

**Texas Commission on Environmental Quality Responses  
to Comments Received on:**

- 1. Hexavalent Chromium (Particulate Compounds)  
Development Support Document**
- 2. Hexavalent Chromium Development Support  
Document Section 4.2 – Carcinogenic Potential -  
Draft Dated March 2013**

# Texas Commission on Environmental Quality (TCEQ)

## Responses to Public Comments

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**August 2014**

### **Hexavalent Chromium (Particulate Compounds) Development Support Document**

The public comment period on the Development Support Document (DSD) for the proposed hexavalent chromium (particulate compounds) ended May 6, 2014. Air Alliance Houston, Recycling Council of Texas and a citizen submitted comments on the proposed DSD. The TCEQ appreciates the effort put forth to provide comments on this proposed DSD for hexavalent chromium (particulate compounds). The goal of the Toxicology Division and TCEQ is to protect human health and welfare based on the most scientifically-defensible approaches possible (as documented in the DSD), and evaluation of these comments furthered that goal. Comments were divided into sections and are provided below, followed by TCEQ responses.

#### **Air Alliance of Houston**

##### **Comment No. 1:**

The undersigned organizations appreciate this opportunity to comment on the Development Support Document (DSD) for hexavalent chromium (CrVI). This proposal will weaken the health standards for CrVI, and TCEQ has not offered adequate justification for such a revision. The CrVI monitoring network in Texas is inadequate to monitor compliance with these standards, particularly with the chronic standard. Given the uncertainty about the health impacts of CrVI, and the inadequacy of the state's monitoring network, we recommend this revision not proceed.

##### **TCEQ Response:**

The TCEQ appreciates Air Alliance Houston's comments. This paragraph suggests that because the monitoring network in Texas is "inadequate" to demonstrate compliance with the proposed chronic standard in particular, the revisions should not proceed. Effects Screening Levels (ESLs) are used in the TCEQ's air permitting process, which is independent of monitoring. The TCEQ would need ESLs to permit facilities even if it did not operate a single air monitor. The TCEQ develops ESLs for thousands of chemicals for which we (or any other agency) do not monitor, nor for which monitoring technology exists. In the interest of public health and based on scientific data, the TCEQ is proposing to lower the chronic ESL air concentration for hexavalent chromium (CrVI) by 2.3-fold, which in turn will more severely restrict short-term emissions through more restrictive and legally enforceable air permit emissions limits. This is because

regardless of what the short-term health-based value is, the long-term average must comply with the much lower health-based chronic ESL, a demonstration accomplished through conservative air dispersion modeling. Lastly, the TCEQ strongly disagrees with the statement by Air Alliance Houston that TCEQ has not offered adequate justification for the proposed revisions; the 101-page proposed DSD more than adequately documented the scientific justification. Additionally, the TCEQ long-term ESL and associated dose-response assessment underwent an independent external expert peer review organized by Toxicology Excellence for Risk Assessment as well as an external scientific peer review prior to being accepted by the prominent scientific journal Regulatory Toxicology and Pharmacology.

### **Comment No. 2:**

I. Available monitoring resources will not allow proper monitoring for compliance with these standards.

A. Texas' Monitoring Network Includes no Continuous Monitoring for CrVI

In a recent interview on this proposal, TCEQ chief toxicologist Mike Honeycutt stated that the long-term standard is the more important of the two and the standard that will be tightened. "Because a company would need to meet both of those, the net result is actually, the value would be more stringent," Honeycutt said. "So it may appear that we'll be more lenient, but actually, when it's all said and done, it'll be more stringent."

This statement could only be true (and we are not saying that it is) if there was a monitoring network in Texas to accurately monitor compliance with the long-term standards. No such monitoring network exists. Indeed, we are not aware of a single continuous CrVI monitor in the state of Texas.

### **TCEQ Response:**

To our knowledge, United States Environmental Protection Agency- (USEPA) approved automated continuous CrVI ambient air monitoring technology is not commercially available. If the TCEQ developed ESLs for only those chemicals that can be measured with continuous monitoring, we would only develop ESLs for less than 100 chemicals, and this would not be health protective. Secondly, Dr. Michael Honeycutt's statement is true and the statement by Air Alliance Houston that it can only be true if the Texas air monitoring network can monitor compliance with the long-term standard demonstrates an inherent misunderstanding of air permitting in Texas and elsewhere. The net result will be more stringent. Because the new lower chronic ESL will have to be complied with, short-term facility emissions will have to be more severely limited through enforceable air permit limits so that the long-term average can meet the new lower chronic ESL.

### **Comment No. 3:**

We are aware of 134 chrome electroplating facilities in Texas. The DSD indicates that TRI data identify some 200-300 facilities in Texas that produce or process chromium. There are at least

170 metal recycling facilities in Houston alone. We are uncertain about which facilities process chrome or stainless steel, and which facilities employ torch cutting. We do know that many metal recycling facilities in Houston are located in or around communities, and that the City of Houston has received some 200 citizen complaints in the last five years. Given the uncertainty about even the scope of industry that emits CrVI, and the total lack of a continuous monitoring network, we do not understand why a lower standard should be proposed.

### **TCEQ Response:**

What industries emit CrVI and what technologies are, or are not (see previous comment), available for the TCEQ to continuously monitor for a chemical are irrelevant to the scientific soundness of the health-basis of a toxicity factor. For example, these peripherally related topics have no relevance to the evaluation of the dose-response data in relevant toxicity studies, the identification of critical adverse effects, etc., but rather simply reflect concerns about the number and types of facilities that health-based values should be applicable to and the ability to address citizen complaints (an enforcement issue). Since Air Alliance Houston indicates “we do not understand why a lower standard should be proposed,” the TCEQ refers them to the underlying science in the DSD which more than adequately documents the scientific rationale for these health-based values. The proposed ESLs are both conservative (i.e., health protective) and scientifically sound. For example, deriving a 24-hour value based on a 30-day, 22 hours/day study in the absence of any upward dosimetric adjustment to account for the much shorter duration of interest is extraordinarily conservative.

### **Comment No. 4:**

#### **B. Self-Monitoring and Reporting is Inaccurate and Incomplete**

The lists of CrVI sources referenced in the DSD, such as the EPA’s Toxic Release Inventory are inaccurate and incomplete. As discussed above, there are a wide variety of sources in Houston, including small metal recyclers, welders, and torch cutters, that are in many cases adjacent to communities. Many of these facilities operate without permits, other on Permits by Rule. Many of these facilities do little to no air monitoring, especially on or beyond their own fencelines. The data they self report to TCEQ and EPA is unverified and likely undercounting actual emissions

### **TCEQ Response:**

The list of CrVI sources provided in the proposed DSD is for general informational purposes only (i.e., it is not used by the TCEQ in any capacity for developing an ESL) and has absolutely no bearing on the scientific or health basis of the values. Similarly, any self-reported emissions data and the availability of facility fenceline monitoring have no bearing on the scientific or health basis of the values proposed in the DSD. For example, while there may not be fenceline

air monitoring available for a facility to demonstrate compliance with a value (e.g., air dispersion modeling may be used for this purpose), this has nothing to do with the scientific soundness of the health-based value itself (e.g., the evaluation of the dose-response data in relevant toxicity studies and the identification of critical adverse effects).

#### **Comment No. 5:**

In the last several years, the City of Houston Department of Health and Human Services (HDHHS) has conducted air monitoring around 25 of the facilities for which the most community complaints were received. Facilities were sampled for eight-hour increments six to ten times over a period of eighteen months. Data from five of these facilities indicate that CrVI was found downwind 92% of the time. All told, HDHHS measured total chromium emissions levels offsite ranging anywhere between 0.1 and 2.0  $\mu\text{g}/\text{m}^3$  over a typical 8 to 10 hour work day.

In other words, the scant CrVI monitoring that has been conducted in recent years has already monitored violations of the new proposed short-term health standard. If TCEQ has any recent CrVI monitoring data that contradicts these findings, we are not aware of it.

#### **TCEQ Response:**

First, whether or not violations of the proposed values have been documented is irrelevant to the scientific defensibility of the health-based values themselves (e.g., the evaluation of the dose-response data in relevant toxicity studies). Secondly, total chromium air concentrations of 0.1-2.0  $\mu\text{g}/\text{m}^3$  do not demonstrate exceedance of the proposed 24-hour ReV for hexavalent chromium of 1.3  $\mu\text{g}/\text{m}^3$ . As presented, this is an apples-and-oranges comparison as it is obviously does not address the key question of what percent of total chromium was in the hexavalent form. Lastly, we fail to see what bearing this has on the scientific basis of the TCEQ's proposed ESLs.

#### **Comment No. 6:**

If the TCEQ does proceed with this revision, it must develop a plan to ensure that adequate monitoring resources are in place to monitor compliance with both the short- and long-term standards. A limit with no means of monitoring compliance is meaningless. If TCEQ has no plans to actually monitor compliance with its standards, then setting or revising them is an exercise in futility.

#### **TCEQ Response:**

Air Alliance Houston indicates that if the TCEQ has no plans to monitor compliance through air monitoring, then revising health-based values is an exercise in futility. The TCEQ strongly disagrees with the implication that in the absence of fence-line monitoring at each and every

facility for each and every chemical, that it is somehow an exercise in futility for the TCEQ to ensure that its health-based values are the most scientifically defensible and sound available. In fact, the Toxicology Division has spent years developing state-of-the-science toxicity factor guidelines for just this purpose. These external expert peer reviewed guidelines have earned high praise from reviewers: "To the best of my knowledge, this guidance is complete and thorough, even exhaustive, in its coverage of relevant guidance on development of toxicity criteria available in the United States and Europe" ... "This draft guidance is not just comprehensive, it is encyclopedic" ... "The authors of this report are to be commended for the thoroughness, accuracy and usefulness instilled into this report." The Toxicology Division has spent additional years publishing health-based values that earn high praise. For example, the Ontario Canada Ministry of Environment deemed the assessment of 1,3-butadiene published by the TCEQ as the most scientifically-sound after reviewing national and international chemical assessments, and USEPA peer reviewers on USEPA's Proposed Mercury Air Toxics Standards Rule called on USEPA to use the TCEQ nickel unit risk factor (e.g., "I would recommend using the TCEQ URE...The risk assessment leading to the derivation of this number was performed recently, included an updated and critical review of the literature, and appears to be comprehensive with an emphasis on health protection"). Due to their high quality, other countries use various TCEQ health-based values (e.g., Canada, Israel, Australia, Taiwan, Austria). Contrary to the Air Alliance Houston comment, the acknowledgment by external experts of the high quality of the TCEQ guidelines and the health-based values developed under them demonstrates to the agency that ensuring its health-based values are the most scientifically defensible and sound available for use in TCEQ programs (e.g., air permitting is a very important use) as our goal and commitment is certainly not an exercise in futility. Since Texas has by far the most extensive air monitoring network in the nation, providing more than 23 million data points per year (<http://www.tceq.state.tx.us/airquality/airsuccess/air-success-toxics>), by the flawed logic of Air Alliance Houston no state or federal agency should bother ever revising any health-based value because they would have far fewer monitors than Texas by which to monitor compliance.

Lastly, Air Alliance Houston indicates that a limit with no means of monitoring compliance is meaningless. ESLs are used in the TCEQ's air permitting process for thousands of chemicals for which we (or any other agency) do not monitor, nor for which monitoring technology exists, and are used to set air permit limits. Air permit limits are not meaningless, they are used by regulatory agencies such as the TCEQ to protect human health and the environment. Most importantly, USEPA-approved ambient monitoring methods are not available for the majority of chemicals that are permitted. Air monitoring, fixed station or mobile, is only one tool to monitor compliance with air permit limits. In fact, the review of facility records (e.g., production) is the most common method used to monitor and identify noncompliance with permit limits, resulting in enforcement actions.

### **Comment 7:**

II. The rationale for developing a 24-hour acute ReV is improper

As the TCEQ acknowledges, acute ReVs are usually based on a 1-hour exposure duration. This is true of the current acute ReV for Cr(VI) of 0.01 µg/m<sup>3</sup> and, as far as we are aware, for all of TCEQ's acute ReVs. In this proposal, TCEQ has developed a 24-hour acute ReV. In this proposal, the TCEQ states that, "development of a 24-h acute ReV for CrVI will allow the TCEQ to more fully evaluate available monitoring data and is more consistent with the longer exposure duration studies available in the toxicological database for identification of a human point of departure (PODHEC)." Availability of monitoring data and consistency with studies available in the toxicological database are inadequate justifications for development of a 24-hour acute ReV.

### **TCEQ Response:**

The TCEQ has developed final and/or draft 24-hour values for several other chemicals (e.g., formaldehyde, benzene, 1,3-butadiene, acrolein). Air Alliance Houston indicates that the availability of air monitoring data and consistency with available toxicity studies are inadequate justifications for development of a 24-hour value. This statement, however, is illogical as these facts go to the utility of the value and the very ability to derive a 24-hour health-based value in the first place. A regulatory agency cannot derive a health-based value for a given duration if toxicity studies relevant to that duration are not available, and the fact that there are monitoring data of that duration increase the utility of the health-based value.

### **Comment 8:**

First: availability of monitoring data. ReVs are defined in TCEQ guidance as, "the health-based values used in the evaluation of ambient air monitoring data and in the calculation of health-based ESLs." This definition indicates that ReVs are "health-based" and that they are used to evaluate air monitoring data. It would seem to get things backward to base an ReV not on health impacts but on availability of air monitoring data.

### **TCEQ Response:**

Entirely consistent with the cited definition of a ReV, the proposed 24-hour health-based values are going to be used for the evaluation of available ambient air data and the calculation of health-based ESLs. Additionally, Air Alliance Houston incorrectly alleges that the 24-hour ReV is not based on health but rather the availability of monitoring data, which seems to demonstrate a lack of understanding of the scientific basis of the health-based values. Through the discussion and consideration of various health endpoints, the proposed DSD makes it abundantly clear that the 24-hour ReV is based on the potential for adverse health effects. For example, in Table 1 on page 1, an increase in relative lung weight is cited as the critical adverse health effect basis for the 24-hour ReV. Thus, it is abundantly clear that the value is based on the potential for adverse health impacts. There is always a duration associated with a health-

based value (e.g., 1-hour, 24-hour, chronic). The consideration of a 24-hour sampling duration for metals only helped to identify the duration of greatest utility for which to develop a health-based value. For example, although 90-day toxicity studies are common, regulatory agencies do not typically derive 90-day health-based values as they are of limited utility, but may derive chronic values based on such studies in consideration of the greater utility of chronic values. Regulatory agencies derive health-based values that are useful for the duration of interest, which is what the TCEQ did in the present case.

In fact, TCEQ guidance on development of ReVs does permit use of other durations for purposes of evaluating air monitoring data. TCEQ's guidelines state that, "If other short-term exposure durations are needed to evaluate air monitoring data, then acute ReVs may be developed using other averaging times; however, the appropriateness of such a ReV will need to be evaluated using the guidelines in Chapter 4."

### **Comment 9:**

Chapter 4 of the Guidelines discusses development of other averaging times using "duration adjustments." Chapter 4 outlines a specific rule for conducting duration adjustments. Chapter 4 does not suggest that, once other short-term exposure durations are used to calculate a new ReV, the old ReV should be discarded. Rather, it seems to suggest that duration adjustments should be applied to a given ReV as necessary according to a prescribed rule. In this case, TCEQ has discarded the existing ReV with 1-hour duration in favor of a 24-hour ReV. The DSD fails to evaluate the appropriateness of this 24-hour ReV using the guidelines in Chapter 4 of the guidance. For this reason, use of a 24-hour ReV in place of a 1-hour ReV is improper.

