Summary of Public Comments received on the Draft Screening Assessment for Certain Azo Acid Dyes

Comments on the draft screening assessment report (dSAR) for Certain Azo Acid Dyes to be addressed as part of the Aromatic Azo and Benzidine-based Substance Grouping were provided by the Canadian Vehicle Manufacturers' Association, the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers and the Learning Disabilities Association of Canada (LDAC). The comments from LDAC were submitted as part of comments on the Certain Aromatic Amines dSAR, but they are also relevant to the substances in this dSAR and are therefore addressed below.

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

TOPIC	COMMENT	RESPONSE
Vulnerable Populations	Infants and children may be more sensitive to food dyes.	The screening assessment is based on consideration of the available data and includes various conservative exposure scenarios that account for both the general population and for vulnerable populations in Canada. If information is available that suggests a specific sub-population would be particularly vulnerable, it will be considered in the screening assessment. However this is not the case in the screening assessment of azo acid dyes, as supported by developmental, reproductive and metabolic studies on tartrazine and amaranth, which are permitted food colouring agents in Canada and part of this screening assessment.

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Data Gaps	The cumulative effects of azo acid dyes are not assessed.	Comment noted. Unlike substances for which a cumulative risk approach based on a common mechanism of toxicity has been undertaken, there is no data (to Health Canada's knowledge), which indicate that all azo acid dyes share a common mechanism of action. In addition, based on the information available, it does not appear that these azo acid dyes result in a common toxic metabolite. Consequently, a cumulative risk assessment would not be appropriate for the 52 substances that fall within the scope of this screening assessment. Furthermore, for many of the azo acid dyes, the use pattern is such that there is neither indication of use in Canada nor evidence of exposure; thus, from a Health Canada and Universal Health Risk perspective, exposure to these substances equates to no risk. With respect to exposure from foods, because the food additive provisions for the use of amaranth and tartrazine permit their use "singly or in combination" according to the *List of Permitted Colouring Agents*, and because the separate exposure estimates for the two substances were conservative in nature, the total estimated exposure to the substances is not expected to exceed the exposure estimates presented in the screening assessment.

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Risk Characterization	Three dyes: Red 40, Yellow 5 and Yellow 6 make up about 90% of all food dyes used. However, one of these, Yellow 6 (Sunset Yellow), does not appear in the groupings, because it does not appear to have met the Domestic Substances List categorization criteria. Yellow 6 should have been included on the basis of direct exposure potential: five million pounds of this dye is used in the United States.	The screening assessment of Certain Azo Acid Dyes includes substances identified as priorities for assessment through the categorization process and were grouped as Certain Azo Acid Dyes based on the subgrouping approach in this initiative and the Colour Index classification. Yellow 6 (Sunset Yellow) did not meet the human health and environmental categorization criteria, and therefore it was not considered a priority for a screening assessment under the *Canadian Environmental Protection Act, 1999* (CEPA). In Canada, food uses of Yellow 6 are regulated under the Food and Drugs Act (through *The List of Permitted Colouring Agents* and Division 6 of the *Food and Drug Regulations*. Although not all permitted azo acid dyes found in the *List of Permitted Colouring Agents* were assessed in the CEPA Groupings Initiative, as with all food additives, should information become available on these food colouring agents that would call into question the safety of these additives, Health Canada would take steps to re-evaluate the safety and appropriately manage the addition of those additives to foods. These actions may include restriction of the permitted conditions of use, or the delisting of the additive.
Risk Assessment	The health effects considered should not be limited to cancer health end points.	Health effects considered were not limited to cancer health end points. Repeat-dose studies of different durations, reproductive and developmental studies, and other relevant studies were considered in the screening assessment.
	The assessment conclusion for the 52 azo acid dyes is supported, particularly the conclusion that these dyes are not released to the environment in amounts that pose a danger to human or ecosystem health, and that they are not expected to bioaccumulate.	Noted.

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Opportunities for Consultation	Industry supports the consideration of options to monitor changes in the use profiles of substances that are focused on consumer uses rather than on industry uses.	Noted.
	Industry would like to remain engaged in any additional potential work or actions for the azo acid dyes, particularly options for identifying and managing future risks related to changes in use and exposure.	Stakeholders are encouraged to participate and provide feedback at all stages of the Chemicals Management Plan (CMP) process. A consultation document on potential options for information gathering or preventative actions will be available for stakeholder feedback after assessment of all substances in the Aromatic Azo and Benzidine-based Substance Grouping are completed. Technical expertise is always welcome from stakeholders including academia, industry, consulting firms, other government jurisdictions or nongovernment organizations.
	The labeling of food dyes should be improved.	The majority of pre-packaged foods sold in Canada already are required to carry a list of ingredients, including food additives on the label. Food colours, which are regulated as food additives under the *Food and Drugs Act* must also be declared on the label, but can be listed either by their common name or by the term “colour”. After a science review of the potential adverse effects associated with the use of particular food colours on the Canadian population and a series of public consultations, Health Canada has concluded that improved colour labelling requirements are warranted. A regulatory proposal that would require food colours to be identified individually by common name was published in the *Canada Gazette* on June 13, 2015. Such mandatory labelling of individual colours is consistent with the current food additive requirements in the Food and Drug Regulations, and it would harmonize Canadian requirements with international standards. Health Canada’s Food Directorate has confirmed that the Canadian Food Inspection Agency supports the proposal.

TOPIC	COMMENT	RESPONSE
Overarching Comment	Stakeholder information sharing was positive throughout the CMP evaluation process for the Aromatic Azo and Benzidine-based Substance Grouping.	Noted.