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The Honourable John Baird, P.C., M.P.
Minister of the Environment
c/o The Executive Director
Program Development and Engagement Division
Department of the Environment
Gatineau, Quebec K1A 0H3
Via email to: Existing.Substances.Existantes@ec.gc.ca

Re: Notice of Objection and Request for Board of Review in relation to the Proposed Order to add Vanadium Pentoxide (V_2O_5), to Schedule 1 of the Canadian Environmental Protection Act (CEPA), 1999; Canada Gazette Vol. 144, No. 44 — October 30, 2010

Dear Minister:

I am writing to you on behalf of the Vanadium Producers & Reclaimers Association (VPRA), a not-for-profit corporation representing the vanadium industry in North America on issues of importance to the industry including technology, trade, health, safety and the environment. By this letter we are filing a section 332(2) Notice of Objection and request that a Board of Review be constituted pursuant to section 333 of CEPA regarding the proposed addition of Vanadium Pentoxide (V2O5) to the list of toxic substances in Schedule 1 of CEPA.

New information has become available as a result of the REACH process in Europe which address uncertainties identified in the V_2O_5 Assessment. The Vanadium Consortium, which shares some members with the VPRA, provided significant information on a series of vanadium-based substances, including V_2O_5. In summary, the new information shows that V_2O_5 is not classifiable as to carcinogenicity. The dossier also indicates that V_2O_5 did not give rise to any mutation in an *in vitro* mammalian cell gene mutation assay. The information provided to Europe also demonstrates that V_2O_5 is not similar to other vanadium-based substances as it relates to bio-availability, which contradicts some of the conclusions found in the SRLA directly. We have provided you with a copy of the all of the materials which were submitted to Europe on V_2O_5. We ask that the information submitted with this application for a Board of Review is considered to be **confidential** under section 313 of CEPA. It is our understanding that you can also access the dossier under a Memorandum of Understanding which was established between Canada and Europe.

In light of these considerations, moving forward on a Proposed Order that is based on overly precautionary assumptions as compared to the best and most current science would be inconsistent with the Government's own *Framework for the Application of Precaution in Science-based Decision Making About Risk* which mandates that "[s]ound scientific information and its evaluation must be the basis for applying precaution." It remains our position that the current conclusion is a significant deviation from the Government's regulatory policy, and we feel that the proposed order should be reviewed in light of this new information.

Summary:

V_2O_5 is a Batch 9 substance under Canada's Chemicals Management Plan (CMP). We remain steadfast in our opposition to the proposed addition of V_2O_5 to Schedule 1 of CEPA because the assessment on which it is based makes significant errors, misinterprets data, and is so overly precautionary that it can only be viewed as hazard based. The reasons supporting our request are outlined below and we believe that significant deficiencies in the Ministers' screening level risk assessment (SLRA) continue to exist and that new scientific information which was not previously available has been produced and should be considered by the Government of Canada in advance of any designation of toxic under section 64 of the Act. We maintain our belief that the broad term "toxic" that the Government uses is inconsistent with other jurisdictions, inflammatory and presents the opportunity for misinterpretation and stigmatization of an important commercial material that has been and is being safely used to the benefit of the Canadian economy.

Notwithstanding our objection to the final designation, it remains our considered view that, a Significant New Activity notice (SNAc) will accomplish all of the goals established by the Government of Canada's Chemical Management Plan, which is to reduce exposure to chemical substances which may cause harm to the environment or human health. The Ministers' conclusion is based on an incorrect extrapolation of the results of a single study on inhalation of a single form of vanadium pentoxide on rats and mice to broad, unsupported, and presumably minimal exposures to Canadians of **other** forms of vanadium. Canadians always have, and always will be exposed to vanadium, without apparent adverse effects, because of its ubiquitous presence in nature.