### **TCEQ Response:**

The first part of these comments simply indicates that the guidelines anticipated derivation of health-based values of different durations for the evaluation of air monitoring data and that the appropriateness of such values should be determined using duration adjustment considerations under Chapter 4 of the TCEQ guidelines. Chapter 4 does not specifically address 24-hour values, although it addresses relevant considerations in deciding how to conduct duration adjustments from longer-to-shorter durations (e.g., 24-hour to 1-hour). When concentration and duration both play a role in toxicity as with increased lung weight due to CrVI exposure, then Chapter 4 indicates that Haber's rule with an "n" value of 3 is to be used to adjust from a longer to a shorter exposure duration (e.g., > 1-h to 1-h). Ironically for Air Alliance Houston, this guidance would suggest that the point of departure (POD) air concentration should perhaps be increased through a similar dosimetric adjustment (e.g., from the 30-day study to 1-day) and highlights the conservatism of the TCEQ not conducting such an adjustment (e.g., an adjustment pursuant to Chapter 4 could increase the 24-hour ReV by approximately 3.1-fold). Thus, consideration of and strict adherence to the specific guidance in Chapter 4 pursuant to the Air Alliance Houston comment could justify a higher 24-hour ReV value (e.g., approximately 4.0 µg/m<sup>3</sup> as opposed to the 1.3 µg/m<sup>3</sup> value proposed). More relevant, the TCEQ has finalized the TCEQ Guidelines



to Develop 24-Hour Inhalation Reference Values

(<https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/whitepaper/24hr.pdf>), which is consistent with the conservative decision in the proposed DSD to use a POD from a subacute multi-day study as a 24-hour POD.

Lastly, the TCEQ has never derived a 1-hour, health-based ReV for CrVI, so is not discarding one. The agency currently only has a 1-hour ESL which while very health protective, is not health based but rather based on the air dispersion modeling relationship between the conservatively modeled, worst-case 1-hour value and the corresponding annual average (i.e., “protection” of the annual average).

Second: consistency with studies available in the toxicological database. Chapter 4 of the Guidelines also proscribes minimum database requirements for development of an acute ReV. Two studies were identified as key studies for CrVI particulate compounds: Glaser et al. 1990 and 1985. These studies are described in the DSD as “very similar” and are both inhalation bioassays performed on male Wistar rats.

The DSD assigns an uncertainty factor for database uncertainty of UFD = 1, reasoning that, “while the acute database is limited, database quality is medium to high for intermediate duration exposure and a much longer duration exposure study (30 d subacute exposure, 22 h/d) was used to determine a 24-h acute ReV.” The DSD describes this as a “very conservative” approach that mitigates the lack of more acute studies.

### **Comment 10:**

Second: consistency with studies available in the toxicological database. Chapter 4 of the Guidelines also proscribes minimum database requirements for development of an acute ReV. Two studies were identified as key studies for CrVI particulate compounds: Glaser et al. 1990 and 1985. These studies are described in the DSD as “very similar” and are both inhalation bioassays performed on male Wistar rats.

The DSD assigns an uncertainty factor for database uncertainty of UFD = 1, reasoning that, “while the acute database is limited, database quality is medium to high for intermediate duration exposure and a much longer duration exposure study (30 d subacute exposure, 22 h/d) was used to determine a 24-h acute ReV.” The DSD describes this as a “very conservative” approach that mitigates the lack of more acute studies.

The DSD fails to explain why the duration of an exposure study should have any impact on database quality. This is significant, as the chosen UFD of 1 is directly counter to the Guidelines, which assign a UFD of 1 only to “two inhalation bioassays in different species” or “two prenatal development toxicity studies in different species.” The database available here justifies a UFD of 3-6, which is appropriate when database confidence is “medium to high” (which is how it is described in the DSD, see above) and when the database includes only “one inhalation bioassay in one species.” Indeed, a UFD of 3 is used in the chronic evaluation, for exactly the reasons listed above.

In conclusion, if it is appropriate to develop a 24-hour ReV due to available studies, a UFD of 3-6, not 1, is needed.

### **TCEQ Response:**

These comments take exception to the use of a database uncertainty factor (UFD) of 1 despite the very conservative approach of using a 30-day, 22 hours/day, 7 days/week study to derive a 24-hour value, citing only “one inhalation bioassay in one species” under Table 4-2 of the acute database guidelines. First of all, basing a 24-hour, health-based value on adverse effects induced by 660 hours of almost continuous exposure is very conservative indeed. Secondly, the 2012 TCEQ Guidelines to Develop Toxicity Factors did not envision (and therefore do not directly address) such a very conservative situation as developing a 24-hour value based on a 30-day, 22 hours/day, 7 days/week study, so the database confidence ratings as presented rather simply in the guidelines do not capture other considerations such as the impact of using studies of much longer durations on the confidence in the database in terms of deriving a health-protective value. Because simple consideration of Table 4-2 as Air Alliance Houston did cannot solely be relied on for a cookie-cutter determination of the UFD value, the guidelines indicate “However, the basic summary information given in Table 4-2 and Table 5-2 may not accurately or adequately represent the completeness of the overall database for a given chemical, as many important details and considerations are not addressed. Therefore, use of these tables alone for this purpose would represent a significant oversimplification of the scientific judgment necessary for the UFD value selection process.” Moreover, more studies (including a rabbit study) are available in the intermediate exposure duration database than are discussed in the proposed DSD, which focuses on the critical studies and adverse effects, and Air Alliance Houston acknowledges that a UFD of 1 may be used when there are inhalation bioassays in two species.

Thus, in addition to inhalation bioassays being available in two species, the 24-hour value is conservatively calculated based on a 30-day, 22 hours/day, 7 days/ week exposure study using an intermediate duration database which is actually robust enough to derive a much longer duration health-based value (e.g., 14-364 day intermediate inhalation MRL in ATSDR 2012). This is a very conservative (i.e., health-protective) approach that mitigates the lack of more acute (i.e., < 1 d) studies. A medium to high confidence database for the intermediate duration exposure combined with the very conservative approach of using a much longer duration exposure study (30 d subacute exposure, 22 h/d) to derive the 24-hour acute ReV makes a UFD greater than 1 unnecessary. Consequently, not only is a UFD of 1 justified and the 24-hour ReV conservative, but the TCEQ could have just as easily derived a similar value based on the same study for a much longer duration. The TCEQ is highly confident that the proposed 24-hour ReV is not only health protective but quite conservative and perhaps more appropriately could have been applied to a much longer duration given the study exposure duration of 30 days, 22 hours/day, 7 days/week (660 hours). In regard to the TCEQ using a UFD of 3 for the chronic evaluation, the database available for the chronic evaluation was unlike that available for the acute evaluation where a much longer duration study (30 day) than the duration of interest (1

day) from a more robust database (intermediate exposure duration database) could be used to conservatively identify a POD.

### **Comment 11:**

III. The Dramatic Increase in the Short-Term Standard is not Justified

The proposed short-term health standard for CrVI is 1.3 µg/m<sup>3</sup>. The existing short-term standard is 0.1 µg/m<sup>3</sup>. This represents an increase of some thirteen times over the existing standard. This increase is complicated by the fact that the existing standard is based on a 1-hour exposure duration, whereas the proposed standard is based on a 24-hour duration. Such a dramatic increase in a health standard requires significant justification that is lacking here. Indeed, the DSD repeatedly states that health effects studies of CrVI are limited.

### **TCEQ Response:**

The TCEQ strongly disagrees with the statement by Air Alliance Houston that TCEQ has not offered adequate justification for the proposed values. The 101-page proposed DSD more than adequately documents the scientific justification for all proposed health-based values. In regard to the database, while the DSD indicates that acute studies are limited, it further indicates that intermediate (e.g., subacute) exposure duration studies can be used to identify an appropriate POD for derivation of short-term, health-protective air concentrations for CrVI. As explained in an earlier response, although certainly health protective, the current 1-hour ESL is not health based. That is, it is based on an air dispersion modeling relationship (with the 1-hour value helping to ensure compliance with the long-term average) instead of specifically the potential adverse health effects due to a 1-hour exposure period, which would result in a higher value as it did in the proposed DSD. Consequently, a comparison of the current 1-hour ESL to the proposed health-based, 24-hour values is entirely apples-and-oranges as the proposed 24-hour values are truly health-based while the previous 1-hour ESL was not.

Furthermore, the proposed 24-hour values are clearly health protective; using a 24-hour value based on protecting against adverse health effects resulting from 660 hours of exposure (30 day, 22 hours/day, 7 days/week) is entirely and obviously conservative. A comparison of the TCEQ 24-hour ReV to an Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk level (MRL) may help put the value into perspective here especially since the same study was used. ATSDR (2012) contains an intermediate duration inhalation MRL of 0.3 µg/m<sup>3</sup>, which is considered health protective for up to 364 days of exposure. So while ATSDR's intermediate MRL is applicable for a duration up to 364 times longer than TCEQ's 24-hour value, it is only 4.3 times lower. Thus, while ATSDR's value is applicable to a duration orders of magnitude longer than TCEQ's value (resulting in doses orders of magnitude higher), they differ by less than an order of magnitude. This highlights the conservativeness of the TCEQ 24-hour value.

## **Comment 12:**

### **A. Comparison to the OSHA Standard Suggest the Proposed Standard is Inadequate**

In 2006, the Occupational Safety and Health Administration (OSHA) completed a review and revision of its standard for worker exposure to hexavalent chromium. OSHA settled on an 8-hour exposure standard of 5 µg/m<sup>3</sup>.

In earlier comments to this proposal, a commenter asked for a comparison to the OSHA standard. A reviewer from TCEQ provided the following response (excerpted in part): If OSHA's PEL of 5 µg CrVI/m<sup>3</sup> is converted to an environmental continuous exposure corresponding to an extra risk of 1 in a 100,000, then the equivalent concentration is  $5 \times (45/70) \times (5/7) \times (8/24) \times (0.00001/0.001) = 0.0077 \mu\text{g CrVI/m}^3$ , which is only 1.78-fold greater than the value of 0.0043 µg CrVI/m<sup>3</sup> derived by TCEQ (this calculation assumes that OSHA is also using 70 years as the age for risk calculations and that there are no other adjustments that OSHA may have done).

This comparison to the OSHA standard shows that it is only 1.78 times greater than the chronic exposure factor developed by TCEQ. This is troubling, as OSHA standards are for healthy adults facing exposure in a work environment. The TCEQ standard, by comparison, is intended to protect people—including children—who face involuntary exposures in ambient air. In Houston, we know that there are homes adjacent to metal recycling facilities that have significant CrVI emissions. Members of the public face exposure to CrVI every day. Their children breathe more, relative to their body weight, than adults. This is a very different set of circumstances than that which an OSHA standard contemplates.

Furthermore, the OSHA standard—a Permissible Exposure Limit (PEL)—is very different from the Recommended Exposure Limit (REL) developed by the National Institute for Occupational Safety and Health (NIOSH). PELs are based on a variety of factors, including political considerations. RELs, by contrast, are based on the best available science. The NIOSH limit is 0.2 µg/m<sup>3</sup>, well below the 1.3 µg/m<sup>3</sup> proposed here.

## **TCEQ Response:**

The TCEQ disagrees that the OSHA standard is only 1.78 times greater than the TCEQ chronic ESL. The OSHA standard of 5 µg CrVI/m<sup>3</sup> is 1,163 times greater than the TCEQ's chronic ESL of 0.0043 µg CrVI/m<sup>3</sup>. Since Air Alliance Houston is intent on making a comparison based on converting the much higher OSHA standard to an environmental concentration, a more appropriate basis for comparison of the levels to which workers and the public may be exposed is the corresponding lifetime average exposure levels for the two values (e.g., the comparison made in the comment, for example, obscures the fact that OSHA uses a higher risk level since this was adjusted away in the conversion). For the OSHA PEL, this is given by permissible occupation exposure averaged over the lifetime, which equates to  $5 \mu\text{g/m}^3 \times (45/70 \text{ years}) \times (5/7 \text{ days}) \times (8/24 \text{ hours}) = 0.765 \mu\text{g/m}^3$  as occupational exposure converted to a continuous lifetime exposure level. This is the analogous value to a long-term ESL, which is also derived on the basis of a continuous lifetime exposure. The TCEQ long-term ESL of 0.0043 µg/m<sup>3</sup> is 178 times lower than the OSHA standard converted to a continuous lifetime exposure level (0.765

$\mu\text{g}/\text{m}^3$ ), which is an apples-to-apples comparison and demonstrates the health protectiveness of the TCEQ chronic ESL.

The comment comparing the NIOSH REL to the proposed TCEQ 24-hour value demonstrates either a lack of familiarity with the use of such occupational values or a blatant disregard for it in order to make an inappropriate comparison. The NIOSH REL of  $0.2 \mu\text{g}/\text{m}^3$  is based on long-term risk rather than the potential for short-term (e.g., 24-hour) health effects. NIOSH (2013) states, "The REL is intended to reduce workers' risk of lung cancer associated with occupational exposure to Cr(VI) compounds over a 45-year working lifetime." Based on a straight comparison, the TCEQ's long-term ESL of  $0.0043 \mu\text{g}/\text{m}^3$  is 46.5 times lower than the NIOSH REL of  $0.2 \mu\text{g}/\text{m}^3$ , and when the REL is converted to a continuous lifetime exposure level ( $0.031 \mu\text{g}/\text{m}^3$ ) it is still 7.2 times higher.

The dose-response assessment which is the basis for the TCEQ long-term ESL underwent independent external expert peer review organized by Toxicology Excellence for Risk Assessment, external scientific peer review prior to being accepted by the prominent scientific journal Regulatory Toxicology and Pharmacology, and two rounds of public comment. Additionally, the TCEQ was asked to present the assessment at the 2014 Society of Toxicology conference, the largest and most prestigious toxicology conference with thousands of toxicologists from dozens of countries around the world. Furthermore, the assessment will soon be available on the International Toxicity Estimates for Risk (ITER) website (<http://www.tera.org/iter/>), which is part of the National Library of Medicine's TOXNET compilation of databases (<http://toxnet.nlm.nih.gov>), and USEPA indicated during the June 25, 2014 Integrated Risk Information System meeting on CrVI that they will consider the TCEQ assessment when conducting their own evaluation. In conclusion, the proposed long-term ESL is 2.3 times lower than the current long-term ESL ( $0.01 \mu\text{g}/\text{m}^3$ ) and is protective of the general population including children.

### **Comment 13:**

A few simple examples will help to illustrate why the proposed short-term standard is problematic. First, suppose a person were exposed to the short-term concentration of  $1.3 \mu\text{g}/\text{m}^3$  for 24 hours. Assuming a breathing rate of 5 liters per minute, this person would breathe in  $9.36 \mu\text{g}$  of CrVI during that 24 hours. Next, imagine a person exposed to the long-term concentration of  $0.0043 \mu\text{g}/\text{m}^3$  for one year. This person would breathe in  $11.3 \mu\text{g}$  of CrVI during that year. This means that someone exposed to the short-term limit for one day could inhale 83% of the CrVI that the long-term limit would allow in one year.

This is a surprising result. It is illogical that exposure to a short-term standard for 24 hours would permit 83% of the exposure that a long-term standard allows in one year. This is in contrast to the relationship created by the newly proposed short- and long-term standards for benzene, in which 24 hours of exposure at the short-term limit would result in 0.31% of exposure allowed by the long-term limit in one year. This is a dramatic difference in relationship between the short- and long-term limits for these pollutants.

Neither is it any consolation to claim that no individual will in fact be exposed to these concentrations for these lengths of time. First, there is not enough understanding of actual exposures throughout Texas to confidently make that claim. Second, there is no monitoring infrastructure in place to gain that understanding any time soon. Third, and most importantly, these standards define what exposure levels are permissible. If such a condition of exposure were to arise, an exposed individual would have no legal recourse against such exposure. That individual would receive a lifetime of exposure to CrVI in under three months.

