Summary of Public Comments received on the Challenge substance Vanadium pentoxide (CAS 1314-62-1) Draft Screening Assessment Report for Batch 9

Comments on the draft screening assessment report for Vanadium pentoxide to be addressed as part of the Chemicals Management Plan Challenge were provided by Vanadium Producers & Reclaimers Association, Inuit Tapiriit Kanatami, Teck Metals Inc. Masterloy Products Co. Nova Scotia Power Inc, Canadian Environmental Law Association and Chemical Sensitivities Manitoba, Forest Products Association of Canada, Dow Chemical Canada and Ecojustice.

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

- New information
- Risk Assessment
- Releases to the Environment
- Risk Management
- Environmental Emergency Regulations

TOPIC	COMMENT	RESPONSE
New information	The mode of carcinogenic action of vanadium pentoxide in mice is not based on DNA reactivity. A study has been provided that attempts to identify characteristics in response that might point towards the mode of action of this compound.	The Government of Canada has incorporated the new information provided into the final screening assessment as part of the overall weight of evidence assessment of the hazards of vanadium pentoxide. The study in female mice provides limited information on the mode of action for vanadium pentoxide in the mouse lung but information is insufficient to support a threshold mode of action for this compound.
	A commenter indicated that, based on their analysis, exposure to the general population is highly unlikely. .	Although exposure to the general population is low, multiple sources of information demonstrate potential for exposure to vanadium pentoxide. The uncertainties in the exposure assessment are documented in the screening assessment.
Risk Assessment	Only studies of vanadium pentoxide should be listed in the section referring to toxicology.	Some modifications to the screening assessment have been made, as appropriate, to address this comment
	While marked differences in the carcinogenic response between rats and mice are apparent, the reasons for this and the relevance of the difference to human exposures have not been determined.	The screening assessment has been updated to provide information on the number of tumours observed at each dose administered to rats and mice . This will illustrate more clearly the difference in the carcinogenic response that exists between the two species. The

	This needs to be discussed in the final screening assessment.	reasons for the differences observed in carcinogenicity between the two species are not clear yet. The final screening assessment will be updated to reflect this.
	The National Toxicology Program (NTP) 2002 Study, on which the International Agency for Research on Cancer (IARC) determination is based, did not show any statistically significant increase in the incidences of lung tumours in either male or female rats at any of the exposure levels studied.	Although not statistically significant biological significance was also taken into consideration; as was the overall evidence for carcinogenicity, when characterizing risk.
	The draft screening assessment document has over-interpreted the "increase" of kidney disease reported in male rats at the 1 mg/m3 exposure level and higher. This was a chronic progressive naturally occurring, degenerative and regenerative disease of rats that begins at about 3 month of age. It is not a toxic response, although it may be exacerbated by exposure to some chemicals, dietary changes or physiological conditions.	The effect was considered to be related to administration of vanadium pentoxide and was therefore documented in the screening assessment. However, It was not considered a critical effect for risk characterization.
	In their "Characterization of Risk to Human Health", the draft screening assessment has inaccurately portrayed the assessment of the European Union as indicating that vanadium pentoxide is a genotoxic carcinogen. The existing regulatory position of this substance within the EU is Mutagen Category 3 and Reproductive toxin Category 3, there being no decision made on carcinogenicity.	Health Canada has reported the existing classification for vanadium pentoxide by the EU (Category 3 for mutagenicity and developmental toxicity) in the screening assessment report (SAR). Health Canada has also reported in the SAR that the European Commission has proposed to classify vanadium pentoxide as Category 2 for carcinogenicity and mutagenicity. Text has been added to ensure that this information is not interpreted as a decision of the European Commission to classify vanadium pentoxide as a genotoxic carcinogen.
	The Health Canada policy dealing with identification of carcinogens has been significantly altered in the Chemical Management Plan. The policy, as applied to vanadium pentoxide is inconsistent with the language of the Canadian Environmental Protection Act.	As required under CEPA 1999, the Government of Canada has applied precaution and weight of evidence in conducting the risk characterization for vanadium pentoxide.
	The available genotoxicity data is frequently	As required under CEPA 1999, the Government of Canada has

