances</i>				
72-57-1	C.I. Direct Blue 14	Certain Benzidine-based Dyes and Related Substances	Health	CFIA monitoring ^d
119-93-7	C.I. Azoic Diazo Component 113	Certain Benzidine-based Dyes and Related Substances	Health	
119-90-4	C.I. Disperse Black 6	Certain Benzidine-based Dyes and Related Substances	Health	
573-58-0	C.I. Direct Red 28	Certain Benzidine-based Dyes and Related Substances	Health	CFIA monitoring ^d
612-82-8	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
992-59-6	C.I. Direct Red 2	Certain Benzidine-based Dyes and Related Substances	Health	
1937-37-7	C.I. Direct Black 38	Challenge Batch 6	Health	
2150-54-1	C.I. Direct Blue 25	Certain Benzidine-based Dyes and Related Substances	Health	
2429-74-5	C.I. Direct Blue 15	Certain Benzidine-based Dyes and Related Substances	Health	
2429-71-2	C.I. Direct Blue 8	Certain Benzidine-based Dyes and Related Substances	Health	
3701-40-4	C.I. Acid Red 99	Certain Benzidine-based Dyes and Related Substances	Health	
6358-57-2	C.I. Acid Red 111	Challenge Batch 6	Health	
6459-94-5	C.I. Acid Red 114	Certain Benzidine-based Dyes and Related Substances	Health	CFIA monitoring ^d
6420-22-0	C.I. Direct Blue 295	Certain Benzidine-based Dyes and Related Substances	Health	
6420-06-0	C.I. Direct Violet 28	Certain Benzidine-based Dyes and Related Substances	Health	
6449-35-0	C.I. Direct Blue 151	Certain Benzidine-based Dyes and Related Substances	Health	
6548-30-7	C.I. Acid Red 128	Certain Benzidine-based Dyes and Related Substances	Health	
6548-29-4	C.I. Direct Red 46	Certain Benzidine-based Dyes and Related Substances	Health	
16071-86-6	C.I. Direct Brown 95	Certain Benzidine-based Dyes and Related Substances	Health	
67923-89-1	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
68318-35-4	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
68400-36-2	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
70210-28-5	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
71215-83-3	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
71550-22-6	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
75659-73-3	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
75659-72-2	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
75673-35-7	N/A	Certain Benzidine-based Dyes and Related Substances	Health	

CAS RN	C.I. name	Assessed under CMP initiative	Effects of concern	Existing action
75673-34-6	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
75673-19-7	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
75673-18-6	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
75752-17-9	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
89923-60-4	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
93940-21-7	N/A	Certain Benzidine-based Dyes and Related Substances	Health	
Monoazo Pigments				
2814-77-9	C.I. Pigment Red 4	Certain Monoazo Pigments	Health	Natural Health Products Ingredients Database
3468-63-1	C.I. Pigment Orange 5	Certain Monoazo Pigments	Health	Cosmetic Ingredient Hotlist
5160-02-1	C.I. Pigment Red 53:1	Certain Monoazo Pigments	Health	
6410-09-9	C.I. Pigment Orange 2	Certain Monoazo Pigments	Health	
6410-13-5	C.I. Pigment Red 6	Certain Monoazo Pigments	Health	
49744-28-7	N/A	Certain Monoazo Pigments	Health	
Azo Solvent Dyes				
85-83-6	C.I. Solvent Red 24	Certain Azo Solvent Dyes	Health	Cosmetic Ingredient Hotlist; CFIA monitoring ^d
97-56-3	C.I. Solvent Yellow 3	Certain Azo Solvent Dyes	Health	
60-11-7	C.I. Solvent Yellow 2	Certain Azo Solvent Dyes	Health	CFIA monitoring ^d
60-09-3	C.I. Solvent Yellow 1	Certain Azo Solvent Dyes	Health	
103-33-3	N/A	Certain Azo Solvent Dyes	Health	
495-54-5	C.I. Solvent Orange 3	Certain Azo Solvent Dyes	Health	
842-07-9	C.I. Disperse Yellow 97, C.I. Solvent Yellow 14; Sudan I ^e	Certain Azo Solvent Dyes	Health and Ecological ^a	CFIA monitoring ^d
1229-55-6	C.I. Solvent Red 1	Certain Azo Solvent Dyes	Health	
2646-17-5	C.I. Solvent Orange 2 / Oil Orange SS	Certain Azo Solvent Dyes	Health	CFIA monitoring ^d
2832-40-8	C.I. Disperse Yellow 3,	Certain Azo Solvent Dyes	Health	