### **TCEQ Response:**

The short- and long-term values are health based. As such, they bear no certain prescribed relationship or magnitude of difference. Depending on a chemical's short-term versus long-term toxicity, etc., the values will differ to varying degrees depending on the specific chemical (e.g., CrVI, benzene). Prior to 2006, almost all short- and long-term values were made to differ by a factor of 10, with the long-term ESL typically being the health driver and determinant of the short-term ESL, which was often unduly conservative as a result (as in the present case). However, although known to the TCEQ to generally be conservative, the agency's process for deriving values was often criticized as not being adequately health based. To fully address this criticism, the 2006 and now the 2012 TCEQ Guidelines to Develop Toxicity Factors were developed to provide guidance for deriving the most scientifically defensible health-based values possible. Consequently, short- and long-term values derived under the guidelines like the 24-hour ReV and long-term ESL for CrVI are purely health based and have no artificially prescribed magnitude of difference (i.e., it depends on the short- versus long-term toxicities of the chemical). Ironically, the commenter appears to be seeking a 24-hour value that is not health based but rather one that helps ensure compliance with the long-term ESL, despite a previous contradictory comment that "it would seem to get things backward to base an ReV not on health impacts..." citing that the definition indicates that ReVs are health based. This would be tantamount to reverting to the same process for which the TCEQ was previously criticized by similar organizations, when short-term values were not based specifically on the potential for adverse health effects due to short-term exposure (although they were known to be health protective) but were set unduly low to protect the long-term average. Consistent with the TCEQ 2012 guidelines, the 24-hour ReV for CrVI is based specifically on protecting against short-term adverse health endpoints (actually resulting from a 30-day exposure) and not on ensuring compliance with the long-term ESL, which is 302 times lower but is based on lifetime exposure (not one year as in the second paragraph of the comment).

Although Texas has the most extensive ambient air monitor Although Texas has the most extensive ambient air monitoring network in the nation by far, providing more than 23 million data points per year (<http://www.tceq.state.tx.us/airquality/airsuccess/air-success-toxics>), knowledgeable toxicologists and risk assessors know that the availability of air monitoring data has no bearing on the numerical values derived for health-protective values based on the critical adverse health effects demonstrated in key toxicological studies (e.g., the availability or

lack of widespread monitoring does not affect the numerical values of USEPA toxicity factors). In regard to a person receiving a lifetime of exposure to CrVI in three months having no legal recourse, such an exposure would be associated with emissions that would clearly violate the facility's air permit as there is noncompliance at the point when the annual average can no longer comply with the long-term ESL due to the short-term emissions that have already occurred. ing network in the nation by far, providing more than 23 million data points per year (<http://www.tceq.state.tx.us/airquality/airsuccess/air-success-toxics>), knowledgeable toxicologists and risk assessors know that the availability of air monitoring data has no bearing on the numerical values derived for health-protective values based on the critical adverse health effects demonstrated in key toxicological studies (e.g., the availability or lack of widespread monitoring does not affect the numerical values of USEPA toxicity factors). In regard to a person receiving a lifetime of exposure to CrVI in three months having no legal recourse, such an exposure would be associated with emissions that would clearly violate the facility's air permit as there is noncompliance at the point when the annual average can no longer comply with the long-term ESL due to the short-term emissions that have already occurred.

#### **Comment 14:**

IV. The Long-Term Health Standard is also Inadequate

A. The Endpoints and Uncertainty Factors Used for the Chronic Evaluation are Problematic, as are the Comparisons with other Factors

The DSD includes a comparison of chronic toxicity factors developed by TCEQ, ATSDR, USEPA, CalEPA, and ChemRisk. These comparisons are problematic, as each agency used different endpoint and different uncertainty factors, and arrives at a different chronic toxicity factor. Typically, an endpoint is chosen based on the first adverse health effects that can be seen upon exposure to a toxic chemical. The DSD uses as its endpoint increase in relative lung weight. The DSD states that this endpoint is "associated with a level of change considered more clearly adverse." The DSD also states that the endpoints used in other evaluations are plagued with uncertainty. Given that there is an admitted lack of studies on the health effects of CrVI, we would expect a more clear justification for the selection of an endpoint that is not used in any comparable evaluations.

Similarly, an uncertainty factor of 270 used in the chronic evaluation and is then compared to other evaluations that used UFs ranging from 30 to 300. The DSD does point out that USEPA and ChemRisk used uncertainty factors of 300, but it fails to explain the significance of UFs of 30 and 100 in the ATSDR and CalEPA studies. Instead, the DSD simply compares the chronic toxicity factor developed by each agency and concludes that TCEQ's is adequate because it falls between certain others. This comparison cannot be made without a more thorough discussion of the significance in the use of different uncertainty factors and endpoints.

## TCEQ Response:

First, there is not a “lack of studies on the health effects of CrVI.” If this were the case, agencies would not be able to derive toxicity factors in the first place. The toxicity database for CrVI covers many studies in several species (although the DSD need not discuss them all) and is sufficiently robust for the TCEQ and other agencies (e.g., ATSDR, USEPA) to calculate toxicity factors. Secondly, the TCEQ strongly disagrees that the comparisons of chronic toxicity factors from different agencies are problematic as different endpoints and uncertainty factors (UFs) were used.

One of the most important steps of a risk assessment is to identify a critical effect that is truly adverse as opposed to being an adaptive response. The 2012 TCEQ Guidelines to Develop Toxicity Factors provide a detailed discussion on the topic and we encourage a review of the guidelines. The two key studies (Glaser et al 1985 and 1990) presented results for multiple endpoints that included: relative organ weights (e.g., lung and spleen), biochemical (e.g., BALF analysis, total protein in BALF, LDH), and other changes (e.g. leucocyte count and accumulation of macrophages). While a ten percent change in organ weight (normalized to body weight) is used to define adversity in regulatory chemical risk assessments, such clear and transparent demarcations are not yet available for the other changes (e.g., biochemical). Because of the critical absence of criteria for classification as to adversity, the TCEQ considers the concentrations associated with other changes (e.g., biochemical, cell counts) as Lowest Observed Effect Levels (LOELs) as opposed to Lowest Observed Adverse Effect Levels (LOAELs). Additionally but less importantly, there was a lack of a clear dose-response for endpoints such as LDH and albumin in BALF. The TCEQ however, considered all the biochemical changes and changes in the macrophage count and leucocyte count as adding to the weight-of-evidence (WOE) for CrVI-induced increases in relative lung weight. In regard to lung weight, an increase in the relative lung weight (normalized by BW) with increase in dose was reported in both key studies. The increase in lung weight began at 50 µg CrVI/m<sup>3</sup> and continued with the higher dose groups clearly indicating a good dose-response. The bottom line in regard to use of this endpoint as the critical effect is that the increase in lung weight was dose dependent, statistically significant, and is considered biologically significant and adverse for purposes of regulatory chemical risk assessment. The biochemical changes do not have these important attributes for use as critical effects.

Providing comparisons of the available toxicity factors is often recommended as a “Best Practice” to regulatory agencies. The TCEQ provided these comparisons only for informational purposes because although agencies follow the same general principles of risk assessment, they might differ from each other somewhat in scientific judgment and methodology, which might consequently result in different values. It is not the purpose of the DSD to provide detailed discussions of each of the agencies use of specific endpoints and UFs but to provide a brief discussion of the available values. However, what it does show is that despite different endpoints and UFs, the TCEQ and CalEPA derived chronic values that are essentially identical and are also very similar to other values (e.g., USEPA). Thus, the bottom line is that there was no appreciable significance in the various agencies having used different uncertainty factors and endpoints as ultimately the values were very similar.



## **Comment 15:**

### **B. The EPA's Risk Level is Dramatically Different**

The Environmental Protection Agency lists a quantitative estimate of carcinogenic risk from inhalation exposure to CrVI in its Integrated Risk Information System. For a risk level of 1 in 100,000—the same risk level the TCEQ uses—the EPA gives a concentration of 0.0008 µg/m<sup>3</sup>. The TCEQ's 1 in 100,000 risk concentration is five times higher at 0.0043 µg/m<sup>3</sup>.

This carcinogenic risk was developed by EPA based on a unit risk factor (URF) of 0.012 per µg/m<sup>3</sup> and a 1975 study. TCEQ acknowledges this URF and the study, which it calls outdated. TCEQ developed its own URF of 0.0023 per µg/m<sup>3</sup>, again differing from the EPA value by a factor of five. TCEQ also compares its value not to EPAs, but to the PEL established by OSHA.

## **TCEQ Response:**

The basis for USEPA's 1984 URF is outdated and indubiously inferior, and it is for this reason that the TCEQ and other agencies have used better, more recent scientific studies to assess the carcinogenic risk associated with CrVI inhalation. With entirely different bases for the URFs, the TCEQ and USEPA values are incomparable other than to be able to determine the numerical difference between USEPA's outdated value and the TCEQ's URF based on superior studies and analyses. Given this, the difference is less than dramatic. Secondly, the comment that the TCEQ compares its value to the OSHA PEL and not to USEPA's URF is untrue, in fact, just the opposite is true (see Section 4.2.3.1.9.1 of the proposed DSD). Section 4.2.3.1.9.1 of the proposed DSD was where the TCEQ compared its URF to others, and a comparison was only made to USEPA's 1984 value. In fact, OSHA is not even cited in that section. Also, please see the TCEQ's Response to III.A., which discusses an OSHA PEL conversion that the TCEQ was asked to provide by a previous commenter but is not contained in the proposed DSD.

## **Comment 16:**

### **V. Comparison to the ChemRisk Study is Troubling**

It is troubling that TCEQ relies in part on CrVI evaluations performed by ChemRisk. ChemRisk's work on CrVI has been hugely criticized. In a lawsuit made famous by the movie "Erin Brockovich," Pacific Gas and Electric (PG&E) was sued over CrVI contamination in groundwater. During the litigation, PG&E hired ChemRisk as a consultant. ChemRisk distorted the results of a Chinese study on CrVI exposure and published their interpretation in a scientific journal over the objections of the original study's authors. ChemRisk was widely criticized and accused of fraud for their actions. ChemRisk's misdeeds were chronicled in a 2005 study by the Environmental Working Group, "Chrome Plated Fraud."

## **TCEQ Response:**

The TCEQ strongly disagrees with *the comment that it relied in part on CrVI evaluations performed by ChemRisk; this Air Alliance Houston comment is a false statement.* The proposed DSD included detailed explanations of why a particular endpoint or critical adverse effect was chosen. The TCEQ conducted its own systematic review and a detailed analysis of all the available toxicity data for CrVI. The TCEQ provided clear reasoning of why it chose increase in relative lung weight as the critical adverse effect. In addition, dose-response data from biochemical and other changes were discussed (with appropriate references) and modeled by the TCEQ. In fact, while the USEPA and ATSDR did not, the TCEQ conducted its own Benchmark Dose modeling (BMD) and Multiple Path Dosimetry (MPPD) modeling using the Glaser et al. 1985 and 1990 studies to determine better estimates for potential extrapolation of animal data to humans.

*It is ATSDR and USEPA that relied on the same study as Chemrisk did (Malsch et al. 1994), not the TCEQ.* For example, the ATSDR (2012) toxicological profile for CrVI reports the following statement “Results of the benchmark concentration (BMC) analysis of the Glaser et al. (1990) data conducted by Malsch et al. (1994) were identified as the basis for derivation of an intermediate-duration inhalation MRL for hexavalent chromium particulate compounds.” Similarly, the USEPA reported the following in the CrVI IRIS assessment, “ One approach for development of an RfC using the data of Glaser et al. (1985, 1990) was offered by Malsch et al. (1994), who generated an inhalation RfC for chromium dusts using a benchmark concentration (BMC) approach. The Agency developed its RfC for particulates based on this approach.” Thus, ATSDR and USEPA both relied on the Malsch et al. (1994) analysis, as did Chemrisk. *Contrary to the Air Alliance Houston comment, the TCEQ did not use the Chemrisk evaluation or the Malsch et al. (1994) analysis results made basis of Chemrisk’s evaluation in any way in deriving TCEQ values, but rather the TCEQ entirely conducted its own evaluation (e.g., identification of critical adverse effects, BMD and MPPD modeling) that provided the sole basis for derivation of TCEQ values.*

## **Comment 17:**

In conclusion, we simply do not understand why TCEQ has undertaken this revision of the hexavalent chromium standard. Given the uncertainty about facilities that emit CrVI, the uncertainty surrounding studies of the health impacts of CrVI, and the lack of an adequate CrVI monitoring network, it is simply baffling that TCEQ would undertake this revision now.

## **TCEQ Response:**

In regard to potential health impacts, the toxicity database for CrVI covers many studies in several species (although the DSD need not discuss them all) and is sufficiently robust for the TCEQ and other agencies (e.g., ATSDR, USEPA) to calculate toxicity factors. The TCEQ refers Air

Alliance Houston to the underlying science in the DSD which more than adequately documents the *scientific* rationale for these *health-based* values. As stated previously, what industries emit CrVI and what technologies are, or are not (see previous comment), available for the TCEQ to continuously monitor for a chemical are irrelevant to the scientific soundness of the *health-basis* of a toxicity factor. For example, these peripherally related topics have no relevance to the evaluation of the dose-response data in relevant toxicity studies, the identification of critical adverse effects, etc., but rather simply reflect concerns about the number and types of facilities that health-based values should be applicable to.

Since Air Alliance Houston indicates “it is simply baffling that TCEQ would undertake this revision now,” the TCEQ notes that among other activities, in 2006 CrVI was listed as a chemical under consideration for DSD development, in 2011 an email was sent out on the Tox listserve soliciting information, and in February 2014 another email was sent out when the proposed DSD was posted. Thus, a proposed DSD with new values should be no surprise to interested parties. Lastly, while the TCEQ is most specifically requesting scientific and technical comments on the scientific defensibility of the health-based values, these and similar Air Alliance Houston comments on mere peripherally related issues (e.g., monitoring, number and type of facilities, TRI self reporting) seem to demonstrate a lack of understanding of the scientific bases of health-based values.

## **Houston Department of Health & Human Services Comments**

### **Comment 1:**

Here are issues that we believe are not adequately addressed in the proposed Cr(VI) standard and need to be examined more closely before the proposed change should be considered for final acceptance: 1) the proposed short term 24 hr AMCV of  $1.3 \mu\text{g}/\text{m}^3$ ; and 2) the short term ESL of  $0.39 \mu\text{g}/\text{m}^3$  are too high.

The list of Cr(VI) sources referenced in the TCEQ document and the EPA’s Toxic Release Inventory (TRI) is incomplete and under counts possible exposures within any given community as a result. For example, sources may be found adjacent to neighborhoods in Houston that are not on the source list. Such sources include many facilities doing torch cutting or welding outside, without any emissions controls, that seldom operate under an air permit (other than permit by rule) and yet the Houston Department of Health and Human Services’ Bureau of Pollution Control & Prevention (BPCP) has measured total chromium emissions levels offsite ranging anywhere between  $0.1$  and  $2.0 \mu\text{g}/\text{m}^3$  over a typical 8 to 10 hour work day.

The EPA Toxic Release Inventory (TRI) which is referenced, as one data source, involves mostly self-reported data. The TRI does not include outdoor welding and torch cutting activities that may generate significant levels of Cr(VI), especially when the material being welded or cut may contain up to 30% chromium in some alloys. Such emissions are well documented, as there have been numerous industrial hygiene studies conducted for the U.S. Navy and others that measured high levels of Cr(VI) release when working with stainless steel and other high chromium alloys. One such study is “Metal Cutting Operations: Emission Factors for

Particulates, Metals and Metal Ions” by Bhaskar Kura at the University of New Orleans, Anthony S. Wisbith from Battelle, Richard Stone at the Puget Sound Naval Shipyard and Tom Judy at the Naval Surface Warfare Center, Bethesda MD.