	inconsistent and does not provide supportive evidence for the carcinogenicity of vanadium pentoxide through a genotoxic mechanism. As a result the government should consider Section 76.1 of the CEPA, and not make a designation where there is significant divergence in the available studies on vanadium pentoxide.	applied precaution and weight of evidence in conducting the risk characterization for vanadium pentoxide. Available information was insufficient to support a threshold mode of action for this substance.
	Vanadium pentoxide should not have been classified as being of "greatest potential for exposure" to Canadians and thus should not have been assessed under the Challenge.	Vanadium pentoxide was identified as a high priority for assessment of human health risk because it was considered to present GPE (greatest potential for exposure) and had been classified by other agencies on the basis of carcinogenicity, genotoxicity and developmental toxicity. As such, it was a substance assessed under the Ministerial Challenge. More precise characterization of exposure to substances in the Challenge is carried out as part of the assessment activity. The screening assessment includes exposure characterization for the general population, based on multiple sources of information including information submitted pursuant to Section 71 of CEPA 1999.
	Long-term toxicity studies should be conducted in species asides from rats alone as epidemiological studies (human studies) are limited. The dermal data set needs strengthening. The potentially synergistic effects of chemical mixtures need to be examined given that exposures to several chemicals occur simultaneously.	Sufficient information was available to characterize risk. Uncertainties in the health effects information is documented in the screening assessment.
	Several data gaps in the draft assessment require attention, such as concentrations in Canadian environmental media, population's exposure via the environmental media and food, cumulative exposures, the relationship between vanadium and its compounds and vanadium pentoxide is not clear.	The Challenge screening assessments are based on considerations of the available data. Data gaps and uncertainties in the exposure assessment, including the very limited information on vanadium pentoxide in environmental media and food, are documented in the screening assessment.
	The assessment does not address the high volumes of vanadium pentoxide being disposed of and recycled.	The assessment focused on the most important sources of releases of vanadium pentoxide to the environment. In particular, diffuse releases, such as atmospheric emissions, and point-source releases, such as effluents, were deemed of potential highest concern and

		assessed. Monitoring data for landfill leachates were also included in the SAR and indicate that this source is not of concern
	There are inaccuracies in the SAR regarding the industrial process used to produce ferrovanadium	The final SAR has been updated to address these inaccuracies.
	The assessment currently has limited human epidemiological and chronic toxicity (human) data. It is uncertain how this data was treated in the assessment.	Sufficient information was available to characterize risk. Uncertainties in the health effects information is documented in the screening assessment.
	The cumulative exposures via food and environmental media present a more realistic situation and should be considered in this assessment. Apart from vanadium pentoxide, there are other forms of vanadium released in some industrial process. The government should consider taking a class approach for these chemicals.	Based on the categorization of the domestic substance list (DSL), vanadium pentoxide was identified as a high priority for action under the Challenge. The screening assessment is specifically characterizing risk from exposure to vanadium pentoxide. In the absence of monitoring data on vanadium pentoxide in environmental media and food, measurements of vanadium were conservatively assumed to be vanadium pentoxide. Other vanadium compounds have been identified as moderate priorities under the Chemicals Management Plan, and consideration will be given to taking a class approach for these substances in the future.
	Data on industrial releases of vanadium pentoxide from industrial processes is lacking and should be monitored. Currently, this chemical is not included for reporting under the National Pollutant Release Inventory (NPRI).	Currently vanadium pentoxide falls under vanadium and its compounds under the National Pollutant Release Inventory. Environment Canada will consider proposing the addition of substances found to be toxic under CEPA 1999 to the NPRI's substances list. Substances declared toxic under the CEPA 1999 in particular are given high priority in NPRI consultations. It should be noted that any party (person, government or organization) in Canada may submit a proposal to Environment Canada for changes to the NPRI program. Changes to the substance list result from the NPRI Consultations process and may include the addition, modification or removal of substances as well as changes in the thresholds at which they must be reported.
	There was no substantial information provided on safe alternatives to vanadium oxide.	Consideration of alternatives is done as part of the development of risk management approaches. The Government of Canada welcomes input from stakeholders on alternatives for substances in

