



ENVIRONMENT AND CLIMATE CHANGE CANADA
FEBRUARY 2019

Official title: Summary of public comments received on the consultation document on the options for addressing certain aromatic azo and benzidine-based substances with effects of concern and the risk management approach for Disperse Yellow 3

The Final Screening Assessment Report of the Aromatic Azo and Benzidine-based Substance Grouping Certain Azo Disperse Dyes, (FSAR) published in March, 2017 concluded that Disperse Yellow 3 (DY3) (CAS RN 2832-40-8) is toxic under section 64 (a) of the Canadian Environmental Protection Act, 1999 (CEPA, 1999) 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. Also identified as having potential ecological effects of concern are 25 other azo disperse dyes, including eight azo disperse dyes evaluated in the screening assessment and an additional 17 azo disperse dyes with molar weights below 360 g/mol.

Given that the current reported uses of DY3 are likely to be phased out in the short term, the pollution prevention (P2) planning notice proposed in the <u>risk management approach</u> (March 2017) is no longer considered as the optimal option since the preparation and implementation of P2 plans are done over many years. Also, the <u>consultation document on the options for addressing certain aromatic azo and benzidine-based substances with effects of concern (March 2017) indicated that the significant new activity (SNAc) provisions may be proposed on the 25 other azo dyes with molar weights below 360 g/mol with ecological effects of concern. Therefore, release guidelines were selected as the optimal risk management instrument to address the toxicity of DY3 and the environmental concerns of the 25 other azo disperse dyes.</u>

Public consultations

Public consultations were held in July 2018 to inform stakeholders on the release guidelines to risk manage releases to the aquatic environment of DY3 and the 25 other azo dyes. This consultation was followed by a public comment period that ended August 30, 2018. No comments were received by the Government of Canada.

The following is a summary of the comments submitted on the consultation document for the options to address certain aromatic azo and benzidine-based substances with effects of concern and the risk management approach for Disperse Yellow 3 provided by:

- Canadian Consumer Specialty Products Association
- Canadian Paint and Coatings Association
- Aqualite Chemical Inc
- Dominion Colour Corporation

- Tri Tex co Inc.
- Ecological Toxicological Association of Dyes and Organic Pigments Manufacturers and
- a private citizen..

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

General Comments	3
International jurisdictions, information and data updates	5
Clear Language and Context	6
Significant new activity (SNAc) proposals	8
Burden on the Industry	11
Voluntary Agreements for Substances of Concern	12
Risk Management	12

Topic	Comment	Response
General Comments	The Aromatic and Azo - Benzidine based substances do not apply to the activities of his company and therefore he has no obligations to respond.	Noted
	Instead of less stringent regulations and protections from the public, CEPA should be eliminating cancer-causing substances from consumer products and from their potential releases into the environment.	The Government of Canada has and continues to develop stringent measures and regulations based on sound scientific evidence. Furthermore, once a risk has been identified, the Government's objective is to eliminate, reduce, control or prevent the risk to environment and/or human health by preventing it at the source. Throughout the process of developing and implementing risk management instruments, which includes data collection, emphasis is placed on consulting, informing and receiving feedback from a broad range of stakeholders including the general public. With regards to the 105 Aromatic Azo and Benzidine – based substances which have been assessed under CEPA 1999, only one of the substances known as Disperse Yellow 3 (DY3) poses a risk to the Canadian environment as it has been declared as toxic while others were identified as having potential ecological effects of concern. Given that the current reported uses of DY3 are likely to be

	phased out in the short term, the Government is currently developing a Release Guideline (RG) to address the risks associated with these azo disperse dyes although these substances will no longer be in use on the market.

International
jurisdictions,
information and data
updates

Recommendation was made that international activities should be continuously monitored such as product recalls and other related issues and to leverage this information.

The Chemicals Management Plan (CMP) assessments primarily focus on the general Canadian public; however as many textile products are imported from international sources, the screening assessment and associated studies include International Risk Management context related to substances under assessment.