### **TCEQ Response:**

What industries emit CrVI and are subject to the various permitting requirements is irrelevant to the scientific soundness of the *health-basis* of a toxicity factor (e.g., the evaluation of the dose-response data in relevant toxicity studies). The DSD more than adequately documents the scientific rationale for these health-based values. The list of CrVI sources provided in the proposed DSD is for general informational purposes only (i.e., is not used by the TCEQ in any capacity) and has absolutely no bearing on the scientific or health basis of the values. Similarly, any self-reported emissions data have no bearing on the scientific or health basis of the values proposed in the DSD. Lastly, total chromium ambient air concentrations are irrelevant to the *scientific health basis* (e.g., the evaluation of the dose-response data in relevant toxicity studies) of the 24-hour ReV. The only relationship is a peripheral one, that ambient air concentrations are evaluated using health-based values. Along these lines, *total chromium* air concentrations of 0.1-2.0  $\mu\text{g}/\text{m}^3$  over an 8-10 hour workday do not demonstrate exceedance of the proposed 24-hour ReV for *hexavalent chromium* of 1.3  $\mu\text{g}/\text{m}^3$  (e.g., even if assumed to be 100% CrVI as worst-case, an 8-10 hour workday concentration of 2.0  $\mu\text{g}/\text{m}^3$  would correspond to a 24-hour level of about 0.83  $\mu\text{g}/\text{m}^3$ ) and realistically would likely be expected to meet the 1-hour chromium ReV of 12  $\mu\text{g}/\text{m}^3$  ([https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/final/october09/chromium3\\_16065-83-1.pdf](https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/final/october09/chromium3_16065-83-1.pdf)).

### **Comment 2:**

The proposed 24 hour AMCV standard of 1.3  $\mu\text{g}/\text{m}^3$  is too high because it could allow a community exposure that is equivalent to 82.7% of the long term AMCV exposure in only one day. Although there are a few facilities that monitor emissions for Cr+VI periodically, to my knowledge there is little or no continuous monitoring being done and the smaller sources that operate under PBRs often do little or no monitoring beyond their fence line and are seldom actively monitored by any environmental agency. By significantly elevating the threshold of proof by which we could identify an emission as unacceptable, this proposal would hinder our ability to effectively respond, troubleshoot, or recommend corrective action in response to citizens' complaints due to emissions from neighboring facilities or sources that contain elevated Cr(VI).

If you compare the total Cr(VI) limit that this proposal would allow in 24 hours to that of one year, you may better understand our concern. The proposed 24 hr AMCV limit of 1.3  $\mu\text{g}/\text{m}^3$  x 24 hours = 31.2  $\mu\text{g}$  per day Cr(VI), while the proposed annual limit is 0.0043  $\mu\text{g}/\text{m}^3$  x 24 hours x 365 days = 37.7  $\mu\text{g}$  Cr(VI) per year. Allowing the possibility of such excess exposure for even one

day puts neighboring communities at elevated risk; it also makes it very difficult to document an overexposure because of the rigors of testing for Cr(VI) that greatly complicate the process.

### **TCEQ Response:**

This comment demonstrates an inherent misunderstanding of air permitting in Texas and elsewhere. *The bottom line is that because the new lower chronic ESL will have to be complied with, short-term facility emissions will have to be more severely limited through enforceable air permit limits so that the long-term average can meet the new lower chronic ESL.* Thus, regardless of the proposed 24-hour health-based values, short-term air permit emission limits will have to be even more restrictive than they are currently. Lastly, the lack of facility continuous CrVI monitoring (e.g., USEPA-approved, automated continuous CrVI monitors are not commercially available) is not relevant to the scientific health basis of a comparison value, and air monitoring is not the method used most often by the TCEQ to identify unacceptable emissions. In fact, the review of facility records (e.g., production) is the most common method used to monitor and identify noncompliance with permit limits, resulting in enforcement actions, and the documentation of nuisance conditions by field staff is a readily available tool to respond to citizen complaints and is also commonly used in enforcement actions.

### **Comment 3:**

With Cr(VI) testing in mind, there is a significant discrepancy between the current EPA methodology for Cr(VI) measurement in air and the NIOSH or OSHA methods. The EPA ambient air method uses a similar ion chromatography analytical procedure to that of OSHA & NIOSH, but the ERG study conducted for the EPA to evaluate the method drew conclusions substantially different from those reached by NIOSH or OSHA as to sample stability, recommended collection media and method interferences. Because the EPA method was aimed primarily at monitoring chrome plating emissions that do not have significant interfering elements present, many real world samples, such as those produced by welding and torch cutting, have 10 to 600 times more Iron (Fe) than Chromium (Cr) and accurately measuring Cr(VI) levels in such samples can be a real challenge. If we acknowledge this measurement challenge then we should require a more health protective AMCV and ESL short term limit, not a less protective limit. It is an important concern to BPCP that the above discussed points be factored into TCEQ's proposed and final actions, so that the health of citizens residing in close proximity to emitters of Cr(VI) be best protected, which will assist local agencies such as BPCP in best responding to citizens' complaints.

### **TCEQ Response:**

The scientific defensibility and soundness of a health-based comparison value (e.g., the evaluation of the dose-response data in relevant toxicity studies) and the potential analytical challenges pertaining to one method of demonstrating compliance with that value are completely different issues. For example, potential accuracy, precision, and uncertainty (e.g.,

potential interference) issues are to be addressed by the analytical laboratory (e.g., data usability summary, control samples, flagged data, etc.). The TCEQ believes in using the best science possible to derive only the most scientifically sound *health-based* comparison values, which specifically pertain to the critical adverse health effects observed in toxicity studies (not potential monitoring issues).

#### **Comment 4:**

It is not that we expect many facilities to actually generate  $1.3 \text{ ug/m}^3$  over a 24 hour period, but that the issue of documenting a problem at any facility will become much more difficult with the proposed higher limit and subsequently our ability to affect positive change for the affected communities is being jeopardized.

#### **TCEQ Response:**

Air monitoring is not the only method available to document conditions warranting action (e.g., unacceptable emissions). In fact, the review of facility records (e.g., production) is the most common method used by the agency to monitor and identify noncompliance with permit limits, resulting in enforcement actions. Additionally, the documentation of nuisance conditions by field staff is a readily available tool to respond to citizen complaints and is also commonly used in enforcement actions.

### **Recycling Council of Texas Comments**

#### **Comment 1:**

TCEQ's evaluation of the carcinogenic risks associated with inhalation exposure to hexavalent chromium has been comprehensive and thorough. This work has advanced the level of knowledge about health risks by inhalation exposure to hexavalent chromium and created a new standard that can be used widely and confidently by toxicologists, risk assessors, and regulators. We thank them for this highly professional document.

#### **TCEQ Response:**

The TCEQ appreciates comments that acknowledge the scientific defensibility of the health-based values as opposed to pertaining to peripherally related issues (e.g., monitoring, TRI) that are irrelevant to the scientific health basis and soundness of the health-protective values.

## Comment 2:

However, we wish to address some earlier public comments that are in the record in this matter. Specifically, some comments submitted by the City of Houston failed to correctly characterize certain data and risks related to emissions from recycling plants in Houston. We call your attention to the City of Houston comments and the TCEQ(2014b) responses on pages 26 and 27 of TCEQ Development Support Document Comments.

## COMMENT #2

In their Comment #2 the City stated that

“Hexavalent chromium (CrVI) is an important air toxic of concern in the City of Houston. ... as recently as 2012 it has been found in the ambient air downwind of some metal recycler facilities at unhealthy levels.”

The main reference to this comment is an article by Raun (2013). The referenced article differs slightly in title and order of the authors from the actual article published in 2013. We assume the content is reflected in the published article. The published article reported on a study through 2012 of a group of five metal recycling facilities in Houston, Texas, by the City of Houston’s Department of Health and Human Services. Using the City of Houston’s Mobile Ambient Air Monitoring Laboratory (MMAAL) data were collected downwind of five metal recycling companies for particulates, metals, VOCs, and meteorological data.

Data analyses and risk assessment calculations led to conclusions by those researchers that unanticipated cancer risks were present near these and, by extrapolation, near other similar recyclers throughout Houston. Most of the cancer risk was attributable to hexavalent Chromium, CrVI. The excess cancer risks were estimated to be  $1 \times 10^{-6}$  to  $8 \times 10^{-4}$ . In most cases, CrVI was responsible for more than 70% of that risk.

However, a major weakness in the analyses and risk assessments by Raun was the paucity of CrVI data available at the time of her analyses. Data collected for *one* metal recycler on *one* sampling date suggested a ratio of CrVI to Total Cr (Cr) of 0.085. This single ratio was then used to *estimate* CrVI from about 45 measurements of Total Cr at the five recyclers. As we

showed in our analysis of additional City data, the relationship between CrVI and Cr is not likely a simple ratio, and the original ratio appears not to be representative. As a result, the risks attributed to CrVI were substantially overestimated by Raun.

After the Raun paper was published, the City monitoring program continued, and the collection of more CrVI data was emphasized, so that, by April 2013, 14 pairs of data points for CrVI and Cr were available. Working with 14 pairs of data rather than only one, we were able to complete a more careful analysis of the critical ratio relating CrVI to Total Cr.

Using the URF proposed in the draft TCEQ document (TCEQ 2013) and the extended data base, we were able to calculate the lifetime cancer risk attributable to CrVI more carefully and to evaluate that risk more appropriately.

Our rebuttal points are as follows:

1. Our analysis showed the potential excess cancer risk is significantly lower than predicted in the Raun (2013) article (*See Attachment A, points 4 and 5*).
2. There never were “unhealthy levels” “...found in the ambient air downwind of some metal recycler facilities.” There never were levels in the plural sense, because there was only one actual CrVI data point. Moreover, the levels were not unhealthy by TCEQ risk criteria.

### **TCEQ Response:**

The TCEQ appreciates the submittal of this additional information. However, the scientific merit of TCEQ’s assessment of CrVI, as opposed to CrVI monitoring in TCEQ Region 12, was the subject of the agency’s request for public comments. As such, City of Houston comments pertaining to monitored levels and potential conclusions (with or without any major weaknesses) are not relevant to the scientific health basis of the proposed comparison values (i.e., they are only peripherally related issues in that health-based values are used to evaluate ambient air data).



### **Comment 3:**

#### **COMMENT #3**

In their Comment #2 the City stated that

“...the locations where the City of Houston has found elevated risk from ambient concentrations are residential...”

Our rebuttal points to this comment are similar:

1. Our analysis showed the risks posed from ambient concentrations of CrVI were not elevated as defined by TCEQ risk criteria.
2. There never were “elevated risk from ambient concentrations...” There never were concentrations in the plural sense, because there was only one actual CrVI data point, and the levels were not unhealthy by TCEQ risk criteria.

Our comments above are based on the work that Dr. Schaezler did for the Task Force. His work was contained in a research paper that we provided to the City of Houston last year. The conclusions section of that paper is attached (as “Attachment A”), and the full version is available should you seek a copy. (Schaezler, 2013).

We appreciate this opportunity to present our comments for the public record. We thank the TCEQ for their valuable work on the Chromium issue and for their consideration of invited and public comment.

#### **TCEQ Response:**

Please see the previous response.

#### **Public Comment from an Individual**

From: Douglas A. Schuler [mailto:schuler@rice.edu]

Sent: Wednesday, May 07, 2014 9:59 AM

To: TOX

Subject: chrome standards - do not weaken them

Hello TCEQ,

I am a concerned citizen of Texas. I heard a radio story about a week ago about the new rules on chromium in the air. It seems that you are developing a short term standard that is welcome by industry but not by the breathing public. It seems to be a standard that allows companies to refrain from making investments towards the public's health needs.

Please do not weaken the current short term standard.

Cordially,

Doug Schuler  
4112 Sunset Blvd, Houston, TX 77005  
Mr. Schuler,

**TCEQ Response:**

Thank you for your comment which expressed concern about the short-term toxicity factor increasing. The proposed 24-hour value is a health-based value derived under the TCEQ external expert peer-reviewed guidelines representing the state of the science, and is certainly health-protective (e.g., it is based on a study using a much longer 30-day, 22 hours/day, 7 days/week exposure duration study). The most important fact to understand is that because the long-term value is going down by 2.3 fold, regardless of what the short-term value is, the long-term value must be complied with and will more strictly limit short-term emissions because companies have to comply with both short-term and long-term air permit limits. That is, industry will have to meet the new lower long-term value, which will require short-term emissions to be lower than they are currently irrespective of the short-term value increasing. We hope this is helpful.

**Appendix**

**From:** [Raun, Loren - HHS](#)  
**To:** [Richner, Donald - HHS](#); [TOX](#)  
**Cc:** [Blanco, Arturo - HHS](#)  
**Subject:** RE: Comments on proposed TCEQ short term AMCV and ESL for Hexavalent Chromium  
**Date:** Saturday, May 03, 2014 2:10:29 PM

---

Don, You have done an excellent job explaining the issues that are of concern with sampling and potential enforcement even though an AMCV and ESL have no real regulatory authority.  
quick question, does this statement and the one after need a volume? 31.2 µg per day Cr(VI).

---

**From:** Richner, Donald - HHS  
**Sent:** Thursday, May 01, 2014 12:29 PM  
**To:** 'tox@tceq.texas.gov'  
**Cc:** adrian@airalliancehouston.org; Raun, Loren - HHS; Blanco, Arturo - HHS  
**Subject:** Comments on proposed TCEQ short term AMCV and ESL for Hexavalent Chromium

Dear Sir or Madam,

Here are issues that we believe are not adequately addressed in the proposed Cr(VI) standard and need to be examined more closely before the proposed change should be considered for final acceptance: 1) the proposed short term 24 hr AMCV of 1.3 µg/m<sup>3</sup>; and 2) the short term ESL of 0.39 µg/m<sup>3</sup> are too high.

- The list of Cr(VI) sources referenced in the TCEQ document and the EPA's Toxic Release Inventory (TRI) is incomplete and under counts possible exposures within any given community as a result. For example, sources may be found adjacent to neighborhoods in Houston that are not on the source list. Such sources include many facilities doing torch cutting or welding outside, without any emissions controls, that seldom operate under an air permit (other than permit by rule) and yet the Houston Department of Health and Human Services' Bureau of Pollution Control & Prevention (BPCP) has measured total chromium emissions levels offsite ranging anywhere between 0.1 and 2.0 µg/m<sup>3</sup> over a typical 8 to 10 hour work day.
- The EPA Toxic Release Inventory (TRI) which is referenced, as one data source, involves mostly self-reported data. The TRI does not include outdoor welding and torch cutting activities that may generate significant levels of Cr(VI), especially when the material being welded or cut may contain up to 30% chromium in some alloys. Such emissions are well documented, as there have been numerous industrial hygiene studies conducted for the U.S. Navy and others that measured high levels of Cr(VI) release when working with stainless steel and other high chromium alloys. One such study is "Metal Cutting Operations: Emission Factors for Particulates, Metals and Metal Ions" by Bhaskar Kura at the University of New Orleans, Anthony S. Wisbith from Battelle, Richard Stone at the Puget Sound Naval Shipyard and Tom Judy at the Naval Surface Warfare Center, Bethesda MD.
- The proposed 24 hour AMCV standard of 1.3 µg/m<sup>3</sup> is too high because it could allow a community exposure that is equivalent to 82.7% of the long term AMCV exposure in only one day. Although there are a few facilities that monitor emissions for Cr+VI periodically, to my knowledge there is little or no continuous monitoring being done and the smaller sources that operate under PBRs often do little or no monitoring beyond their fence line and are seldom actively monitored by any environmental agency. By significantly elevating the threshold of proof by which we could identify an emission as unacceptable, this proposal would hinder our ability to effectively respond, troubleshoot, or recommend corrective action in response to citizens' complaints due to emissions from neighboring facilities or sources that contain elevated Cr(VI).
- If you compare the total Cr(VI) limit that this proposal would allow in 24 hours to that of one year, you may better understand our concern. The proposed 24 hr AMCV limit of 1.3 µg/m<sup>3</sup>



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May 20, 2014

Toxicology Division, MC 166  
Texas Commission on Environmental Quality  
P.O. Box 13087  
Austin, TX 78711-3087

**Re: Comment on Development Support Document: Hexavalent Chromium and Compounds**

The undersigned organizations appreciate this opportunity to comment on the Development Support Document (DSD) for hexavalent chromium (CrVI). This proposal will weaken the health standards for CrVI, and TCEQ has not offered adequate justification for such a revision. The CrVI monitoring network in Texas is inadequate to monitor compliance with these standards, particularly with the chronic standard. Given the uncertainty about the health impacts of CrVI, and the inadequacy of the state's monitoring network, we recommend this revision not proceed.