It is our considered view that any toxic declaration which is based on the information provided in the final Screening Level Risk Assessment of V_2O_5 would be made in violation of the *Cabinet Directive on Streamlining Regulations.* The directive specifies that the Government shall make decisions on "the best available knowledge and science in Canada and worldwide." In this case, the Assessments prepared by Health Canada and Environment Canada are not based on the best available data and scientific knowledge regarding the chemical properties of vanadium, and specifically,V_2O_5. In fact, it relies on the unsupported conclusions, ignores available data and makes overly precautionary assumptions which are out of line with established principles of chemistry. This results in the development of completely unreasonable exposure scenarios. That directive also requires that the use of precaution must be balanced (this is also a statutory

requirement found in CEPA). This is clearly elucidated in the *Framework for the Application of Precaution in Science-based Decision Making About Risk (the Framework).*

At section 4.3, the Framework states that "(s)ound scientific information and its evaluation must be the basis for applying precaution" and further states "(s)cientific data relevant to the risk must be evaluated through a sound, credible, transparent and inclusive mechanism … (a)vailable scientific information must be evaluated with emphasis on securing high quality scientific evidence (not quantity)." The SLRA upon which the toxic declaration is based fails in this regard as it selectively interprets and ignores important studies from the large database of material available on V_2O_5. The basis for Health Canada's conclusion that there is no safe level of exposure to V_2O_5 is also not rooted in the sound science necessitated by the Framework.

The precautionary approach mandated by CEPA is a stop-gap measure that should be used when there is significant uncertainty around the existing science and where there is a sound and reasonable case for a conservative conclusion based on the availability of reasonable, peer-reviewed evidence. That same precautionary approach must be balanced against the weight-of-evidence. It is our view that the Ministers failed to appropriately and reasonably implement the weight-of-evidence approach while considering all available scientific evidence pertaining to V_2O_5. Instead, the Ministers appear to have exclusively relied on a misinterpretation of an evaluation completed by the IARC, which is simply further compounding the previous errors of already rebutted studies. Accordingly, consistent with the *Framework*, we believe this new evidence should be considered and reviewed to ensure the correct decision is made and the errors of others are not compounded.

II - Overview of the Screening Level Risk Assessment

The SLRA as written contains numerous instances where V_2O_5 and other vanadium compounds are mistakenly interchanged. The document "conservatively" assumes that vanadium emissions resulting from the combustion of fossil fuels are V_2O_5, despite the fact that there is no evidence of this, and there is no basis in chemistry that could support this position. While the physical chemical parameters listed at the outset of the document may be for V_2O_5, beyond that it appears that the assessment mistakenly broadens the scope to include several other species of vanadium. Basic chemistry errors about vanadium speciation colour the entire assessment because, by not limiting the scope to V_2O_5, it is not a risk assessment of that specific substance. The errors in the assessment do not accurately describe and evaluate how V_2O_5 specifically interacts with, and breaks down in, the environment, nor does it accurately describe its continued presence in the environment.

That having been said, the precondition for the determination of toxicity is based on an improper characterization and subsequent misinterpretation of a U.S. National Toxicology Program (NTP) inhalation study (Technical Report #507) (NTP 2002). This study provides chronic data on the granular orthorhombic crystalline form of V_2O_5; however, the study raises many questions that limit its utility. The study results include non-statistically significant tumour incidence findings

in rats at all studied exposures. It concluded that clear evidence of lung tumors was seen in mice of both sexes, while some evidence of carcinogenicity was seen in male rats and the response in female rats was equivocal. The NTP study is also not informative about the question of thresholds in mice because of the narrow range of doses used and the high dose. Nor does the NTP study support this conclusion in rats because of the species and sex differences in the observed response. While marked differences in the carcinogenic response between the species are apparent, the reasons for this and the relevance of the difference to human exposures have not been determined.

As a result, the relevance of the effects of V_2O_5 for human health are not known. The study was conducted over a narrow range of high doses, and a No-Observable Adverse Effect Level (NOAEL) was not established, making extrapolation of the results to realistic exposures ineffective. The resulting conclusion made by Health Canada that there is no threshold for the carcinogenic and genotoxic effects is not supported by any existing studies of V_2O_5.

