Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Reports on C.I. Pigment Yellow 34 (CAS RN 1344-37-2) and C.I. Pigment Red 104 (12656-85-8)

Formal comments made during the 60-day public comment period that took place from May 17, 2008 to July 16, 2008 on the draft screening level assessment reports on C.I. Pigment Yellow 34 and C.I. Pigment Red 104, two substances included in Batch 2 of substances to be addressed as part of the Chemical Management Plan Challenge under the Canadian Environmental Protection Act 1999 (CEPA 1999), were provided by the Canadian Environmental Law Association and Chemical Sensitivities Manitoba, and the Color Pigments Manufacturers Association, Inc..

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

- Human exposure
- Validity of evidence
- Weight of evidence and precautionary principle
- Effects on wildlife
- Persistence and bioaccumulation
- Releases to the environment
- Data collection
- Substitution and Alternatives
- Regulations

Topic	Comment	Response
Human exposure	More information should be provided in the screening assessment with regards to the precise use-pattern of silica encapsulated pigments.	Since silica encapsulation of pigments increases their heat stability and chemical resistance in plastics, they would likely be used in plastic processing requiring high temperatures. As noted in the screening assessment, these pigments, silica encapsulated or otherwise, are not used for the manufacture of products for use by the general population.
	There were data gaps in the screening assessment for the sub-populations of hobbyists, workers, and their families. The amount of pigment used in hobbies should be investigated. Industry should be required to submit data on occupational exposure.	With regards to hobbyists, the screening assessment indicates that the use of artists' paints that contain these pigments or activities such as automotive restoration and repair of vehicles painted with these pigments could lead to increased exposure. However, information is not available to further quantify these exposures. The *Surface Coating Materials Regulations* under the *Hazardous Products Act* (Canada 2005) limit the total lead concentration to not more than

		600mg/kg when a dried sample is tested. This requirement does not apply to the above situations (touch-up paints for metal surfaces or materials used in arts, crafts or hobbies, unless it is for children). Those types of products may exceed the 600 mg/kg lead limit but must display a specified warning on the product label. In terms of residents in close proximity to industrial facilities manufacturing or using these pigments, since theses pigments have negligible vapour pressure, any industrial releases would be in the form of particulates which would be expected to settle before significant transport had occurred. Extremely conservative estimates of exposure through ambient air predicted a low concentration of 0.36 µg/m3. The information gathered through the Challenge may be used as the basis for additional actions to minimize exposure of workers through the appropriate federal and/or provincial statutes. Information was not available regarding the possibility of transfer of these pigments to workers homes.
	Although the *Hazardous Products Act* outlines specific restrictions on lead levels in products, a commenter expressed concerns regarding misuse of the pigment products in Canada, which may result in consumer exposure to the lead chromate pigments. The commenter stated that is unclear as to whether end products such as playground equipment are painted with industrial paints or at what level people with hobbies may be exposed to these substances.	As mentioned in the screening assessment, the *Surface Coating Materials Regulations* limit the total lead concentration in surface coatings materials to not more than 600 mg/kg when a dry sample is tested. This limit does not apply to surface coating materials for the purposes of arts, crafts or hobbies for adults and for other defined uses outlined in the screening assessment. However, in the instances where the total lead concentration exceeds 600 mg/kg for these purposes, a specified lead-content warning must appear on the label of the surface coating container which includes the statement "Do not apply to surfaces accessible to children or pregnant women". Although the *Surface Coating Materials Regulations* do not apply to

		the use of surface coating materials on playground structures, the Canadian Standards Association has published a voluntary standard entitled "*Z614-07 Children's playspaces and equipment*". Some provinces and/or school boards mandate that the requirements of this standard be met for playground structures. This standard requires that all paints or other similar finishes be non-toxic and that non-lead-based paints be used in all new equipment and when repainting existing equipment to eliminate the risk of childhood lead poisoning from playground equipment. Items 2, 9 and 18 of Schedule I, Part I to the *Hazardous Products Act* prohibit furniture and other articles for children, toys, equipment and other products for use by a child in learning or play and pencils and artists' brushes that have had a surface coating material applied to them that contains more than 600 mg/kg of total lead.
Validity of evidence	The screening assessment does not provide experimental data to support the following claims: 1. That both pigments have low water solubility but there will be dissolution and dissociation of the pigments into the moieties – Pb^{2+} and CrO_4^{2-} with the lead sulphate portion having greater solubility than the lead chromate portion. 2. Encapsulation with amorphorous silica will further decrease the solubility of these pigments therefore reducing the bioavailability of the moieties in water, sediments and soil.	The screening assessments contains data that support these two claims: 1. The experimental solubilities of both pigments and their constituents are available in Table 2. 2. Although experimental data regarding the solubility of silica encapsulated pigments are not available, information indicative of reduced bioavailability of silica encapsulated pigments is available from experimental animal data cited in the screening assessment (Clapp et al. 1991; Pier et al. 1991). This information coupled with professional judgement lead to the statement that encapsulation with amorphorous silica will further decrease the solubility of these pigments. It should be noted that the ecological assessment of effects to aquatic