**I. Available monitoring resources will not allow proper monitoring for compliance with these standards.**

**A. Texas' Monitoring Network Includes no Continuous Monitoring for CrVI**

In a recent interview on this proposal, TCEQ chief toxicologist Mike Honeycutt stated that the long-term standard is the more important of the two and the standard that will be tightened. "Because a company would need to meet both of those, the net result is actually, the value would be more stringent," Honeycutt said. "So it may appear that we'll be more lenient, but actually, when it's all said and done, it'll be more stringent."<sup>1</sup>

This statement could only be true (and we are not saying that it is) if there was a monitoring network in Texas to accurately monitor compliance with the long-term standards. No such monitoring network exists. Indeed, we are not aware of a *single* continuous CrVI monitor in the state of Texas.<sup>2</sup>

We are aware of 134 chrome electroplating facilities in Texas. The DSD indicates that TRI data identify some 200-300 facilities in Texas that produce or process chromium.<sup>3</sup> There are at least 170 metal recycling facilities in Houston alone. We are uncertain about which facilities process chrome or stainless steel, and which facilities employ torch cutting. We do know that many metal recycling facilities in Houston are located in or around communities, and that the City of Houston has received some 200 citizen complaints in the last five years. Given the uncertainty about even the scope of industry that emits CrVI, and the total lack of a continuous monitoring network, we do not understand why a lower standard should be proposed.

<sup>1</sup> Martin, Florian, "Air Quality Watchdog Worried About Proposed TCEQ Standard Change," KUHJ 88.7 FM (May 1, 2014) (available at <http://www.houstonpublicmedia.org/news/air-alliance-houston-worried-about-proposed-tceq-standard-change/>).

<sup>2</sup> See, e.g. <http://tceq.tspmgwebpl.tceq.texas.gov/8060/geotam/>.

<sup>3</sup> DSD p. 7.

## B. Self-Monitoring and Reporting is Inaccurate and Incomplete

The lists of CrVI sources referenced in the DSD, such as the EPA's Toxic Release Inventory are inaccurate and incomplete. As discussed above, there are a wide variety of sources in Houston, including small metal recyclers, welders, and torch cutters, that are in many cases adjacent to communities. Many of these facilities operate without permits, other on Permits by Rule. Many of these facilities do little to no air monitoring, especially on or beyond their own fences. The data they self report to TCEQ and EPA is unverified and likely undercounting actual emissions.

In the last several years, the City of Houston Department of Health and Human Services (HDHHS) has conducted air monitoring around 25 of the facilities for which the most community complaints were received. Facilities were sampled for eight-hour increments six to ten times over a period of eighteen months. Data from five of these facilities indicate that CrVI was found downwind 92% of the time. All told, HDHHS measured total chromium emissions levels offsite ranging anywhere between 0.1 and 2.0  $\mu\text{g}/\text{m}^3$  over a typical 8 to 10 hour work day.<sup>4</sup>

In other words, the scant CrVI monitoring that has been conducted in recent years has already monitored violations of the new proposed short-term health standard. If TCEQ has any recent CrVI monitoring data that contradicts these findings, we are not aware of it.

If the TCEQ does proceed with this revision, it must develop a plan to ensure that adequate monitoring resources are in place to monitor compliance with both the short- and long-term standards. A limit with no means of monitoring compliance is meaningless. If TCEQ has no plans to actually monitor compliance with its standards, then setting or revising them is an exercise in futility.

## II. The rationale for developing a 24-hour acute ReV is improper

As the TCEQ acknowledges, acute ReVs are usually based on a 1-hour exposure duration. This is true of the current acute ReV for Cr(VI) of 0.01  $\mu\text{g}/\text{m}^3$  and, as far as we are aware, for all of TCEQ's acute ReVs. In this proposal, TCEQ has developed a 24-hour acute ReV. In this proposal, the TCEQ states that, "development of a 24-h acute ReV for CrVI will allow the TCEQ to more fully evaluate available monitoring data and is more consistent with the longer exposure duration studies available in the toxicological database for identification of a human point of departure (PODHEC)."<sup>5</sup>

Availability of monitoring data and consistency with studies available in the toxicological database are inadequate justifications for development of a 24-hour acute ReV. First: availability of monitoring data. ReVs are defined in TCEQ guidance as, "the health-based values used in the evaluation of ambient air monitoring data and in the calculation of health-based ESLs."<sup>6</sup> This definition indicates that ReVs are "health-based" and that they are used to evaluate air monitoring data. It would seem to get things backward to base an ReV not on health impacts but on availability of air monitoring data.

In fact, TCEQ guidance on development of ReVs does permit use of other durations for purposes of evaluating air monitoring data. TCEQ's guidelines state that, "If other short-term exposure durations are needed to evaluate air monitoring data, then acute ReVs may be developed using other averaging times; however, the appropriateness of such a ReV will need to be evaluated using the guidelines in Chapter 4."<sup>7</sup>

<sup>4</sup> The full results of this study are published as: Ryan L. H, Pepple K., Hoyt D., Richner D, Blanco A, Li J. Community scale air pollution area source impact and public health: Neighborhoods identify an under-regulated area source of metal particulates. 2013; 41:70-7.

<sup>5</sup> DSD p. 8.

<sup>6</sup> Guidelines p. 3.

<sup>7</sup> "TCEQ Guidelines to Develop Toxicity Factors" (TCEQ 2012) at 4 ("Guidelines") (available at <http://www.tceq.texas.gov/publications/rg/bg-442.html>).

Chapter 4 of the Guidelines discusses development of other averaging times using "duration adjustments."<sup>8</sup> Chapter 4 outlines a specific rule for conducting duration adjustments. Chapter 4 does not suggest that, once other short-term exposure durations are used to calculate a new ReV, the old ReV should be discarded. Rather, it seems to suggest that duration adjustments should be applied to a Given ReV as necessary according to a prescribed rule. In this case, TCEQ has discarded the existing ReV with 1-hour duration in favor of a 24-hour ReV. The DSD fails to evaluate the appropriateness of this 24-hour ReV using the guidelines in Chapter 4 of the guidance. For this reason, use of a 24-hour ReV in place of a 1-hour ReV is improper.

Second: consistency with studies available in the toxicological database. Chapter 4 of the Guidelines also prescribes minimum database requirements for development of an acute ReV.<sup>9</sup> Two studies were identified as key studies for CrVI particulate compounds: Glaser et al. 1990 and 1985. These studies are described in the DSD as "very similar" and are both inhalation bioassays performed on male Wistar rats.<sup>10</sup>

The DSD assigns an uncertainty factor for database uncertainty of  $UF_D = 1$ , reasoning that, "while the acute database is limited, database quality is medium to high for intermediate duration exposure and a much longer duration exposure study (30 d subacute exposure, 22 h/d) was used to determine a 24-h acute 10 ReV."<sup>11</sup> The DSD describes this as a "very conservative" approach that mitigates the lack of more acute studies.

The DSD fails to explain why the duration of an exposure study should have any impact on database quality. This is significant, as the chosen  $UF_D$  of 1 is directly counter to the Guidelines, which assign a  $UF_D$  of 1 only to "two inhalation bioassays in different species" or "two prenatal development toxicity studies in different species."<sup>12</sup> The database available here justifies a  $UF_D$  of 3-6, which is appropriate when database confidence is "medium to high" (which is how it is described in the DSD, *see above*) and when the database includes only "one inhalation bioassay in one species."<sup>13</sup> Indeed, a  $UF_D$  of 3 is used in the chronic evaluation, for exactly the reasons listed above.<sup>14</sup>

In conclusion, if it is appropriate to develop a 24-hour ReV due to available studies, a  $UF_D$  of 3-6, not 1, is needed.

### III. The Dramatic Increase in the Short-Term Standard is not Justified

The proposed short-term health standard for CrVI is  $1.3 \mu\text{g}/\text{m}^3$ . The existing short-term standard is  $0.1 \mu\text{g}/\text{m}^3$ . This represents an increase of some *thirteen times* over the existing standard. This increase is complicated by the fact that the existing standard is based on a 1-hour exposure duration, whereas the propose standard is based on a 24-hour duration. Such a dramatic increase in a health standard requires significant justification that is lacking here. Indeed, the DSD repeatedly states that health effects studies of CrVI are limited.<sup>15</sup>

#### A. Comparison to the OSHA Standard Suggest the Proposed Standard is Inadequate

A comparison of other standards for CrVI exposure shows that this standard is inadequate. In 2006, the Occupational Safety and Health Administration (OSHA) completed a

<sup>8</sup> See generally, Guidelines Chapter 4.

<sup>9</sup> See generally, Guidelines, Section 4.3.

<sup>10</sup> DSD p. 12.

<sup>11</sup> DSD p. 23.

<sup>12</sup> Guidelines, p. 131.

<sup>13</sup> Guidelines, p. 131.

<sup>14</sup> See DSD, p. 40. It should be noted that we also believe the total uncertainty factor of 270 used in the chronic evaluation to be too high.

<sup>15</sup> See, e.g., DSD p. 8.



review and revision of its standard for worker exposure to hexavalent chromium. OSHA settled on an 8-hour exposure standard of  $5 \mu\text{g}/\text{m}^3$ .<sup>16</sup>

In earlier comments to this proposal, a commenter asked for a comparison to the OSHA standard. A reviewer from TCEQ provided the following response (excerpted in part):

If OSHA's PEL of  $5 \mu\text{g CrVI}/\text{m}^3$  is converted to an environmental continuous exposure corresponding to an extra risk of 1 in a 100,000, then the equivalent concentration is  $5 \times (45/70) \times (5/7) \times (8/24) \times (0.00001/0.001) = 0.0077 \mu\text{g CrVI}/\text{m}^3$ , which is only 1.78-fold greater than the value of  $0.0043 \mu\text{g CrVI}/\text{m}^3$  derived by TCEQ (this calculation assumes that OSHA is also using 70 years as the age for risk calculations and that there are no other adjustments that OSHA may have done).<sup>17</sup>

This comparison to the OSHA standard shows that it is only 1.78 times greater than the chronic exposure factor developed by TCEQ. This is troubling, as OSHA standards are for healthy adults facing exposure in a work environment. The TCEQ standard, by comparison, is intended to protect people—including children—who face involuntary exposures in ambient air. In Houston, we know that there are homes adjacent to metal recycling facilities that have significant CrVI emissions. Members of the public face exposure to CrVI every day. Their children breathe more, relative to their body weight, than adults. This is a very different set of circumstances than that which an OSHA standard contemplates.

Furthermore, the OSHA standard—a Permissible Exposure Limit (PEL)—is very different from the Recommended Exposure Limit (REL) developed by the National Institute for Occupational Safety and Health (NIOSH). PELs are based on a variety of factors, including political considerations. RELs, by contrast, are based on the best available science.<sup>18</sup> The NIOSH limit is  $0.2 \mu\text{g}/\text{m}^3$ , well below the  $1.3 \mu\text{g}/\text{m}^3$  proposed here.

#### B. The Relationship between the Short- and Long-Term Standards is Illogical

A few simple examples will help to illustrate why the proposed short-term standard is problematic. First, suppose a person were exposed to the short-term concentration of  $1.3 \mu\text{g}/\text{m}^3$  for 24 hours. Assuming a breathing rate of 5 liters per minute, this person would breathe in  $9.36 \mu\text{g}$  of CrVI during that 24 hours. Next, imagine a person exposed to the long-term concentration of  $0.0043 \mu\text{g}/\text{m}^3$  for one year. This person would breathe in  $11.3 \mu\text{g}$  of CrVI during that year. This means that someone exposed to the short-term limit for one day could inhale 83% of the CrVI that the long-term limit would allow in *one year*.

This is a surprising result. It is illogical that exposure to a short-term standard for 24 hours would permit 83% of the exposure that a long-term standard allows in one year. This is in contrast to the relationship created by the newly proposed short- and long-term standards for benzene, in which 24 hours of exposure at the short-term limit would result in 0.31% of exposure allowed by the long-term limit in one year.<sup>19</sup> This is a dramatic difference in relationship between the short- and long-term limits for these pollutants.

Neither is it any consolation to claim that no individual will in fact be exposed to these concentrations for these lengths of time. First, there is not enough understanding of actual exposures throughout Texas to confidently make that claim. Second, there is no monitoring infrastructure in place to gain that understanding any time soon. Third, and most importantly, these standards define what exposure levels are permissible. If such a condition of exposure were to arise, an exposed individual would have no legal recourse against such exposure. That individual would receive a lifetime of exposure to CrVI in under three months.

<sup>16</sup> See 71 Fed. Reg. 10100 (Feb. 28, 2006).

<sup>17</sup> See

[http://www.tceq.texas.gov/assets/public/implementation/tox/dsd/proposed/feb14/hexavalent%20chromium\\_responses%20to%20comments.pdf](http://www.tceq.texas.gov/assets/public/implementation/tox/dsd/proposed/feb14/hexavalent%20chromium_responses%20to%20comments.pdf)

<sup>18</sup> See, e.g., <http://chemsdq.blogspot.com/2010/10/what-is-difference-between-rel-and-pel.html>.

<sup>19</sup> See Benzene DSD at p. 1 (available at

<http://www.tceq.texas.gov/assets/public/implementation/tox/dsd/proposed/feb14/benzene%20d%20lr.pdf>).

#### **IV. The Long-Term Health Standard is also Inadequate**

##### **A. The Endpoints and Uncertainty Factors Used for the Chronic Evaluation are Problematic, as are the Comparisons with other Factors**

The DSD includes a comparison of chronic toxicity factors developed by TCEQ, ATSDR, USEPA, CalEPA, and ChemRisk. These comparisons are problematic, as each agency used different endpoint and different uncertainty factors, and arrives at a different chronic toxicity factor.

Typically, an endpoint is chosen based on the first adverse health effects that can be seen upon exposure to a toxic chemical. The DSD uses as its endpoint increase in relative lung weight. The DSD states that this endpoint is "associated with a level of change considered more clearly adverse."<sup>20</sup> The DSD also states that the endpoints used in other evaluations are plagued with uncertainty. Given that there is an admitted lack of studies on the health effects of CrVI, we would expect a more clear justification for the selection of an endpoint that is not used in any comparable evaluations.

Similarly, an uncertainty factor of 270 used in the chronic evaluation and is then compared to other evaluations that used UFs ranging from 30 to 300.<sup>21</sup> The DSD does point out that USEPA and ChemRisk used uncertainty factors of 300, but it fails to explain the significance of UFs of 30 and 100 in the ATSDR and CalEPA studies. Instead, the DSD simply compares the chronic toxicity factor developed by each agency and concludes that TCEQ's is adequate because it falls between certain others. This comparison cannot be made without a more thorough discussion of the significance in the use of different uncertainty factors and endpoints.