Further complicating the interpretation of the study results is the criticism of the test material's chemical identification and analysis of the chamber exposures. In a 2007 paper, Prof. J.H. Duffus provides critical commentary regarding the chemistry limitations of the NTP study.[1] He argues that, because of inherent weaknesses in design and procedure, the NTP study of the carcinogenicity of inhaled vanadium pentoxide does not provide adequate evidence to support the classification of vanadium pentoxide as a Group 2B (possible) human carcinogen. For oxygen-containing compounds like vanadium pentoxide, a toxicological assessment needs to acknowledge and account for their oxygen content since it is likely to be the most reactive component of such compounds.

However, to conclude from those findings that a direct interaction of V_2O_5 with DNA cannot be excluded is contrary to the established scientific method, and creates a situation where critics of the results must prove a negative – which cannot be done even with a comprehensive set of chromosomal, genetic and DNA toxicological data.

The IARC Monographs Programme on the Evaluation of Carcinogenic Risks to Humans is well-respected internationally, but it is not a regulatory authority with access to all relevant data and does not undertake risk assessments. Its classifications are solely on the basis of carcinogenic hazard identification (in spite of the title of the publications). Although published genetic toxicity and reproductive toxicity data are summarized, these endpoints are not classified in any way. As the conclusions of the NTP have limited utility for the study of V_2O_5 in Canada, we would

[1] Carcinogenicity classification of vanadium pentoxide and inorganic vanadium compounds, the NTP study of carcinogenicity of inhaled vanadium pentoxide, and vanadium chemistry. Duffus, JH. Regulatory toxicology and pharmacology. 2007. 47, 110-114.

respectfully submit that determinations by international agencies on which relied on the NTP be reviewed carefully.

In their "Characterization of Risk to Human Health", the SRLA has inaccurately portrayed the assessment of the European Union as indicating that V_2O_5 is a genotoxic carcinogen. The existing regulatory position of V_2O_5 within the EU is Mutagen Category 3 and Reproductive toxin Category 3, there being no decision made on carcinogenicity. However, this position was taken before publication of the NTP study and the UK was assigned the task of 'Responsible Member State' for this compound.

Given the disparity between these results and those relied upon by Health and Environment Canada, a thorough review of the basis for the Proposed Order is warranted. The *Framework for the Application of Precaution in Science-based Decision Making About Risk* mandates that a "credible scientific basis" must inform the Government's application of precaution to decision making. Given the unfounded assumptions made by the Ministers in their SLRA findings and in light of the fundamental scientific questions with the Assessments underlying the Proposed Order, a Board of Review is warranted to ensure the scientific credibility and validity of the SLRA for V_2O_5.

III - Genotoxic Policy and the Probability of Harm at any Level

We feel that it is important to specifically point out that the conclusion of toxicity is based on the erroneous conclusion that V_2O_5 gives rise to possible harm at any level of exposure. This is simply not true and it is not supported by any scientific evidence. Fused flake vanadium pentoxide is a large particulate solid. In that form, it is not biologically available. In that large particulate form V_2O_5 is minimally dusty and is in any case handled only in specialist applications by skilled, trained operators under highly controlled conditions. It is not a general risk to Canadians. We have provided photographs of the two forms below. The picture on the left, the yellow powder, is the orthorhombic granular form of V_2O_5which was originally tested by the NTP. The picture on the right is the fused flake which is currently imported into Canada by Masterloy.

The conclusion that the fused flake form of V_2O_5 has the potential for equivalent harm to the granular form is not based on any independent work done by Health Canada, or any scientific study. There is no peer reviewed scientific literature that suggests that this form of V_2O_5 is a risk to human health. In the case at bar, any risk management program which does not focus specifically on the granular orthorhombic crystalline form, and in particular the inhalation of fine particles of that material, is reaching well beyond the actual risk identified by IARC and the National Toxicology Program. Both of these authoritative bodies have clearly attributed their conclusions to the granular orthorhombic form of vanadium pentoxide. In past submissions, we have referenced the physico-chemical differences of these materials.