		organisms considered the acute effects to aquatic organisms due to the presence of both metals in solutions assumed saturated.
	These pigments have not been shown to be carcinogenic or genotoxic in studies specific to lead chromate pigments. As well, they were aware of no credible experimental data developed using actual lead chromate pigments in the form sold in commerce which substantiates this claim. Nor is any such data cited in the screening assessment.	It is acknowledged that the database specific to these two pigments is limited. However, as presented in the screening assessment, data specific to the pigments included cytogenicity in mammalian cells and, when solubilized, induction of gene mutation in bacteria. In addition, lead chromate pigment induced tumours were observed in the experimental animals exposed via subcutaneous administration. Bronchial squamous metaplasia and dysplasia were observed in experimental animals after bronchial implantation of lead chromate pigments. As well, increased lung cancer risk was observed among workers involved in chromate pigment production.
	The results of subcutaneous and intramuscular induced carcinogenesis in experimental animals and the results of in vitro and in vivo genotoxicity studies are not relevant to human health and are inappropriate to form the basis of carcinogen classification of the two pigments.	The results from animal studies via parenteral administration and in vitro testing, although not exposure routes directly relevant to human exposure, provides insight into the carcinogenic and genotoxic potential of the pigments.
	Three epidemiological investigations (Davies et al. 1979, 1984; Cooper et al. (EEH) 1983; Kano et al. 1993) indicated that lead chromate pigment production did not show an increased risk of carcinogenicity.	Although no significantly increased risk of lung cancer incidence were observed in some of the epidemiological investigations (Davies et al. 1979, 1984; Cooper et al. (EEH) 1983) conducted in the lead chromate pigment production plants, the authors speculated that the numbers of observed and expected deaths were too small in these studies for definitive conclusions. In the Kano et al. study (1993), the authors speculate that exposures may have been reduced due to improved workplace hygiene practices, thereby reducing lung cancer risk among the workers in the production of various chromate pigments, including lead chromate, zinc chromate and strontium chromate pigments. The exposure levels in the Kano et al (1993)

		study were not quantified. The description of these studies has been refined in the screening assessment and noted in the uncertainties.
	The government has placed excessive reliance on in vitro studies (for genotoxicity), which are not relevant to human exposure to C.I. Pigment Yellow 34 and C.I. Pigment Red 104. Their concern focused particularly on the dissolved nature or test particle size of the substances used in the studies as they were of the opinion the test substances would not be relevant surrogates for the actual pigments moving through commerce.	The results from in vitro genotoxicity testing, although not exposure routes directly relevant to human exposure, provides insight into the genotoxic potential of the pigments. Although limited data were available for the pigments themselves, positive results were obtained in *in vitro* assays, even in cases where strong dissolution methods were not used (i.e. Levis and Majone 1981, Venier et al. 1985). As well, in the Nestmann and Zhang 2007 study, a small increase in chromosomal aberrations was also observed although the results were not statistically significant.
	Cumulative or additive effects of lead and chromium along with other carcinogenic substances should be considered in the screening assessment.	The ecological assessments of effects to aquatic organisms are based on experimental toxicity data for Pigment Yellow 34; therefore, they already consider the potential for acute effects to aquatic organisms due to the measured presence of both metals in solution. A cumulative or additive analysis is beyond the scope of the health screening assessment for the two pigments. For most classes of substances, the available data are insufficient to conduct a cumulative risk assessment.
Weight of evidence and precautionary principle	Comments were received indicating both agreement and disagreement with the draft CEPA 64c conclusions in the screening assessment reports for C.I. Pigment Yellow 34 and C.I. Pigment Red 104. One commenter disagreed with the human health conclusions of the screening	As stated in the screening assessment, Health Canada agrees that inhalation exposure to the general population is negligible. With respect to carcinogenicity, consistent with the Ministers' Notice of Intent (December 9, 2006), Health Canada considers that evidence of carcinogenicity (i.e., classification by one or more international/national agencies), in the absence of a fully elucidated