For instance, risk management measures implemented in other jurisdictions (US EPA, EU, Australia, etc.) are detailed in Section 7.2 of the RMA and Section 4.2 of the Consultation Document and provide an indication of how the textile sector has been regulated globally in the context of DY3.

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)

Clear Language and Context

Certain terms such as hypothetical future "risks" must be put into better context. It is clear that any substance could pose increased risks due to potential increased levels in the future. What is relevant is whether it is an acceptable or unacceptable risk based on the criteria set out under Section 64 of CEPA.

The FSAR published on March, 2017 clearly outlines the risks related by the use of DY3 and other azo disperse dyes. The RMA for DY3 and the Consultation document published in March 2017, proposed risk management actions to prevent the risks posed by DY3 and other azo dyes in the textile sector. While DY3 was concluded to be toxic, exposure to environment from the other 25 azo substances with ecological effects of concern is currently not expected or is low as they were not found to be in commerce in Canada. These substances 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.

Additionally, it is important to note that DY3 is the only substance out of all the substances evaluated in this assessment that was found to be toxic under Section 64 of CEPA and reported as being in commerce in Canada according to the Section 71 survey; therefore, Government of Canada is developing a specific instrument (The Release Guidelines) to mitigate the risks associated with DY3 and potentially with 25 other azo disperse dyes identified with environmental concerns.

Suggestion to use effective language when discussing on options to risk manage chemical substances.

There is a risk of misinterpretation by the implicated parties of the proposed risk management options. Specifically, the statement "to limit the sale of products" could be misinterpreted as a ban on substances, whereas the real intent is to continue the uses of the products.

Following the declaration of substance toxicity, the government considers different options throughout an Instrument Choice Framework to best manage the risk associated to a substance.

Section 5.1.1 of the *Consultation Document* proposed a voluntary agreement to "limit the sale of product available to consumer that may contain or release these substances" as an option to risk manage these substances. It should be noted that the intend of this option was not to ban these substances. The above statement clearly demonstrated that it was only an option and not a considered action. Moreover, the release guidelines were chosen as the best instrument to risk manage these substances and their intent is to limit the releases of DY3 and the 25 other azo disperse dyes with molar weights below 360 g/mol to the environment via manufacturing and importing of this substance.

SNAc Proposals	Request that stakeholders are given the opportunity to comment on Significant New Activity (SNAc) proposals to help ensure they	Please note that SNAcs are no longer being considered as an option to risk manage DY3 and the 25 other azo disperse dyes in the textile sector.
	are most effective.	disperse dyes in the textile sector.
		Environment and Climate Change Canada (ECCC) has set high standards for openness and transparency for stakeholder consultations that meet the requirements of the cabinet directives on regulations. Stakeholder engagement is an ongoing part of the CMP and begins with data gathering stage through development of risk management measures or refining/developing risk management proposals and instruments, which includes SNAc proposals
		The public consultation is an example of stakeholder engagement where their comments and concerns are
		considered in the development of the risk management instrument.

Concerns that mandatory reporting or SNAc provisions would impose a stigma on the 104 substances that were flagged as potentially being a concern to the environment or human health. Though mandatory reporting tools can result in more information as opposed to voluntary action, it could impose stigma onto these substances that have not been concluded as CEPA toxic.

The SNAc is a CEPA 1999 prevention approach that would allow the Government to be aware of potential re-introduction of DY3 (manufacture, import and use) and would help identify the need for further Risk Management.

Moreover, as the SNAc ensures that no new substance is introduced into the Canadian market place before an assessment of its toxicity has been completed, therefore the Government of Canada will be aware of any potential introduction of the other azo dyes with environmental concerns into the Canadian market. Note that the proposed RG for DY3 and 25 other azo disperse dyes in the textile sector is a voluntary instrument which covers the re-introduction of DY3 and the other azo dyes into the Canadian market.

Stakeholders caution that inclusion of "CMP-assessed substances in IU and NPRI exercises could create large administrative burdens. Instead of continuously being asked to do surveys about uses of substances, they "prefer that inappropriate uses be clearly flagged *via* the SNAc process".

SNAcs can not capture existing activities. Furthermore, this instrument would only ask for information that can't be accessed through other means and that is directly linked to assessing instrument effectiveness.