CAS RN	C.I. name	Assessed under CMP initiative	Effects of concern	Existing action
	C.I. Solvent Yellow 77 [†]			
3118-97-6	C.I. Solvent Orange 7	Challenge Batch 6	Health	Cosmetic Ingredient Hotlist; CFIA monitoring ^d
6368-72-5	C.I. Solvent Red 19	Certain Azo Solvent Dyes	Health	CFIA monitoring ^d
21519-06-2	N/A	Certain Azo Solvent Dyes	Health	
Azo Acid Dyes				
3761-53-3	C.I. Acid Red 26, C.I. Food Red 5	Certain Azo Acid Dyes	Health	CFIA monitoring ^d
75949-73-4	N/A	Certain Azo Acid Dyes	Health	
Azo Basic Dyes				
136-40-3	N/A	Certain Azo Basic Dyes	Health	
532-82-1	C.I. Basic Orange 2	Certain Azo Basic Dyes	Health	
63681-54-9	N/A	Certain Azo Basic Dyes	Health	
75660-25-2	N/A	Certain Azo Basic Dyes	Health	
79234-33-6	N/A	Certain Azo Basic Dyes	Health	
71032-95-6	N/A	Challenge Batch 9	Health	
75199-20-1	N/A	Certain Azo Basic Dyes	Health	
125329-01-3	N/A	Certain Azo Basic Dyes	Health	
Aromatic Amines				
90-04-0	N/A	Certain Aromatic Amines	Health	
91-59-8	N/A	Certain Aromatic Amines	Health	Cosmetic Ingredient Hotlist
95-53-4	N/A	Certain Aromatic Amines	Health	Cosmetic Ingredient Hotlist ^b
95-80-7	C.I. Oxidation Base 35	Certain Aromatic Amines	Health	Cosmetic Ingredient Hotlist
106-47-8	N/A	Certain Aromatic Amines	Health	Cosmetic Ingredient Hotlist
106-49-0	C.I. Azoic Coupling Component 107	Certain Aromatic Amines	Health	Cosmetic Ingredient Hotlist ^c
540-23-8	N/A	Certain Aromatic Amines	Health	Cosmetic Ingredient

CAS RN	C.I. name	Assessed under CMP initiative	Effects of concern	Existing action
				Hotlist ^b
615-05-4	C.I. Oxidation Base 12	Certain Aromatic Amines	Health	Cosmetic Ingredient Hotlist
Azo Direct Dyes				
3687-80-7	C.I. Direct Red 26	Certain Azo Direct and Reactive Dyes	Health	
6420-43-5	C.I. Direct Red 62	Certain Azo Direct and Reactive Dyes	Health	
72749-87-2	N/A	Certain Azo Direct and Reactive Dyes	Health	
72749-88-3	N/A	Certain Azo Direct and Reactive Dyes	Health	
83232-30-8	N/A	Certain Azo Direct and Reactive Dyes	Health	
83232-32-0	N/A	Certain Azo Direct and Reactive Dyes	Health	
84878-16-0	N/A	Certain Azo Direct and Reactive Dyes	Health	
Azo Disperse Dyes				
730-40-5	C.I. Disperse Orange 3	Not Assessed	Ecological	
2581-69-3	C.I. Disperse Orange 1	Not Assessed	Ecological	
2734-52-3	C.I. Disperse Red 19	Not Assessed	Ecological	
2872-52-8	C.I. Disperse Red 1	Not Assessed	Ecological	
3179-89-3	C.I. Disperse Red 17	Not Assessed	Ecological	
3180-81-2	C.I. Disperse Red 13	Not Assessed	Ecological	
4314-14-1	C.I. Disperse Yellow 16	Not Assessed	Ecological	
6054-48-4	C.I. Disperse Black 1	Not Assessed	Ecological	
6250-23-3	C.I. Disperse Yellow 23	Challenge Batch 6 / Certain Azo Disperse Dyes	Health and Ecological	
6253-10-7	C.I. Disperse Orange 13	Certain Azo Disperse Dyes	Ecological	
6300-37-4	C.I. Disperse Yellow 7	Challenge Batch 6 / Certain Azo Disperse Dyes	Health and Ecological	CFIA monitoring ^d
6439-53-8	C.I. Disperse Yellow 5	Not Assessed	Ecological	
6657-00-7	N/A	Certain Azo Disperse Dyes	Ecological	
12222-69-4	C.I. Disperse Black 9	Not Assessed	Ecological	
16889-10-4	C.I. Disperse Red 73	Not Assessed	Ecological	
21811-64-3	C.I. Disperse Yellow 68	Certain Azo Disperse Dyes	Ecological	
27184-69-6	N/A	Certain Azo Disperse Dyes	Ecological	
31464-38-7	C.I. Disperse Orange 25:1	Not Assessed	Ecological	