Health Canada has not provided any evidence that supports its conclusion that V_2O_5 causes carcinogenic and genotoxic effects at any level of exposure. There is no scientific basis for this conclusion, and the conservative assumptions made in the FSLRA compound the error we have previously highlighted. We have previously referred to the National Research Council report on vanadium, and while it was referenced to in the FSLRA, the very conservative assumptions made about V_2O_5 emissions, and the subsequent conclusions that were drawn in the final document are inconsistent with the NRC findings.

Through our examination of the previous batches of substances in the Chemicals Management Plan, we have been made aware of a serious inconsistency in policy as it relates to the treatment of genotoxic substances by Health Canada. This treatment is very precautionary, and its overly precautionary nature is directly at odds with the Government of Canada's *Cabinet Directive on Streamlining Regulation* and the *Framework for the Application of Precaution in Science-based Decision Making About Risk.* At section 4.3, the Framework states that "(s)ound scientific information and its evaluation must be the basis for applying precaution" and further states "(s)cientific data relevant to the risk must be evaluated through a sound, credible, transparent and inclusive mechanism … (a)vailable scientific information must be evaluated with emphasis on securing high quality scientific evidence (not quantity)."

Health Canada and Environment Canada appears to base its conclusion that V_2O_5 qualify as "toxic" under CEPA section 64 on the allegation that there is no safe level of exposure to the substance, and that there is no threshold of exposure for which there is an effect at a DNA/cellular level. There is no scientific evidence on which this assumption is founded, and this conclusion is based on an inappropriate policy determination on the erroneous conclusions of other bodies.

In their application of the precautionary principle approach, the Ministers appear to have stretched the principle beyond its original intention – to act as a bridge in the absence of scientific certainty where there is sufficient evidence to allow a conclusion to be "reasonable" as outlined in the framework on risk. The precautionary principle is a measure that can be used when there is significant uncertainty around the existing science and where there is sound and reasonable case for a conservative conclusion based on the availability of reasonable, peer reviewed evidence.

The approach taken in the SLRA for V_2O_5 does not follow this approach as no reasonable case is presented for genotoxic carcinogenicity that is of any relevance for humans. Instead toxicity is deemed to be the case due to a Health Canada policy that presupposes certain substances to be toxic without regard to exposure just because they appear on a list that was not developed for Canadian regulatory purposes and has nothing to do with a finding of toxic under *CEPA*. There was never a clear statement of that policy and the basis for the new direction was never published by Health Canada.

As a result of this overly precautionary approach, we believe the conclusions are unreasonable in the sense that they are based on implausible (or impossible) exposure scenarios. As such, the conclusions far exceed reasonable and appropriate precaution levels required by *CEPA* and the aforementioned regulatory policies. The current policy (absent the unstated policy shift noted above) of Health Canada states that carcinogens require exposure assessments to determine if they qualify under section 64 of the Act to be declared as CEPA toxic and changes to this policy would place Health Canada significantly out of step internationally. On an even larger scale, we are concerned that the manner in which the screening assessments have been conducted under the CMP is resulting in unannounced changes in the Government's policies for chemical assessments. This significant change appears to be occurring without the usual openness and transparency which has marked previous Government actions and is of great concern. We believe that many of these changes are embodied in the draft Screening Assessment for V_2O_5. As such, we feel that there is no evidence that section 4.3 of the Framework on risk was followed in the case of V_2O_5. The truth is that a decision on the toxicity of V_2O_5 was based on a literature review and a misinterpretation of the findings of other jurisdictions and bodies. That is the antithesis of the suggested application of precaution laid out by the Government.

Traditionally, Health Canada has taken a balanced approach to the classification of carcinogens and the un-stated policy shift for this substance has not been taken in other Health Canada determinations for carcinogenicity under other regulatory regimes, most notably the Priority Substances List assessments (PSL). VPRA suggests that there should be clear policy direction that only realistic exposure scenarios based on Canadian-use practices will be used to reach the conclusion of CEPA toxic. The evidence provided in the draft assessment is not based on a sound and reasonable exposure scenario, and there is little reasonable evidence of the exposure conclusions reached by the draft risk assessment.