		all batches of the Challenge.
	Vanadium pentoxide and other species of vanadium are repeatedly referred to as vanadium oxide. Also, when there is uncertainty on the form of vanadium, it is assumed to be vanadium pentoxide.	The language in the screening assessment has been refined. Although the DSL name of the substance is "vanadium oxide", the name used in the final screening assessment has been changed to "vanadium pentoxide" for the sake of clarity. The assumption that all vanadium is under the pentoxide form is recognized as being conservative.
	Additional consideration should be given to the impacts and toxicity of these chemicals to all vulnerable subpopulations such as northern communities, indigenous groups, workers, pregnant women, children, babies, and people with sensitivities.	The Challenge screening assessments are based on considerations of the available data. The various conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada. However, if information is available which suggests that a specific sub-population would be particularly vulnerable, this information would be considered in the assessment.
Releases to the Environment	Based on various evidences published in the scientific literature, assuming all releases of vanadium from the combustion of wood, bark and oil to be vanadium pentoxide formed in the boiler is an over-estimate.	Assuming all releases of vanadium from the combustion of fossil fuel, wood and bark to be vanadium pentoxide is recognized as being an overestimate. As mentioned in the draft SAR, this assumption was used as a worst-case scenario. Because none of the exposure scenarios that were assessed indicated that total vanadium in aquatic or terrestrial ecosystems poses a risk to ecological receptors, further refinement regarding the portion of total vanadium measured in the environment that actually originates from vanadium pentoxide was not deemed necessary.
	The draft screening assessment report does not address long-range transport potential.	Long-range transport potential was not quantified in the draft SAR, as this source is not expected to contribute significantly to Predicted Environmental Concentrations that are used to quantify exposure.
Risk Management	The government's risk management for vanadium pentoxide should incorporate phase out and elimination of anthropogenic sources of vanadium pentoxide.	Vanadium is found in coal and fossil currently being used in industrial combustion processes including electricity generation. These processes will incidentally produce vanadium pentoxide. Having said this, the Government of Canada plans to phase-out the electricity sector's inefficient coal-fired generators.
	The policy discussion for Future Use Notification is pending with the regulated community and any action on vanadium pentoxide should be subject to those outcomes.	The decision to use the SNAc provisions would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration These provisions will be

		implemented in place of the Future Use Notification tool identified in the Risk Management Scope document.
	A Future Use Notification is not needed for Vanadium pentoxide unless some risk is identified that would illustrate why the notification is needed.	The decision to use the SNAc provisions would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration.
	It is not necessary to prohibit vanadium pentoxide in natural health products as there is little to no indication that these products pose a risk.	Vanadium pentoxide was never identified to be used as a medicinal or non-medicinal ingredient or as a source of vanadium in natural health products that are licensed for use in Canada under the *Natural Health Products Regulations.* The Natural Health Products Directorate's (NHPD) multi-vitamin/mineral monograph does not indicate that vanadium pentoxide is a potential source of vanadium in natural health products nor is it found to be in any current drug products. As a preventative measure, the Government of Canada has changed the listing for vanadium pentoxide on the Natural Health Products Ingredients Database from a restricted substance to a substance which will not be authorized for use in natural health products. There is scientific evidence indicating vanadium pentoxide is unsafe and therefore its use in Natural Health Products for medicinal or non-medicinal purposes will not be authorized.
	In the Risk Management Scope, Proposed Risk Management, it states some aspects of the risk management have already been put in place (i.e. the Natural Health Ingredients Database has already been changed to prohibit authorization.) This risk management implementation has occurred before consultation and before the regulated community was aware of the change. Changes to requirements without notification or time to adjust in the market can cause severe disruptions and have unintended consequences up to and including non-compliance where the regulated community had no opportunity	Vanadium pentoxide was never identified to be used as **a** medicinal or non-medicinal ingredient or as a source of vanadium in natural health products that are licensed for use in Canada under the *Natural Health Products Regulations.* Previously, applicants were required to submit additional evidence indicating the safety of vanadium pentoxide when it was used in the formulation of natural health products as a medicinal ingredient or as a source of vanadium. The Natural Health Products Directorate's (NHPD) multi-vitamin/mineral monograph does not indicate that vanadium pentoxide is a potential source of vanadium in natural health products nor is it found to be in any current drug products. Applicants are required to use the limitations outlined in the NHP