##### **B. The EPA's Risk Level is Dramatically Different**

The Environmental Protection Agency lists a quantitative estimate of carcinogenic risk from inhalation exposure to CrVI in its Integrated Risk Information System.<sup>22</sup> For a risk level of 1 in 100,000—the same risk level the TCEQ uses—the EPA gives a concentration of 0.0008  $\mu\text{g}/\text{m}^3$ . The TCEQ's 1 in 100,000 risk concentration is five times higher at 0.0043  $\mu\text{g}/\text{m}^3$ .

This carcinogenic risk was developed by EPA based on a unit risk factor (URF) of 0.012 per  $\mu\text{g}/\text{m}^3$  and a 1975 study. TCEQ acknowledges this URF and the study, which it calls outdated.<sup>23</sup> TCEQ developed its own URF of 0.0023 per  $\mu\text{g}/\text{m}^3$ , again differing from the EPA value by a factor of five. TCEQ also compares its value not to EPA's, but to the PEL established by OSHA.

#### **V. Comparison to the ChemRisk Study is Troubling**

It is troubling that TCEQ relies in part on CrVI evaluations performed by ChemRisk. ChemRisk's work on CrVI has been hugely criticized. In a lawsuit made famous by the movie "Erin Brockovich," Pacific Gas and Electric (PG&E) was sued over CrVI contamination in groundwater. During the litigation, PG&E hired ChemRisk as a consultant. ChemRisk distorted the results of a Chinese study on CrVI exposure and published their interpretation in a scientific journal over the objections of the original study's authors. ChemRisk was widely criticized and accused of fraud for their actions. ChemRisk's misdeeds were chronicled in a 2005 study by the Environmental Working Group, "Chrome Plated Fraud."<sup>24</sup>

<sup>20</sup> DSD, p. 43.

<sup>21</sup> Elsewhere, we noted that the use of a UF<sub>D</sub> of 1 for the acute evaluation was not justified by the Guidelines.

<sup>22</sup> See <http://www.epa.gov/iris/subst/0144.htm>.

<sup>23</sup> DSD, p. 43.

<sup>24</sup> Available at <http://www.ewg.org/research/chrome-plated-fraud>.



In conclusion, we simply do not understand why TCEQ has undertaken this revision of the hexavalent chromium standard. Given the uncertainty about facilities that emit CrVI, the uncertainty surrounding studies of the health impacts of CrVI, and the lack of an adequate CrVI monitoring network, it is simply baffling that TCEQ would undertake this revision now.

Thank you for the opportunity to submit comments. For further discussion of these issues, please contact Adrian Shelley at 713-528-3779, [adrian@airalliancehouston.org](mailto:adrian@airalliancehouston.org).

Sincerely,

Adrian Shelley  
Executive Director, Air Alliance Houston

Luke Metzger  
Founder and Director, Environment Texas

Ilan Levin  
Associate Director, Environmental Integrity Project

Gabriel Clark-Leach  
Attorney, Environmental Integrity Project

Tom "Smitty" Smith  
Texas Director, Public Citizen

Karen Hadden  
Executive Director, SEED Coalition

Neil Carman  
Clean Air Program Director, Sierra Club Lone Star Chapter

Melanie Scruggs  
Houston Program Director, Texas Campaign for the Environment

Robin Schneider  
Executive Director, Texas Campaign for the Environment

Juan Parras  
Director and Founder, Texas Environmental Justice Advocacy Services

**From:** Richner, Donald - HHS

**Sent:** Thursday, May 01, 2014 12:29 PM

**To:** 'tox@tceq.texas.gov'

**Cc:** [adrian@airalliancehouston.org](mailto:adrian@airalliancehouston.org); Raun, Loren - HHS; Blanco, Arturo - HHS

**Subject:** Comments on proposed TCEQ short term AMCV and ESL for Hexavalent Chromium

Dear Sir or Madam,

Here are issues that we believe are not adequately addressed in the proposed Cr(VI) standard and need to be examined more closely before the proposed change should be considered for final acceptance: 1) the proposed short term 24 hr AMCV of  $1.3 \mu\text{g}/\text{m}^3$ ; and 2) the short term ESL of  $0.39 \mu\text{g}/\text{m}^3$  are too high.

- The list of Cr(VI) sources referenced in the TCEQ document and the EPA's Toxic Release Inventory (TRI) is incomplete and under counts possible exposures within any given community as a result. For example, sources may be found adjacent to neighborhoods in Houston that are not on the source list. Such sources include many facilities doing torch cutting or welding outside, without any emissions controls, that seldom operate under an air permit (other than permit by rule) and yet the Houston Department of Health and Human Services' Bureau of Pollution Control & Prevention (BPCP) has measured total chromium emissions levels offsite ranging anywhere between  $0.1$  and  $2.0 \mu\text{g}/\text{m}^3$  over a typical 8 to 10 hour work day.
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- The proposed 24 hour AMCV standard of  $1.3 \mu\text{g}/\text{m}^3$  is too high because it could allow a community exposure that is equivalent to 82.7% of the long term AMCV exposure in only one day. Although there are a few facilities that monitor emissions for Cr+VI periodically, to my knowledge there is little or no continuous monitoring being done and the smaller sources that operate under PBRs often do little or no monitoring beyond their fence line and are seldom actively monitored by any environmental agency. By significantly elevating the threshold of proof by which we could identify an emission as unacceptable, this proposal would hinder our ability to effectively respond, troubleshoot, or recommend corrective action in response to citizens' complaints due to emissions from neighboring facilities or sources that contain elevated Cr(VI).

- If you compare the total Cr(VI) limit that this proposal would allow in 24 hours to that of one year, you may better understand our concern. The proposed 24 hr AMCV limit of  $1.3 \mu\text{g}/\text{m}^3 \times 24 \text{ hours} = 31.2 \mu\text{g}$  per day Cr(VI), while the proposed annual limit is  $0.0043 \mu\text{g}/\text{m}^3 \times 24 \text{ hours} \times 365 \text{ days} = 37.7 \mu\text{g}$  Cr(VI) per year. Allowing the possibility of such excess exposure for even one day puts neighboring communities at elevated risk; it also makes it very difficult to document an overexposure because of the rigors of testing for Cr(VI) that greatly complicate the process.
- With Cr(VI) testing in mind, there is a significant discrepancy between the current EPA methodology for Cr(VI) measurement in air and the NIOSH or OSHA methods. The EPA ambient air method uses a similar ion chromatography analytical procedure to that of OSHA & NIOSH, but the ERG study conducted for the EPA to evaluate the method drew conclusions substantially different from those reached by NIOSH or OSHA as to sample stability, recommended collection media and method interferences. Because the EPA method was aimed primarily at monitoring chrome plating emissions that do not have significant interfering elements present, many real world samples, such as those produced by welding and torch cutting, have 10 to 600 times more Iron (Fe) than Chromium (Cr) and accurately measuring Cr(VI) levels in such samples can be a real challenge. If we acknowledge this measurement challenge then we should require a more health protective AMCV and ESL short term limit, not a less protective limit. It is an important concern to BPCP that the above discussed points be factored into TCEQ's proposed and final actions, so that the health of citizens residing in close proximity to emitters of Cr(VI) be best protected, which will assist local agencies such as BPCP in best responding to citizens' complaints.

It is not that we expect many facilities to actually generate  $1.3 \mu\text{g}/\text{m}^3$  over a 24 hour period, but that the issue of documenting a problem at any facility will become much more difficult with the proposed higher limit and subsequently our ability to affect positive change for the affected communities is being jeopardized.

Donald R. Richner, CIH  
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Houston Department of Health & Human Services  
Bureau of Pollution Control & Prevention  
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# Recycling Council of Texas, Inc.

5785 E. Houston Street • San Antonio, TX 78220 • Office (210) 661-2341

May 6, 2014

**Received**

**MAY 12 2014**

**OFFICE OF AIR**

Mr. Michael Honeycutt  
Director, Toxicology Division, MC 168  
Texas Commission Environmental Quality  
P O Box 13087  
Austin, TX 78711-3087

Re: Comments on TCEQ's Development Support Document for Hexavalent Chromium and Compounds

Dear Mr. Honeycutt:

I serve as head of a task force created by the Recycling Council of Texas (RCOT), the Institute of Scrap Recycling Industries (ISRI) and the Gulf Coast Chapter of ISRI (collectively "The Task Force"). We appreciate the opportunity to offer brief comments on the Development Support Document for Hexavalent Chromium and Compounds prepared by TCEQ's Toxicology - Division (Joseph Haney and Neerja Erragontla).

The Task Force was formed last year in response to work by the City of Houston to study air emissions (smoke and dust) from selected facilities in our industry, and to media reports related to the City's work. The City initiative is not an enforcement activity. The Task Force has retained the services of Dr. Don Schaezler, a licensed professional engineer and certified industrial hygienist, to evaluate the testing protocols, data assembly and analyses, and risk evaluation work performed by the City. The Task Force has worked with the City researchers and officials over the past 18 months by providing technical input in each of those areas. Our relationship with the City has been cooperative, substantive, and candid. The Task Force has kept its Houston members informed about the City's research, and several of those companies have already adjusted certain practices to reduce smoke and dust emissions.

TCEQ's evaluation of the carcinogenic risks associated with inhalation exposure to hexavalent chromium has been comprehensive and thorough. This work has advanced the level of knowledge about health risks by inhalation exposure to hexavalent chromium and created a new standard that can be used widely and confidently by toxicologists, risk assessors, and regulators. We thank them for this highly professional document.

However, we wish to address some earlier public comments that are in the record in this matter. Specifically, some comments submitted by the City of Houston failed to correctly characterize certain data and risks related to emissions from recycling plants in Houston. We call your attention to the City of Houston comments and the TCEQ(2014b) responses on pages 26 and 27 of TCEQ Development Support Document Comments.

## COMMENT #2

In their Comment #2 the City stated that

“Hexavalent chromium (CrVI) is an important air toxic of concern in the City of Houston. ... as recently as 2012 it has been found in the ambient air downwind of some metal recycler facilities at unhealthy levels.”

The main reference to this comment is an article by Raun (2013). The referenced article differs slightly in title and order of the authors from the actual article published in 2013. We assume the content is reflected in the published article. The published article reported on a study through 2012 of a group of five metal recycling facilities in Houston, Texas, by the City of Houston's Department of Health and Human Services. Using the City of Houston's Mobile Ambient Air Monitoring Laboratory (MMAAL) data were collected downwind of five metal recycling companies for particulates, metals, VOCs, and meteorological data.

Data analyses and risk assessment calculations led to conclusions by those researchers that unanticipated cancer risks were present near these and, by extrapolation, near other similar recyclers throughout Houston. Most of the cancer risk was attributable to hexavalent Chromium, CrVI. The excess cancer risks were estimated to be  $1 \times 10^{-6}$  to  $8 \times 10^{-4}$ . In most cases, CrVI was responsible for more than 70% of that risk.

However, a major weakness in the analyses and risk assessments by Raun was the paucity of CrVI data available at the time of her analyses. Data collected for *one* metal recycler on *one* sampling date suggested a ratio of CrVI to Total Cr (Cr) of 0.085. This single ratio was then used to *estimate* CrVI from about 45 measurements of Total Cr at the five recyclers. As we

showed in our analysis of additional City data, the relationship between CrVI and Cr is not likely a simple ratio, and the original ratio appears not to be representative. As a result, the risks attributed to CrVI were substantially overestimated by Raun.

After the Raun paper was published, the City monitoring program continued, and the collection of more CrVI data was emphasized, so that, by April 2013, 14 pairs of data points for CrVI and Cr were available. Working with 14 pairs of data rather than only one, we were able to complete a more careful analysis of the critical ratio relating CrVI to Total Cr.

Using the URF proposed in the draft TCEQ document (TCEQ 2013) and the extended data base, we were able to calculate the lifetime cancer risk attributable to CrVI more carefully and to evaluate that risk more appropriately.

Our rebuttal points are as follows:

1. Our analysis showed the potential excess cancer risk is significantly lower than predicted in the Raun (2013) article (*See* Attachment A, points 4 and 5).
2. There never were “unhealthy levels” “...found in the ambient air downwind of some metal recycler facilities.” There never were levels in the plural sense, because there was only one actual CrVI data point. Moreover, the levels were not unhealthy by TCEQ risk criteria.

### **COMMENT #3**

In their Comment #2 the City stated that

“...the locations where the City of Houston has found elevated risk from ambient concentrations are residential...”

Our rebuttal points to this comment are similar:

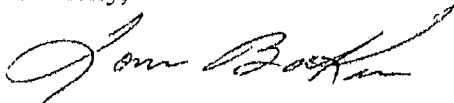
1. Our analysis showed the risks posed from ambient concentrations of CrVI were not elevated as defined by TCEQ risk criteria.
2. There never were “elevated risk from ambient concentrations...” There never were concentrations in the plural sense, because there was only one actual CrVI data point, and the levels were not unhealthy by TCEQ risk criteria.

Our comments above are based on the work that Dr. Schaezler did for the Task Force. His work was contained in a research paper that we provided to the City of Houston last year.

The conclusions section of that paper is attached (as "Attachment A"), and the full version is available should you seek a copy. (Schaezler, 2013).

We appreciate this opportunity to present our comments for the public record. We thank the TCEQ for their valuable work on the Chromium issue and for their consideration of invited and public comment.

Sincerely,

A handwritten signature in cursive script that reads "Tom Baker". The signature is written in black ink and is positioned above the typed name.

Tom Baker

/tb

cc: Mark Harmon (TCEQ)  
Robin Weiner (ISRI)  
David Waggoner (ISRI)

## REFERENCES

“Unanticipated potential cancer risk near metal recycling facilities,” Raun, L. et al., Environmental Impact Assessment Review 4 (2013) 70-77

Texas Commission on Environmental Quality, “Hexavalent Chromium and Compounds, Development Support Document,” Final Draft, March 2013

Texas Commission on Environmental Quality, “Hexavalent Chromium and Compounds, Development Support Document,” Proposed, February 2014 (TCEQ 2014a)

Texas Commission on Environmental Quality, “Responses to Comments Received, Hexavalent Chromium and Compounds, Development Support Document, Section 4.2, Carcinogenic Potential” February 2014 (TCEQ 2014b)

“[DRAFT] Further Developments on the Assessment of Risk Attributed to Hexavalent Chromium near Metal Recycling Facilities in Houston, Texas,” Donald J. Schaezler, Ph.D., P.E., CIH, draft report to ISRI and RCOT, May 2013



## ATTACHMENT A

### Further Developments - Hexavalent Chromium Risk

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#### 5. CONCLUSIONS

1. The City of Houston has collected a significant number of new data points in 2013 for CrVI and Total Cr (subsequent to the 2012 data used for the published article by Raun et al.); these can be used to evaluate the excess cancer risk from environmental exposure to CrVI much more accurately than the use of an assumption for the ratio of CrVI to Cr.
2. 17 actual measurements of CrVI in 2013 produced 15 values less than the reporting level; the only two values above the reporting level were 0.007 and 0.009 ug/m<sup>3</sup>. These values are far below the assumed CrVI values in the original article.
3. The relationship between CrVI and Total Cr is not likely a constant, as Raun assumed, and a ratio of 10% for CrVI to Cr would greatly overestimate CrVI at concentrations of concern.
4. Using a value of 0.009 ug/m<sup>3</sup> as representative of a high value for the population of CrVI measurements, and making the same assumptions as in the original article, the excess cancer risk for exposure to CrVI was calculated to be  $1.5 \times 10^{-6}$ ; this is less than the risk of  $1 \times 10^{-5}$  that TCEQ has defined as a "no significant excess risk level" for a carcinogenic chemical with a nonthreshold assessment. It is far less than the risk of  $2.1 \times 10^{-5}$  calculated in the original article for the facility with the highest CrVI concentrations.
5. Using the new IUR for CrVI proposed by TCEQ, the risk calculation detailed above is  $2.9 \times 10^{-7}$ , nearly two orders of magnitude lower than the TCEQ no significant excess risk level.