	assessment based on the assumption that the pigments are inhaled carcinogens, which is not a relevant route of exposure to the general population.	mode of action analysis, is sufficient to propose a conclusion that there is a probability of harm at any level of exposure and that the criterion in paragraph 64c of CEPA 1999 is met. The application of a precautionary approach is required under CEPA 1999. Information regarding the assessment of non-threshold toxicants under the Existing Substances Program is available at http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/approach/index_e.html
	The Government of Canada has inappropriately relied on the weight of evidence based classification of C.I. Pigment Yellow 34 and C. I. Pigment Red 104 by the European Commission and other international agencies, which is not specific to, or appropriate for, an analysis of these two specific pigments.	The screening assessments for human health are prepared in light of the stated intents of the Challenge, to conduct screening assessments of high priority substances. For these high priorities it is considered appropriate to base information on health hazards principally on weight of evidence based assessments by other agencies. The European Commission classifications were specifically for C.I. Pigment Yellow 34 and C.I. Pigment Red 104. As well, Health Canada's Priority Substances List assessment on chromium, included consideration of some of the toxicological information on lead chromate and its derived pigments in its evaluation of chromium. The PSL assessment concluded that chromium VI compounds, as a whole, were carcinogenic to humans.
Effects on wildlife	Water is the most likely candidate for contamination from application and post application releases but they were not quantified. The commenter also stated that no estimate data were provided to assess impacts to aquatic wildlife species or the quality of water from sewer systems.	A reasonable worst-case exposure scenario for the receiving water bodies and the aquatic organisms showed that the substances were not found to cause acute aquatic ecotoxic effects. It is also unlikely that terrestrial wildlife or other organisms living in other compartments (e.g. soils/sediments) would be harmed by exposure to this substance or by contaminated food considering the low solubility of these pigments. A quantitative estimation of risks, including the calculation of exposure concentrations and risk quotients was thus not warranted

		considering the properties of these pigments (particularly their low solubility). Furthermore, the particles containing these pigments may be removed during sewage treatment. The low solubility of the pigments would prevent dissolution of the pigments, leading to extremely low concentrations of dissolved metals from this source.
Persistence and bioaccumulation	Government assessors should develop an appropriate testing protocol to determine the bioaccumulation factor for these substances.	At the moment, the current state of scientific understanding on bioaccumulation potential for metal-containing inorganic substances is limited. Interpretation of the significance of various measures of bioaccumulation (e.g., BCFs, BAFs) for metal-containing inorganic substances is complicated (e.g. presence as micronutrients, or detoxified forms). Research is ongoing to develop methodologies for BCF and BAF measurements and unambiguous interpretation for non-essential and sparingly essential metals. Additionally, to be bioaccumulated or to cause ecotoxicity, the substance and/or an ion released from the substance must be taken up by the organism – that is, they are to be bioavailable. However, the pigments have a low bioavailability (mainly because of a very low solubility), and therefore would also be unlikely to bioaccumulate significantly.
Releases to the environment	The screening assessment appears to contain a contradiction regarding estimated releases and losses of C.I. Pigment Yellow 34 as compared to C.I. Pigment Red 104, which have almost identical manufacture and use. The screening assessment states that the distribution to water is 35.3 % for C.I. Pigment Yellow 34 and 7.9% for Pigment Red 104. Distribution to waste disposal is stated as 62.7% for C.I. Pigment Yellow	The higher proportion of releases of C.I. Pigment Yellow 34 to water (35.3%) compared to C.I. Pigment Red 104 (7.9%) is mainly due to a higher use proportion of C.I. Pigment Yellow 34 for activities having higher post-application or service life releases. The higher proportion of C.I. Pigment Yellow 34 lost to water compared to C.I. Pigment Red 104 also explains principally the difference in the proportion sent to waste disposal.