CAS RN	C.I. name	Assessed under CMP initiative	Effects of concern	Existing action
31482-56-1	C.I. Disperse Orange 25/Disperse Orange 36	Not Assessed	Ecological	
40880-51-1	C.I. Disperse Red 50	Not Assessed	Ecological	
43047-20-7	C.I. Disperse Orange 138	Not Assessed	Ecological	
58104-55-5	N/A	Certain Azo Disperse Dyes	Health	
65122-05-6	N/A	Certain Azo Disperse Dyes	Health and Ecological	
69472-19-1	C.I. Disperse Orange 33	Certain Azo Disperse Dyes	Ecological	
70210-08-1	C.I. Disperse Red 151	Certain Azo Disperse Dyes	Health	
83249-52-9	C.I. Disperse Yellow 241	Not Assessed	Ecological	
93805-00-6	N/A	Challenge Batch 6	Health	

^a Also considered as an azo disperse dye with ecological effects of concern

^b Substance releases toluidine, a prohibited ingredient on the Cosmetic Ingredient Hotlist

^c Substance releases aniline, a prohibited ingredient on the Cosmetic Ingredient Hotlist

^d None of the colours listed in this table have approved uses as food additives in Canada

^e Sudan I may be considered a subsidiary dye of Sunset Yellow (E110) if found at very low levels (2011 email from the Food Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced)

^f This substance has been identified to be harmful to the environment at current levels of exposure and has been found to meet the criteria under section 64 of CEPA. More information on the risk management approach for Disperse Yellow 3 can be found on the Government of Canada's Chemical Substances website

Appendix II: Aromatic azo and benzidine-based substances to which the SNAc provisions have been applied

CAS RN	Substance name	Assessed under CMP initiative	Assessment link or anticipated publication	Publication/Anticipated date of SNAc rescission	Rescission order link
Diarylide Yellow Pigments					
78952-70-2	CPAOBP	Diarylide Yellow Pigments	Canada 2014a	Dec.17, 2014	CGII, Vol.148, No.26 (CGII 2014)
29398-96-7	Pigment Brown 22	Challenge Batch 7	Not reassessed	No rescissions	No rescissions
Benzidine-based Dyes and Related Substances					
1871-22-3	TDBD	Certain Benzidine-based Dyes and Related Substances	Canada 2014b	Mar. 11, 2015	CGII, Vol.149, No.5 (CGII 2015)
1937-37-7	Direct Black 38	Challenge Batch 6/Certain Benzidine-based Dyes and Related Substances	Canada 2014b	No rescissions	No rescissions
3701-40-4	Acid Red 99	Certain Benzidine-based Dyes and Related Substances	Canada 2014b	No rescissions	No rescissions
6420-06-0	Direct Violet 28	Certain Benzidine-based Dyes and Related Substances	Canada 2014b	No rescissions	No rescissions
68400-36-2	NAAHD	Certain Benzidine-based Dyes and Related Substances	Canada 2014b	No rescissions	No rescissions
Azo Solvent Dyes					
1229-55-6	Solvent Red 1	Challenge Batch 6/ Certain Azo Solvent Dyes	Canada 2016b	No rescissions	No rescissions
2653-64-7	Solvent Red 4	Certain Azo Solvent Dyes	Canada 2016b	October 19, 2016	CGII, Vol.150, No.21
3118-97-6	Sudan II	Challenge Batch 6/ Certain Azo Solvent Dyes	Canada 2016b	No rescissions	No rescissions
6368-72-5	Solvent Red 19	Certain Azo Solvent Dyes	Canada 2016b	No rescissions	No rescissions
6407-78-9	Solvent Yellow 18	Challenge Batch 7/ Certain Azo Solvent Dyes	Canada 2016b	October 19, 2016	CGII, Vol.150, No.21