**From:** [Douglas A. Schuler](#)  
**To:** [TOX](#)  
**Subject:** chrome standards - do not weaken them  
**Date:** Wednesday, May 07, 2014 9:58:41 AM

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Hello TCEQ,

I am a concerned citizen of Texas. I heard a radio story about a week ago about the new rules on chromium in the air. It seems that you are developing a short term standard that is welcome by industry but not by the breathing public. It seems to be a standard that allows companies to refrain from making investments towards the public's health needs.

Please do not weaken the current short term standard.

Cordially,

Doug Schuler

4112 Sunset Blvd, Houston, TX 77005

**Texas Commission on Environmental Quality  
Responses to Comments Received on the  
Hexavalent Chromium Development Support Document  
Section 4.2 – Carcinogenic Potential  
Draft Dated March 2013**

**February 2014**

Prepared by:

Joseph T. Haney, Jr., M.S.  
Neeraja K. Erraguntla, Ph.D.

Toxicology Division  
Office of the Executive Director

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## INTRODUCTION

Toxicology Excellence for Risk Assessment (TERA) supported the Texas Commission on Environmental Quality (TCEQ) by conducting an external expert peer review as a letter peer review of Section 4.2 (Carcinogenic Potential, Draft March 2013) of the Development Support Document for Hexavalent Chromium. The review materials, including the draft document, charge to reviewers, and key references (available at <http://www.tera.org/Peer/crvi/index.html>) were distributed to the panel in May 2013. External expert panel members reviewed draft Section 4.2 of the Development Support Document (DSD) and submitted written comments that addressed the charge questions in May 2013. These written comments represent the panel's review of the carcinogenic potential section (Section 4.2) of the draft hexavalent chromium DSD. A June 17, 2013 report containing expert panel member comments was prepared by TERA and is available at the above-referenced website. The written comments submitted by the expert panel and the TERA report comprise the complete peer review of Section 4.2 (Carcinogenic Potential) of the draft hexavalent chromium DSD.

*The Toxicology Division (TD) of the TCEQ appreciates the significant effort put forth by the panel members to provide technical comments on carcinogenic potential section (Section 4.2) of the draft DSD for hexavalent chromium. The TD made appropriate revisions to the March 2013 draft DSD based on panel member comments consistent with the goal of the TCEQ to protect human health and welfare based on the most scientifically-defensible approaches possible (as documented in the DSD) given the studies available and use of the derived values (i.e., evaluation of ambient air data and air permit applications). The TD's careful consideration and evaluation of expert panel member comments furthered that goal. The comments within each section below correspond to a specific charge question. The comments are followed by TCEQ responses which include what changes, if any, were deemed appropriate and made to the draft DSD in response to the comment. Similarly, public comments made by the City of Houston and the Ontario Ministry of the Environment (contained in TERA's expert panel review report) are addressed in Section 4.*

Please refer to Haney et al. (2014) for the published manuscript "Development of an inhalation unit risk factor for hexavalent chromium."

### ***Panel Written Comments***

The purpose of this document is to provide responses to comments from the panel, with any potentially significant issues being of particular interest. When necessary, lengthy comments were divided into smaller sections and separate responses provided. Written comments on the same issue which appear in more than one section of the written comments (i.e., reiterated written comments) may only be stated and addressed once below to avoid redundancy. Extraneous text contained in written comments is also not provided below, such as text extraneous to the charge question posed, text unnecessary for an understanding of the potential issue identified, etc. *While responding to some expert panel member comments required revisions to the text (e.g., clarifications, additional language or discussion), as can be seen below, no comments identified issues which affect the draft inhalation unit risk factor (URF) for hexavalent chromium and compounds.*

# 1. General Questions

## 1.1 Approaches used by TCEQ to develop the URF

### Does the draft DSD clearly describe the approaches used by TCEQ to develop the URF?

**Reviewer #1:** Yes, especially the derivation of the slope factor (beta) relating cumulative chromium VI to lung cancer from two key studies. If anything could use more transparency, it would be the final steps of deriving the URF and the ESL. Although the steps to arrive at these numbers are outlined in methods, some further description of their derivation could be given in section (p 27) where the final numbers are present

**Response:** Additional descriptive text was added to the DSD per the comment.

**Reviewer #2:** The draft DSD clearly and extensively describes the approaches used by the TCEQ to develop the unit risk factor (URF). Section 3.1.2 provides a good review of the mode of action (MOA) for Chromium VI. Section 4.2.1 provides a good review of the weight of evidence for the selection of lung cancer as the primary toxicological effect. Section 4.2.2 provides a good discussion of the carcinogenic MOA. Section 4.2.3 it is appropriately stated on page 8 that default liner low-dose extrapolation is utilized for the cancer dose response. The choice of cumulative exposure is justified. The selection of epidemiological studies and choice of dose response regression models are adequately discussed. The duration of exposure, lagged exposure, and covariates such as smoking are appropriately considered. An adjustment of dose from occupational exposure to continuous exposure to chromium VI is appropriately applied. Texas background cancer rates were used to appropriately calculate standard mortality ratios. A weighted estimate of two URFs was correctly employed for the final URF estimate.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** The approaches are described very clearly. The document is well focused, succinct and informative, clearly outlining the considerations on which judgments were based, within the confines of the procedures outlined in the TCEQ Guidelines to Develop Toxicity Factors. It appears to have been prepared by an experienced team who is to be congratulated on the transparency with which they have presented their analysis. It also seems to draw meaningfully on previous assessments, as a basis to increase efficiency.

I would only suggest that consideration be given to adding a description of the process for preparation and review to date and basis for the specific focus of this assessment up front. This would provide even greater transparency on aspects of evaluation relevant for review and permit perhaps, even greater focus on critical components thereby additionally increasing efficiency. While this is generally addressed in the TCEQ Guidelines to Develop Toxicity Factors, additional information which is currently lacking includes a priori criteria for determining the extent of reliance on previous assessments versus the nature of, timeframe for and extent of consideration of primary data – e.g., standard searching of identified electronic sources for recent

data with criteria specified and cut-off date past which no additional data were considered (What were a priori exclusion criteria for particular studies – e.g., unpublished; published after a certain date?).

**Response:** TCEQ appreciates the positive feedback in the first paragraph. Descriptive text was added to the DSD per the comments in the second paragraph.

**Reviewer #4:** The draft is very clear in its description of the various epidemiology studies, and in its recommendation to conduct a novel quantitative analysis in the development of the chosen URF. I was particularly gratified to see TCEQ lead this analysis with a discussion on the potential Modes of Action (MOAs). The conclusions of this MOA section seem reasonable to me.

Rather than agree with TCEQ's chosen approach to develop the URF, I suggest an alternative to consider (see response to question 6 below). Several places are noted in the text where the concepts might be further clarified (see attached annotated text).

**Response:** TCEQ appreciates the positive feedback in the first paragraph. A response to the Reviewer #4 recommendation for an alternative approach, which in some ways is less conservative than the linear low-dose extrapolation procedure employed in Section 4.2 of the draft DSD, is provided below under question 6. See the responses below regarding the potential textual clarifications referred to by this reviewer.

## ***1.2 Procedures Followed by the TCEQ***

### **Were procedures outlined in RG-442 TCEQ Guidelines to Develop Toxicity Factors (TCEQ 2012) followed by the TCEQ in this assessment?**

**Reviewer #1:** It's hard to know for sure, as the guidelines are over 200 pages. However, with a brief look at them, it seems that that the TCEQ has followed the guidelines.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** As described above in the response to Question 1, the options and issues outlined in RG-442 TCEQ Guidelines to Develop Toxicity Factors were followed in the draft DSD.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** It appears that the procedures outlined in RG-442 TCEQ Guidelines to Develop Toxicity Factors (TCEQ 2012) were appropriately followed, to the extent reasonable.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #4:** I believe so.

**Response:** TCEQ appreciates the positive feedback.

### 1.3 Relevant Studies or Data

**Please identify any relevant studies or data that have not been cited and would affect an important part of the assessment and explain how they would impact the assessment specifically.**

**Reviewer #1:** I don't think there are any relevant studies not cited. However, I would be curious how this risk assessment coincides or differs from the OSHA 2006 risk assessment which led to a lowering of the occupational standard from 52 to 5  $\mu\text{g}/\text{m}^3$ .

**Response:** A comparison of an occupational assessment based on a worker exposure scenario and an inhalation URF assessment for the general public derived assuming a lifetime of environmental exposure is beyond the scope and purpose of the DSD. The differences would be numerous (see below). Regarding the ultimate regulatory air concentrations, based on the final URF in the draft DSD ( $2.3\text{E}-03$  per  $\mu\text{g CrVI}/\text{m}^3$ ) the air concentration corresponding to an excess lung cancer risk of 1 in 100,000 is  $0.0043 \mu\text{g CrVI}/\text{m}^3$ , which is approximately 1,163 times lower than the  $5 \mu\text{g CrVI}/\text{m}^3$  occupational value cited by Reviewer #1.

For purposes of this response, note that  $5 \mu\text{g CrVI}/\text{m}^3$  is an occupational concentration corresponding to an excess risk of 1 in 1,000 for an exposure period of 45 years (20 to 65 years of age), 5 days per week, and 8 out of 24 hours per day, based on Gibb et al. (2000). This is opposed to TCEQ's  $0.0043 \mu\text{g CrVI}/\text{m}^3$  which is an environmental concentration corresponding to an excess risk of 1 in 100,000 for 70 years, 7 days per week, and 24 hours per day, based on Gibb et al. (2000) and Crump et al. (2003). If OSHA's PEL of  $5 \mu\text{g CrVI}/\text{m}^3$  is converted to an environmental continuous exposure corresponding to an extra risk of 1 in a 100,000, then the equivalent concentration is  $5 \times (45/70) \times (5/7) \times (8/24) \times (0.00001/0.001) = 0.0077 \mu\text{g CrVI}/\text{m}^3$ , which is only 1.78-fold greater than the value of  $0.0043 \mu\text{g CrVI}/\text{m}^3$  derived by TCEQ (this calculation assumes that OSHA is also using 70 years as the age for risk calculations and that there are no other adjustments that OSHA may have done).

**Reviewer #2:** Not aware of additional relevant studies or other important data.

**Response:** No comment needed.

**Reviewer #3:** There is a series of articles, both published and in press, which additionally articulate principles and robust approaches for mode of action analysis, building on considerable evolving experience internationally. These include the following:

- Seed et al. (2005) Crit Rev Toxicol 35: 663
- Boobis et al. (2006) Crit Rev Toxicol 36:781
- Boobis et al. (2008) Crit Rev Toxicol 38:87
- Meek (2008) Env Mol Mutagenesis 49(2): 110
- Meek & Klaunig (2010) Chemico-Biological Interactions 184:279–285
- Meek et al. (submitted) Toxicol. Appl. Pharmacol.



While not part of the assessment, specifically, this experience has implications for the analysis included in the Haney et al. (2012) paper which serves as the reference for the statement in the assessment (page 7, last paragraph) “wherein available scientific data relevant to the carcinogenic MOA for CrVI are interpreted as adequate to support considering nonlinear-threshold assessments for inhalation carcinogenicity for comparison to default linear low-dose extrapolation approaches.” In my view, while the content of the paper is interesting from the perspective of hypothesis generation, the mode of action analysis included therein does not constitute adequate basis in itself to support considering non-linear threshold assessments (see additional comments below).

While this observation is not at odds with the critical conclusion to rely on linear extrapolation, it has implications also for the rationale by which this conclusion was reached. (page 8, first paragraph):

“However, while data relevant to the carcinogenic MOA and the epidemiological analyses conducted support consideration of nonlinear-threshold assessments for CrVI inhalation carcinogenicity, the uncertainties associated with the assessment (e.g., limited statistical power of epidemiological studies to detect increased risk at low exposure levels, lack of a statistically better fitting threshold model, lack of data on competing rates of extracellular CrVI reduction and lung tissue absorption) appear to preclude a robust scientific justification for deviation from the default linear low-dose extrapolation approach. Thus, the nonlinear-threshold assessment is not a focus of this document and the default linear low-dose extrapolation approach is utilized in the following sections to derive URF estimates based on various epidemiological studies”.

**Response:** These additional references are noted. The referenced text in the DSD was revised pursuant to this comment and related comments below from this reviewer.

**Reviewer #4:** I am not aware of additional studies that could be cited other than the draft IRIS assessment for chromium of the U.S. Environmental Protection Agency (EPA). However, we understand why TCEQ might not wish to refer to this EPA text since it is in review, especially since EPA asks for it not to be cited or quoted.

**Response:** No comment needed.

## **2. Cancer Assessment and Unit Risk Factor (URF)**

### *2.1 Carcinogenic Weight of Evidence Classification*

**Section 4.2.1 presents carcinogenic weight of evidence classification information and conclusions of authoritative bodies. Is TCEQ’s weight of evidence conclusion appropriate? If not, what alternative conclusion is appropriate and why? Is the decision to apply the URF to all forms of CrVI appropriate for public health protection purposes?**

**Reviewer #1:** I believe the weight of the evidence conclusion appropriate. I also agree that lumping all forms of CrVI together is appropriate given the epidemiology, which essentially does the same.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** The carcinogenic weight of evidence presented by the TCEQ in the DSD is scientifically appropriate, supported by authoritative bodies, and follows the TCEQ RG-422 guidelines. The decision to apply the URF to all forms of CrVI appears most appropriate for public health protection.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** TCEQ's weight of evidence conclusion seems appropriate and consistent with those of other authoritative bodies. The assessment has, then, reasonably drawn upon the conclusions of others in providing adequate documentation for the purpose at hand. The additionally informative narrative descriptors concerning route and dose under which cancer is likely to result are also helpful as a basis to increase understanding of the classification. In the absence of presentation or consideration of information relevant to distinction of various forms of CrVI in this context, the decision to apply the URF is conservative, consistent with public health protection policy.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #4:** TCEQ's weight of evidence conclusion, that "TCEQ considers CrVI and CrVI compounds as a group to be carcinogenic to humans via inhalation (at least at sufficiently high long-term doses)" is appropriate based on its analysis, and on the analysis of other expert bodies. This conclusion is consistent with TCEQ's evaluation of the possible MOAs of chromium's tumorigenicity and its guidelines. The choice to consider all CrVI forms as carcinogenic also appears to be scientifically appropriate based on TCEQ's MOA discussion.

One apparent inconsistency in TCEQ's text is that the ability of the CrVI form to cross a cell membrane is paramount to the MOA conclusions, but that "particulate forms of CrVI, relatively water insoluble compounds more specifically (e.g., moderate to low solubility), appear to be more potent lung carcinogens." [TCEQ text page 4] This also occurs with inhaled nickel compounds, due to the fact that moderate to low soluble forms of nickel stay in the lung longer and result in more intracellular nickel--in this case, more soluble nickel forms are more readily excreted, or absorbed systemically, resulting in less intracellular-lung nickel. TCEQ may wish to discuss this for chromium compounds as well, or at least reference the nickel discussion [Goodman et al. 2011].

**Response:** TCEQ appreciates the positive feedback in the first paragraph. While comments in the second paragraph are not relevant to the charge questions posed under this section, additional clarifying text was added to the DSD pursuant to the comments.