The bottom line is that the policy, as applied to V_2O_5, is also inconsistent with the language of the *Canadian Environmental Protection Act*. As noted in our comments on the substance profile. V_2O_5 does not enter into the environment under conditions that constitute or may constitute a danger in Canada to human life or health. The genotoxic policy is a measure which is designed to prevent all exposures to a non-threshold toxicant. Outside of the employees of the Masterloy facility in Ottawa, Ontario, which the Government concedes at page 44 of its SLRA use V_2O_5 in a way that does not constitute a risk to human health, there are no Canadians who are exposed to

V_2O_5. The only exposure of concern noted in the SLRA is an exposure resulting from industrial emissions which is unfounded in chemistry and unsubstantiated by emissions monitoring.

IV- Exposures from Fossil Fuels

There are specific aspects of the final substance profile and final assessment which draw in exposure scenarios from the combustion of fossil fuels that inappropriately discuss vanadium and not V_2O_5. With respect to fossil fuel combustion, the SLRA notes that vanadium enters the environment as a result of the aquatic breakdown of certain vanadium species. This discussion is not relevant to V_2O_5. Additionally, although bottom ash (which is not emitted) from petroleum-fired facilities has been reported to contain up to 70% V_2O_5, and fly-ash residues commonly processed have been reported to contain 5-18% V_2O_5, the vanadium present in fly-ash is rarely in this form and most probably exists in one of several reduced forms as vanadium tetraoxide (dioxide) and vanadium trioxide, but not necessarily in the form of plain V_2O_5.[2]

While the NRC's study was referred to in the FSLRA, the conclusions drawn in the document leads us to conclude that the NRC study was ignored. This error must be corrected in the final screening level risk assessment. We refer the Minister to the comments made by the Canadian Electricity Association (CEA), who note that the SLRA presents an overestimation of V_2O_5 emissions from coal and oil-fired electricity generation and the influence of this overestimation on regulatory decisions; that the assumption of 100% conversion of vanadium in the fuel to V_2O_5 (CAS no 1314-62-1) is unfounded; that coal fly-ash contains little to no concentration of V2O5; and that fly-ash from oil-fired generation contains V_2O_5, nickel vanadium oxide (NiV_3O_8) and other **bound** compounds which will not break down as described in the SLRA. In summary, CEA members "are confident that the depiction of the V_2O_5 emissions from the electricity industry presented in the proposed SLRA does not properly reflect actual emissions."

V - A Conclusion that V_2O_5 Meet the CEPA Section 64 Definition of "Toxic" is Premature Pending a Board of Review of all the Available science on V_2O_5 and New Data Address Uncertainties Identified in the Assessment and Refute an Overly-Precautionary Assertion that the Substance Poses a Hazard to Human Health

As a result of the information that was compiled for the European REACH program, new data are available that address the concerns raised by Health Canada with V_2O_5. As the Government of Canada has negotiated and executed a memorandum of understanding for the exchange of information with Europe, it should have full access to this confidential information once it was submitted to the ECHA (European Chemicals Agency), which occurred in mid-November 2010. We have attached a copy of all of the information which was provided to Europe by the

[2] National Research Council. Committee on Biologic Effects of Atmospheric Pollutants. Vanadium. Medical and biologic effects of environmental pollutants. p. 11. WA754 N278v 1973. ISBN 0-309-02218-5. Printing and Publishing Office, National Academy of Sciences, 2101 Constitution Avenue, Washington, D.C. 20418

Vanadium Consortium, and respectfully request that it be held in confidence pursuant to section 313 of the Act.