Burden incurred only when company plans to begin new activity as defined in the notice or order - need to submit a Significant New Activity Notification.

SNAcs cannot be easily modified or removed, The Government of Canada would not declare toxic a and the modifications or removals are not substance that is not manufactured or in commerce easy to track by the industry. We believe into the Canadian market. Therefore, SNAcs ensure SNAcs are mostly used and should be mostly that no new substance is introduced into the Canadian used for substances declared toxic market place before an assessment of its toxicity has been completed. Stakeholders' preference of the application of SNAc ensures that no new substance is introduced SNAc provisions which control potential reinto the Canadian market place before an assessment introduction of the azo disperse dyes of its toxicity has been completed, therefore the (manufacture, import and use) not currently Government of Canada will be aware of any potential in commerce in Canada, and apply to introduction of the other azo dyes with environmental companies responsible for the increased concerns into the Canadian market. commercial status. It is important to note that the proposed RG for DY3 and 25 other azo disperse dyes in the textile sector covers the re-introduction of the others azo dyes with environmental concerns into the Canadian market.

These guidelines are a voluntary instrument which requires informing the Minister of the Environment six months prior to the initial use of DY3 and any of the 25 other azo disperse dyes with environmental concerns.

	Stakeholders emphasized the importance for	The Government is working with associations and
Burden on the Industry	the government not to place excessive burden	stakeholders to solicit data and information in a less
	on the industry in setting up monitoring	burdensome manner thereby develop risk
	activities for the 105 Azo and Benzidine -	management instruments where required. Taking into
	derived substances.	consideration the use of this substance, a voluntary
		risk management approach, the RG, has been
		proposed as opposed to more burdensome mandatory
		approaches.
		The RG is a voluntary instrument, it is flexible in terms
		of implementation, and therefore it is expected that
		industry will prefer this approach.

Voluntary Agreements for Substances of Concern	Voluntary agreements with respect to reporting or monitoring should be the choice of instrument for the Government of Canada as opposed to mandatory reporting or SNAc provisions. Voluntary agreements are effective in imposing compliance and observation, flexible (in their format and implementation time), less burdensome, negotiable and can lead to clearer objectives. The voluntary agreements can also prevent increased uses of the substances in the future, and can be readily accessible to Government upon request and at any time. Another advantage of voluntary agreements when tailored to specific companies or sectors, is that they can yield timely information but can also provide the Government the option to negotiate codes of practices to further reduce/ensure the status quo.	Given that the current reported uses of DY3 are likely to be phased out in the short term, ECCC proposes to manage the risk of DY3 and the 25 other azo disperse dyes through the release guidelines. Release guidelines are voluntary RM instrument, which would recommend quantitative release limits for DY3. However, this instrument could also be used to manage toxic or high hazard chemicals released from textile or dyeing operations in the future. Therefore, this instrument is optimal in comparison to regulations, which is not necessary in the current situation (substance use). Moreover, the release guidelines are flexible in terms of implementation, and therefore it is expected that industry will prefer this approach as it is less burdensome.
Risk Management	Should risk management measures be implemented, the thresholds should reflect the hazard potential of the substances to the environment/or human life.	Section 5 of the proposed RG provides the recommended thresholds, expressed as concentrations or quantities for the releases of DY3 and the 25 other azo dyes into the environment from textile chemical formulations and textile dyeing activities.

The environmental risks predicted for DY3 are overstated because it has low water solubility (less than 0.1mg/l), therefore it is unlikely to cause adverse effects to aquatic organisms and therefore does not warrant risk management.

The FSAR for Certain Azo Disperse Dyes concludes that DY3 is toxic and meets the criteria under section 64 (a) of CEPA. Despite, its low water solubility, DY3 may persist in water, soil and sediment. Therefore, precautionary risk management measures must be taken since DY3 is identified to be in commerce in Canada. The FSAR also states that Azo Disperse dyes with molar weights below 360g/mol have demonstrated higher levels of toxicity to aquatic organisms, most likely due to their increased bioavailability and therefore are substances with ecological effects of concern.