	34 and 87.9% for C.I. Pigment Red 104.	
	Recorded releases and assumed low quantities of the pigments are insufficient evidence to conclude that all requirements for being CEPA toxic are not met. Releases from landfills and incinerators should not be assumed to be zero and the level of leaching to groundwater or surrounding soil should be critical to the assessment because the substances remain in these locations for a very long time. Incineration may enhance the problems since the by-products (i.e. dioxins, other heavy metals, particulate matter) may have impacts on health or environment and are not considered in the assessment reports.	In the context of the mass flow tool, releases from waste management sites were not considered in the calculations because they are difficult to estimate and are expected to be small. In the case of landfills, considering the properties of the substances (low vapour pressure, low solubility, moderate to very high partition coefficients for the dissolved metals), the presence and the migration of the dissolved metals through soil or leaching to groundwater is expected to be minimal. Additionally, the dissolution of the pigments is further reduced by the incorporation of the substances in products (plastics, paints and coatings). Additionally, it is important here to note that all products sent to waste disposal and incineration are managed through waste management programs at Environment Canada and/or provincial jurisdictions, such as programs to meet the Canada Wide Standards for dioxins and furans.
Data collection	The government should use section 71 of CEPA to fill in data gaps in exposure estimates for these pigments (i.e. leaching rates; incineration activities; scrap metal yards; occupational exposure; hobbies with materials containing these pigments; and exposure to children and other vulnerable populations). As well, the government should further investigate the ability of all grades of silica encapsulation to decrease the potential toxicity of these pigments.	In the Notice of Intent published in Canada Gazette, Part 1, the Government of Canada invited industry and other stakeholders to provide specific information that may be used to inform risk assessment and to develop and benchmark best practices for the risk management and product stewardship of those substances identified as the highest priorities. In addition to the data collected under the section 71 surveys, the screening assessments use the available scientific data from a range of sources including published literature in scientific journals and other international reviews. The Government of Canada has stated that the absence of new information will not preclude the Ministers from issuing a decision

		that safeguards human health and the environment. Thus the process being used for the Challenge substances is not to wait until data gaps are filled, but to act on what we know now.
Substitution and alternatives	The manufacture, use, release and disposal of lead chromate pigments in Canada are regulated through the complete life cycle in Canada. Termination or unnecessary additional restriction on the production of lead chromate pigments would unnecessarily impact a number of high paying manufacturing jobs in Canada. The impact of such restrictions must be analyzed against the gain in safety or environmental protection, which, in the case of lead chromate pigments would be minimal or nonexistent. There are potential alternatives, but not one for one substitutes for lead chromate pigments. The alternative products require tradeoffs in performance characteristics and in formulation with multiple replacement ingredients for final products. When cost is considered there are no substitutes which perform equivalently to C.I. Pigment Yellow 34 or C.I. Pigment Red 104 in most product formulations.	The Government of Canada does not intend to restrict the use of lead chromate pigments for specialized technical purposes for which there are no suitable alternatives.
	To support and achieve the goal of	Alternatives to these pigments are currently being developed and

	elimination, an appropriate regime should include the establishment of a stakeholder task force to identify and assess alternatives to C.I. Pigment Yellow 34 and C.I. Pigment Red 104 for all applications. There is an understanding that cost and chemical properties are often issues when alternatives are sought. All pertinent data should be available for alternatives used by industry in order to effectively assess their safety. Where the technology is not available, the encapsulated versions of these pigments could be used – if applicable.	gradually adopted as replacements. However for specialized technical applications the alternatives must meet certain performance standards and criteria which are set by non-governmental agencies such as the ASTM, CSA, and ISO.
	It is noteworthy to mention the increased cancer rates in occupations where these pigments and chemically similar pigments, are used or manufactured. There is the refinish market where sanding has to be done, possibly under less than optimum conditions. Several safe replacements have been readily available for many years. Safe alternatives to these pigments should be identified, assessed and pursued by the government.	The results of Challenge assessments and management actions may have an impact on occupational health practices in the workplace. The practices are often developed and enforced by provincial governments, as well as the federal government where federal labour laws apply. For these reasons, we are exploring how best to inform organizations involved in occupational health/workplace safety of the findings of Challenge assessments and the risk management actions recommended. The Challenge often represents the most up to date assessment of a substance and therefore we intend ensure this information is shared as widely as possible to enable appropriate risk management actions to be taken by these organizations. These risk management actions could include replacement by an alternative where appropriate.
Regulations	C.I. Pigment Yellow 34 should be added to CEPA Schedule 1 (Toxic Substances List). C.I. Pigment Red 104 should be added to CEPA Schedule 1 (Toxic	Both C.I. Pigment Yellow 34 and C.I. Pigment Red 104 will be proposed for addition to CEPA Schedule 1 (Toxic Substances List) as they are considered non-threshold carcinogens.

	Substances List).	
	The federal government should establish an action plan for ultimate elimination of these substances based on carcinogenicity. Clear timelines for reduction targets with ultimate elimination should be established particularly for the non-essential use of these pigments.	There are specialized industrial and military uses for these pigments for which there are yet no suitable alternatives. The predominant current use of these pigments as well as their entry into the environment is due to their use as traffic marking paint. After December 31, 2010 this use will no longer be permitted. As a result of this use pattern change we can expect a reduced potential human exposure to these substances.
	Although a commenter disagreed with the need for future controls on new uses of lead chromate pigments, he strongly supported a system in which existing uses would be described in the regulation and new uses would be those which are not included in the description.	The details of the future notification process have yet to be established.