	to act.	Ingredients Database. Regarding industry consultation, one of the objectives of the NHP Online System is to capture and validate scientific data in licence applications. If there is scientific evidence indicating a substance is unsafe to use in Natural Health Products, it gets implemented in the NHP Ingredients Database without further notification. There is scientific evidence indicating Vanadium pentoxide is unsafe and therefore its use in Natural Health Products for medicinal or non-medicinal purposes will not be authorized, which has been implemented in the NHP Ingredients Database.
	A requirement for changes in use-pattern is not adequate as a risk management tool. Its use in the pesticide industry and pharmaceuticals is not even addressed. Furthermore, relying on the co-benefit of reductions in PM emissions from existing programs for the electricity sector is unlikely to be an effective strategy on its own.	The decision to use the SNAc provisions would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration. Vanadium pentoxide was not identified for use in pesticides. Vanadium pentoxide was previously identified to be present as a medicinal ingredient in two final pharmaceutical products listed in the Drug Product Database (DPD), each product contained a total of 5 µg of vanadium pentoxide per tablet. These products have since been discontinued. The Government of Canada anticipates that the SNAc for vanadium pentoxide in conjuction with reductions of vanadium pentoxide as a result of co-benefits of existing and proposed programs to reduce particulate emissions from combustion of certain fossil fuels and addition to the *Environmental Emergency Regulations* will be effective risk management tools for vanadium pentoxide.
	Because of the toxic properties of this substance, vanadium pentoxide should not be used in pharmaceutical products unless there was an extraordinary application with no safe alternatives available. Therefore, we recommend that the use of this substance in pharmaceuticals be eliminated – both as an active ingredient and as a non-active ingredient.	There are currently no uses of vanadium pentoxide as an active or inactive ingredient in drug products. The Government of Canada has changed the listing for vanadium pentoxide on the Natural Health Products Ingredients Database from a restricted substance to a substance which will not be authorized for use in natural health products

	The federal government's plans to further investigate current measures using existing programs to reduce emissions of chemicals, including vanadium pentoxide from combustion of certain fossil fuels is unclear. The exact nature of this investigation was not revealed and this approach will not sufficiently address the concerns associated with vanadium pentoxide use, release, and disposal.	The risk management being considered for vanadium pentoxide includes reductions of vanadium pentoxide as a result of co-benefits of existing and proposed actions to reduce particulate emissions from combustion of certain fossil fuels. The following actions are expected to reduce particulate matter emissions: The Government of Canada is taking action to reduce greenhouse gas emissions in the electricity sector by moving forward with regulations on coal-fired electricity generation, which will result in the closing of some Coal-Fired Electrical Power Generation Plants. This action to reduce greenhouse gas emissions in the electricity sector by moving forward with regulations on coal-fired electricity generation is complementary to Provincial initiatives. As it is associated with particulate matter, vanadium pentoxide concentrations in air may also be influenced by actions taken by the Government of Canada and provinces to work towards the Canada-Wide Standards (CWS) for Particulate Matter (PM) and Ozone measured in ambient air. The CWS for PM2.5 is 30 μg/m3 (24 hour average) to be achieved by year 2010. Similarly, actions taken to meet the CWS for Mercury Emissions from Coal-fired Electric Power Generation Plants are expected to reduce emissions of particulate matter and other metals from these sources.
Environmental Emergency Regulations	It is suggested Vanadium pentoxide be reviewed to establish if the substance is present or used in any Canadian facilities under conditions that would be specified by the *Environmental Emergency Regulations*. It is not clear that any facility would meet these requirements.	A consultation process will be conducted with industrial stakeholders and any other interested parties as part of the process for adding this substance to the *Environmental Emergency Regulations*. During these consultations, the effectiveness of adding this substance to the regulations will be examined using criteria such as the number of facilities that will meet the proposed threshold limits.
	Based on the human health and environmental impacts and the possibility of increased volume usage of vanadium pentoxide, this substance should	All substances listed in the *Environmental Emergency Regulations* have an associated threshold quantity and concentration. These values are scientifically determined based on the toxicity and/or

	be added to the *Environmental Emergency Regulations* for all facilities regardless of the threshold for use or release of vanadium pentoxide.	hazards of the substances. When these substances are present in quantities and concentrations at or above the listed thresholds, they are considered to pose an environmental emergency hazard. Any substance in quantities and concentrations below the listed thresholds is not considered to pose an environmental emergency hazard.
	Environmental Emergency Regulations should be connected to other aspects of action plans that would call for the elimination of this substance, including the identification of other toxic chemicals that may be produced as a result of combustion.	The *Environmental Emergency Regulations* do not require the reduction or elimination of substances; instead, the regulations require anyone who possesses the substance in regulated quantities and concentrations, to prepare environmental emergency plans. These plans identify how the person in charge of the substance will prevent, prepare for, respond to and recover from an environmental emergency.