CAS RN	Substance name	Assessed under CMP initiative	Assessment link or anticipated publication	Publication/Anticipated date of SNAc rescission	Rescission order link
6535-42-8	Solvent Red 3	Challenge Batch 6/ Certain Azo Solvent Dyes	Canada 2016b	October 19, 2016	CGII, Vol.150, No.21
73528-78-6	-	Certain Azo Solvent Dyes	Canada 2016b	October 19, 2016	CGII, Vol.150, No.21
85392-21-8	-	Certain Azo Solvent Dyes	Canada 2016b	October 19, 2016	CGII, Vol.150, No.21
Monoazo Pigments					
2425-85-6	Pigment Red 3	Challenge Batch 3/ Certain Monoazo Pigments	Canada 2016c	No rescissions	No rescissions
6407-74-5	Pigment Yellow 60	Certain Monoazo Pigments	Canada 2016c	October 19, 2016	CGII, Vol.150, No.21
74336-60-0	Pigment Red 251	Certain Monoazo Pigments	Canada 2016c	October 19, 2016	CGII, Vol.150, No.21
85005-63-6	NANPAP	Certain Monoazo Pigments	Canada 2016c	October 19, 2016	CGII, Vol.150, No.21
94199-57-2	NAPNPA	Certain Monoazo Pigments	Canada 2016c	October 19, 2016	CGII, Vol.150, No.21
Azo Disperse Dyes					
2537-62-4	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
6232-56-0	Disperse Orange 5	Challenge Batch 5/ Certain Azo Disperse Dyes	TBD	TBD	TBD
6250-23-3	Disperse Yellow 23	Challenge Batch 6/ Certain Azo Disperse Dyes	TBD	No rescissions	No rescissions
6253-10-7	Disperse Orange 13	Challenge Batch 6/ Certain Azo Disperse Dyes	TBD	No rescissions	No rescissions
6300-37-4	Disperse Yellow 7	Challenge Batch 6/ Certain Azo Disperse Dyes	TBD	No rescissions	No rescissions
6465-02-7	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
15958-27-7	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
19745-44-9	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
21811-64-3	Disperse Yellow 68	Challenge Batch 6/ Certain Azo Disperse Dyes	TBD	No rescissions	No rescissions

CAS RN	Substance name	Assessed under CMP initiative	Assessment link or anticipated publication	Publication/Anticipated date of SNAc rescission	Rescission order link
24610-00-2	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
25150-28-1	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
28824-41-1	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
31030-27-0	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
33979-43-0	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
41362-82-7	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
42852-92-6	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
55252-53-4	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
56532-53-7	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
61799-13-1	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
63133-84-6	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
63134-15-6	Disperse Red 338	Certain Azo Disperse Dyes	TBD	TBD	TBD
63833-78-3	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
68214-66-4	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
68516-64-3	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
68877-63-4	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
70210-08-1	Disperse Red 151	Certain Azo Disperse Dyes		No rescissions	No rescissions
70660-55-8	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
72828-63-8	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
72828-64-9	Disperse Blue 287	Certain Azo Disperse Dyes	TBD	TBD	TBD
73003-64-2	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
73398-96-6	Disperse Brown 21	Certain Azo Disperse Dyes	TBD	TBD	TBD
79542-46-4	Disperse Red 349	Certain Azo Disperse Dyes	TBD	TBD	TBD

CAS RN	Substance name	Assessed under CMP initiative	Assessment link or anticipated publication	Publication/Anticipated date of SNAc rescission	Rescission order link
83249-47-2	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
83249-49-4	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
83249-53-0	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
83249-54-1	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
90729-40-1	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
93805-00-6	-	Challenge Batch 6/ Certain Azo Disperse Dyes	TBD	No rescissions	No rescissions
127126-02-7	-	Certain Azo Disperse Dyes	TBD	TBD	TBD
Azo Acid Dyes					
71720-89-3	-	Certain Azo Acid Dyes including Amaranth	Canada 2016d	October 19, 2016	CGII, Vol.150, No.21
83027-51-4	-	Certain Azo Acid Dyes including Amaranth	Canada 2016d	October 19, 2016	CGII, Vol.150, No.21
83027-52-5	-	Certain Azo Acid Dyes including Amaranth	Canada 2016d	October 19, 2016	CGII, Vol.150, No.21
90218-20-5	-	Certain Azo Acid Dyes including Amaranth	Canada 2016d	October 19, 2016	CGII, Vol.150, No.21
90459-02-2	-	Certain Azo Acid Dyes including Amaranth	Canada 2016d	October 19, 2016	CGII, Vol.150, No.21
114910-04-2	-	Certain Azo Acid Dyes including Amaranth	Canada 2016d	October 19, 2016	CGII, Vol.150, No.21
Azo Metal Complexes					
63281-10-7	-	145 PBiT	Not reassessed	No rescissions	No rescissions
Azo Basic Dyes					
59709-10-3	-	Certain Azo Basic Dyes	Canada 2016e	October 19, 2016	CGII, Vol.150, No.21