When this data is examined closely, and the studies on which the Canadian conclusion is based are correctly interpreted, we believe that the only conclusion that Health Canada will be able to make is that V_2O_5 does not enter into the environment under conditions that constitute or may constitute a danger in Canada to human life or health, as defined by section 64 of the *CEPA*. Moreover, we feel that this new data effectively disputes the underlying assumption made by Health Canada, that there is no safe level of exposure to V_2O_5. ***The REACH dossier is very comprehensive, and incorporates significant new toxicological work which was done specifically to determine how vanadium based substances react with animal species***. We believe that you will agree that the dossier contains new information aboutV_2O_5, including:

1) Significant data was submitted by the Vanadium Consortium on carcinogenicity, but the Vanadium Consortium concluded that there can be no conclusion drawn on the carcinogenicity of V_2O_5 based on the available information.
2) V_2O_5 did not give rise to any mutation in an *in vitro* mammalian cell gene mutation assay.
3) New data created and submitted to Europe demonstrates that V_2O_5 is not similar to other vanadium based substances as it relates to bio-availability.

We note that Section 4.4 of the Government's *Framework for the Application of Precaution in Science-based Decision Making About Risk* specifically provides that a reevaluation of a risk decision may be triggered by the emergence of new scientific information. We believe the new data described above qualify as information that necessitates such consideration. Similarly, when viewed in combination with our detailed concerns regarding the chemistry discussion in the SLRA, we believe that the Minister has a duty to grant a Board of Review to provide for a considered examination of the true nature and extent of danger, if any, posed to human health by V_2O_5.

Conclusion

In conclusion, in the Government paper "*A Framework for the Application of Precaution in Science-based Decision Making About Risk*" it states precautionary measures should be proportional to the potential severity of the risk being addressed and to society's chosen level of protection. Regulating non-existent/negligible potential exposures to something incorrectly assumed to be V_2O_5 from anthropogenic sources flies in the face of this stated regulatory policy objective. The severity of the risk contemplated in the final SLRA does not take a proportional, risk-based approach, as it ignores fundamental realities about vanadium-based chemistry. It also does not effectively justify what risks are being prevented by declaring V_2O_5 toxic, when there is no dangerous exposure to the substance in Canada. The conclusion that there is harm at any level of exposure is not founded in science, rather, it is founded in policy. To use the policy determination to justify a science-based decision is the converse of what the framework was designed to accomplish.

More to the point, the *CEPA* requires that the Ministers apply both precaution AND a weight of evidence approach under Section 76.1 of the Act. It is our considered view that in this case, and in the case of many other genotoxic substances, that only the former has been properly applied.

It remains our view that V_2O_5 does not meet the statutory definition for toxic as laid out in Section 64 of the *CEPA.* We disagree that there is any evidence that emissions to the environment from the combustion of fossil fuels will lead to harmful human exposure to V_2O_5 which can give rise to the concerns laid out in the FSLRA.

Finally, since the FSLRA envisioned exposure to V_2O_5 is entirely theoretical at this time, and because the risk assessment is based on a potential future risk, the SNAc is the only risk management tool required. The SNAc is the only proposed initiative that can protect human health from the risk identified by the draft screening level risk assessment because that risk is based on direct exposure to the granular orthorhombic crystalline form of V_2O_5. That is the form of V_2O_5 which was used in the National Toxicology Program study which was the basis of the IARC conclusions on V_2O_5. A SNAc can achieve all the goals of the program, without incorrectly imposing the stigma of the toxic designation or running afoul of Canada's regulatory policy.

For the foregoing reasons, VPRA objects to the Proposed Order to add V_2O_5 to Schedule 1 and requests that a Board of Review be convened under Section 333 of the Act. We would welcome the opportunity to appear before a Board of Review to explain our concerns with the original assessment, the importance of the attached data which was developed for Europe, and to find an amicable, mutually agreeable and practical resolution to the difference of opinion between our members and the Government of Canada. If you have any questions or concerns, please do not hesitate to contact either me or VPRA's Canadian consultant on this matter, Mr. Scott Thurlow, directly.

Sincerely

John Hilbert
President, Vanadium Producers and Reclaimers' Association
att.
c.c.: The Honourable Leona Aglukkaq, Minister of Health Canada
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