## **2.2 Carcinogenic Mode of Action**

**Section 4.2.2 discusses hexavalent chromium’s carcinogenic mode of action (MOA). Have the authors clearly and accurately summarized the proposed hypotheses for the MOA, given the current state of knowledge?**

**Reviewer #1:** I think the presentation of the MOA is appropriate and limited interferences from it are also appropriate. There is not sufficient evidence to justify an alternative to the linear low-dose extrapolation.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** The DSD clearly and accurately summarizes the proposed hypotheses for the Mode of Action (MOA) of CrVI. The DSD correctly concludes that sufficient information on the MOA is not available to justify deviation from default linear low-dose extrapolation.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** It’s appropriately noted in Section 4.2.2 that “a thorough discussion of the MOA evaluations conducted to date are (sic) beyond the scope of this document” and readers are referred “to the cited references and scientific literature for detailed information.”

In addition, it is indicated that “there should be a reasonably scientifically-rigorous standard for demonstration of a mutagenic MOA and the TCEQ believes such a standard has not been met for CrVI (i.e., merely demonstrating plausibility is not tantamount to an adequately robust demonstration that mutagenicity is in fact THE initiating event in target tissues).”

Taking into account the first qualification above which transparently indicates the bounds of appropriate investment in considering mode of action for the purpose at hand, I believe that TCEQ has presented a clear summary of the hypothesized modes of action, based on available data.

**Response:** TCEQ appreciates this positive feedback.

What is not presented, currently, is a meaningful analysis of the extent of experimental support for the various hypothesized modes of action based on robust analysis of comparative weight of evidence as a basis for justification that “the available scientific data relevant to the carcinogenic MOA for CrVI are interpreted as adequate to support considering nonlinear-threshold assessments for inhalation carcinogenicity for comparison to default linear low-dose extrapolation approaches.” The latter is not, in my view, adequately supported on the basis of the content of the Haney et al. (2012) paper, based on the rationale provided below.

**Response:** A comparative weight of evidence for various potential MOAs is beyond the scope of the DSD and would not change the conservative extrapolation approach (i.e., linear low-dose extrapolation) ultimately adopted by the DSD. An extensive and comprehensive MOA weight of evidence analysis is not necessary for purposes of the DSD and is better left to papers in the scientific peer reviewed literature which focus

exclusively on this issue (as cited in the DSD). The purpose of the DSD is to document the derivation of the URF and ESL as opposed to being a comprehensive weight of evidence paper on the MOA. Therefore, if data on the MOA are not sufficient to justify an alternate approach to linear low-dose extrapolation, the DSD only needs to generally summarize the primary proposed MOAs, MOA issues, and justify use of the default extrapolation method. This reviewer acknowledges, "I believe that TCEQ has presented a clear summary of the hypothesized modes of action, based on available data." Furthermore, although Haney et al. (2012) is referenced: (1) it is not the focus of the document; (2) adoption of the linear low-dose extrapolation approach in the DSD does not rely on the MOA information presented in Haney et al.; and (3) it was peer reviewed prior to publication and explicitly states, "It should be noted that the intent of the current study is not to perform an exhaustive weight of evidence evaluation of all data potentially relevant to the MOA (or MOAs), but rather to present available summary MOA information and statistical evidence interpreted as consistent with (albeit not proof of) a potential practical threshold for CrVI-induced inhalation carcinogenicity..." Nevertheless, the referenced sentence in the DSD was revised pursuant to the comment.

It is assumed in the Haney et al. (2012) paper and summarized in the TCEQ assessment that: "While the proposed MOAs differ, what they have in common as the earliest key events is an assumption (inherent or explicitly stated) that CrVI has escaped extracellular reduction to enter cells of the target tissue, followed by the intracellular reduction of CrVI. Experimental data support the reduction of CrVI to CrIII as an important detoxification mechanism, which may represent a hurdle to CrVI-induced carcinogenicity in some instances (e.g., low exposure well within lung CrVI reductive capacity extracellular to target tissue)."

The assumption presented above appears to be predicated on a misunderstanding of the nature of key events as defined based on the EPA (2005) Cancer Guidelines in the TCEQ guidance and the relevant roles of consideration of kinetics and dynamics in scaling of dose-response assessment in mode of action/human relevance analysis. While metabolism to the toxic entity (considered part of dynamics) is often an important early key event, absorption, distribution and excretion (and factors which influence same) are not normally considered in this context. Rather, such aspects are addressed as critical components of the quantitative concordance analysis. For example, if conversion to the toxic entity is considered a critical determinant of interspecies differences or human variability, this is addressed in quantitative scaling between species and within humans.

**Response:** Regardless of whether CrVI escaping reduction to enter target tissue cells comfortably fits into the key events of an MOA as normally or historically envisioned in guidance, this is a *de facto* key event in the broader sense at very least in the chemical-specific case of CrVI toxicity. That is, this must occur (i.e., is key) upstream of any scaling between species because in its absence there are no CrVI-induced toxicological effects requiring interspecies scaling of dose or consideration of intrahuman variability.

It is inappropriate, in my view, then, to propose that the available data on the required reduction of CrVI to CrIII constitutes adequate basis to justify considering nonlinear-threshold assessments for inhalation carcinogenicity for comparison to default linear low-dose extrapolation approaches for chromium VI. This is not to say that more robust analyses of the weight of evidence of

supporting data might justify this approach but rather, that the exploratory analyses included in Haney et al. (2012) is only sufficient, in my view, to provide bounding of quantitative estimates of risk based on epidemiological studies or as a basis to recommend an appropriate strategy for additional investigation to more meaningfully quantitatively inform estimates of risk.

**Response:** The DSD does not propose this argument, only cites Haney et al. which makes an argument for simply “consideration” of nonlinear-threshold approaches in the context of additional MOA-relevant information. Furthermore, the DSD does not actually rely on Haney et al. (2012) for adoption of the linear low-dose extrapolation approach employed therein (i.e., all reference to it could be removed and the carcinogenic dose-response assessment would be entirely unaffected). Nevertheless, as indicated above, the referenced sentence in the DSD was revised pursuant to the comment.

In addition, there is no indication of the nature of conducted analyses (within available reviews, for example) in which weight of evidence for a mutagenic mode of action has been considered to understand the basis for the conclusion that “the TCEQ believes such a standard has not been met for CrVI (i.e., merely demonstrating plausibility is not tantamount to an adequately robust demonstration that mutagenicity is in fact THE initiating event in target tissues). This necessarily requires additional analysis of the cited references. My own recollection of the McCarroll et al. (2009) reference is that the evidence for a potentially mutagenic mode of action may not have been adequately considered (in my view), taking into account, for example, dose-response for the relevant genotoxicity assays.

In this context, additional insight can often be gained from considering the pattern of results in relation not only to level of biological organization but dose response. Such results can be presented graphically as per genetic activity profiles (example below; there is likely one available for Cr VI) and increases understanding of the expectation of different types of genetic damage (including mutation) which may be completely consistent with a hypothesized nonmutagenic mode of action. Note that the lengths of the lines for positive results (above the line) represent the lowest effective dose for positive results; those for negative results represent the lowest ineffective dose.

**Response:** Additional text has been added to the DSD regarding considerations relevant to TCEQ’s conclusion that a mutagenic MOA has not been adequately demonstrated.

**Reviewer #4:** TCEQ’s discussion of carcinogenic MOA is well done. Based on this discussion, TCEQ’s conclusions regarding the MOA are well wrought, specifically that:

- The bioavailability and carcinogenic/toxic potential of Cr compounds depend upon the oxidative state? and thus solubility of the Cr atom,
- CrVI carcinogenicity/toxicity appears to be mediated through reactive intermediates, and
- The human body has a significant ability to reduce CrVI to CrIII, extracellular to target tissue as well as intracellularly.

I was somewhat disappointed to then read later in the document that TCEQ was going to conduct a dose response assessment for chromium’s carcinogenicity in a linear fashion, presumably since “the scientific community has not reached a consensus on the specific MOA(s) for CrVI-induced

lung carcinogenesis, or the role lung reductive capacity may play at low, environmentally-relevant concentrations in terms of risk (e.g., nonlinearity).” [TCEQ page 7]. This choice of linear assessment does not appear to be consistent with TCEQ’s MOA discussion, and is not consistent with TCEQ’s weight of evidence statement shown in question 4 above, “carcinogenic to humans via inhalation (at least at sufficiently high long-term doses).” Because otherwise, if TCEQ believed that the carcinogenic response was linear to the low dose, why would it need to specify “at least at sufficiently high long-term dose”?

I propose an alternative approach as described in response to question 6 below.

**Response:** TCEQ appreciates the positive feedback in the first paragraph. In regard to the comments on linear low-dose extrapolation in the second paragraph (below the bullets), when the MOA is unknown (“the scientific community has not reached a consensus on the specific MOA(s) for CrVI-induced lung carcinogenesis”) or information on the carcinogenic MOA suggestive of low-dose nonlinearity is not adequately robust to sufficiently support an alternate approach for the protection of public health with an acceptable level of scientific certainty (as is the case with CrVI), linear low-dose extrapolation is used as a conservative default by regulatory agencies. A response to the Reviewer #4 recommendation for an alternative approach, which in some ways is less conservative than the linear low-dose extrapolation procedure employed in Section 4.2 of the draft DSD, is provided below under question 6.

## ***2.2 Rationale for Not Using a Nonlinear-Threshold Dose Response Approach***

**In Section 4.2.3 TCEQ provides a rationale for not using a nonlinear-threshold dose response approach; do you agree with TCEQ’s conclusion that there is not adequate scientific justification to deviate from use of the default linear low-dose extrapolation approach given the inherent uncertainties of available data.**

**Reviewer #1:** I agree. Park and Stayner (2006) make this clear as well, and Crump (2003) recognizes the low power of any effort to define a threshold.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** Given the inherent uncertainties of available data and information, as stated in the DSD there is not adequate scientific justification to deviate from use of the default linear low-dose extrapolation.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** I agree that there is not adequate scientific justification to deviate from the use of the default low-dose extrapolation approach not only due to the inherent uncertainties of available data, but to the limitations of the analyses, currently, of mode of action. (See other responses). In this context, I’m wondering if the Haney et al. analysis might be best referenced in

the context of exploratory analysis to “bound” uncertainty associated with the low dose risk estimates.

**Response:** TCEQ appreciates the positive feedback and the text referencing Haney et al. was revised pursuant to the comment.

**Reviewer #4:** The two reasons stated for not deviating from the default linear approach on the top of page 8 are labored. The first reason that uncertainties are associated with this assessment, are true of any assessment; epidemiological studies and studies in experimental animals always have limited statistical power to detect increased risk at low exposure levels. Thus, this reason cannot be used as a justification for a default position. One would need to evaluate whether or not these uncertainties are understandable within the MOA framework discussed by TCEQ. Moreover, the second reason, specifically the lack of data on competing rates of extracellular CrVI reduction and lung tissue absorption, is another weak argument. One could equally ask for the receipt of data to justify the linear default, which would then allow a judgment based on a comparison of relative uncertainties. Perhaps TCEQ should describe data to support or refute for a linear and its suggested non-linear MOA.

**Response:** TCEQ acknowledges the main point implied by the comment that the default linear approach is perhaps no more justified than a nonlinear-threshold dose response approach. However, TCEQ believes information on the carcinogenic MOA suggestive of low-dose nonlinearity is not adequately robust to sufficiently support a specific alternate approach for the protection of public health with an acceptable level of scientific certainty (as is the case with CrVI). In such cases regulatory agencies err on the side of conservatism (potentially overestimating risk) and linear low-dose extrapolation is used as a conservative default regardless of whether available MOA data clearly justify its use (i.e., the absence of MOA data deemed to adequately support an alternate plausible approach triggers use of the conservative default approach), at least until more definitive MOA information adequately supporting a particular alternate approach is available.

Although we are reluctant to agree with the authors’ use of a linear low-dose approach, TCEQ might consider, or at least describe, an alternative approach. Specifically, a mode of action (MOA) is possible that is linear at low dose reflecting a hypothesized mutagenic key event, but also reflects a regenerative hyperplasia at the higher doses due to a second key event related to cellular damage from oxygen radicals as described by TCEQ in its MOA section. Careful consideration of the information on mutagenic potential taking into account dose-response would help inform the development of the possible mode of action. In fact, EPA’s cancer guidelines (2005, page 3-22) supports this kind of approach and Dourson et al. (2008) give an example with acrylamide. Alternatively, it might be that TCEQ’s choice of existing models could reflect a dual MOA, but if so, then TCEQ should consider describing their modeling results in this fashion.

**Response:** The DSD has been revised to mention the possibility of a dual MOA and that existing modeling results could be reflective of this.

### ***2.3 Is Lung Cancer Mortality The Best Cancer Endpoint?***

**Do you agree that lung cancer mortality is the best cancer endpoint for this**

**dose-response assessment? Are lung cancer incidence and mortality sufficiently similar as to be comparable for purposes of this assessment for the reasons discussed in the DSD?**

**Reviewer #1:** Yes incidence and mortality are essentially equivalent for lung cancer.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** For the available data, lung cancer mortality appears to be the best choice for a dose response assessment. As discussed in the DSD and shown in Figure 3, lung cancer incidence and mortality are sufficiently similar to be nearly comparable for the purposes of this risk assessment.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** I agree that lung cancer mortality is the best cancer endpoint for this dose-response assessment and well substantiated as the critical effect in a large number of assessments, including several that have been conducted relatively recently. The similarity between lung cancer incidence and mortality (Figure 3) is sufficiently similar as to be comparable for purposes of the assessment; analyses of likely limited available data on lung cancer incidence in study cohorts would provide limited opportunity to consider various aspects of causality and dose-response.

**Response:** TCEQ appreciates this positive feedback. Lung cancer mortality is the endpoint available for this dose-response assessment, and Reviewer #3 agrees that lung cancer mortality is sufficiently similar to incidence and the best cancer endpoint. As Reviewer #4 indicates, currently available data preclude the use of incidence.

**Reviewer #4:** Yes, lung cancer mortality is the best cancer endpoint for this assessment. Lung cancer incidence would be a better endpoint (if it were available) because it also captures those few persons who develop lung cancer and survive, but the currently available data preclude its use. Lung cancer also appears to be the most sensitive of the respiratory cancer endpoints, as TCEQ has stated, based on the information provided in Table 1 of Crump et al. (2003). Although the reported SMR for other respiratory system cancers is much higher (941 versus 241, using Ohio reference rates), their prevalence is extremely low, indicating that they occur rarely and may not be appropriate for consideration.

Lung cancer mortality is predictive of incidence for lung cancer (as shown in Figure 3).

**Response:** TCEQ appreciates this positive feedback.

## ***2.4 Cumulative CrVI Exposure as the Dose Metric***

**Cumulative CrVI exposure (mg CrVI/m<sup>3</sup>-yr) was chosen as the dose metric.**

**Reviewer #1:** Cumulative exposure is the appropriate metric for most chronic diseases, including cancer. Some explanation in the text could be presented about the relationship between



CrO<sub>3</sub> (used in Park et al. 2004, and in the present text) and CrVI. It is not until the appendix that we learn more about this. At one point in the text a slope factor from the Park et al. is presented in terms of CrVI which is mysterious, as the results from Park et al. are all in units of CrO<sub>3</sub>.

**Response:** TCEQ appreciates this positive feedback regarding the dose metric. The referenced clarifying language on Park et al. (CrVI versus CrO<sub>3</sub>) from Appendix A was added to the main text of the DSD.

**Reviewer #2:** From the available data on exposure, cumulative CrVI exposure (mg CrVI/m<sup>3</sup>-yr) appears to be the best dose metric.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** The rationale provided in this context relates principally to it being the only common measure available from the key studies, but also, because cumulative exposure is the dose metric used for dose-response modeling based on epidemiological studies. It's also noted that information on target tissue in the lung (a much preferred metric) is not available.

I wondered if any thought had been given to doing any sub-analyses based on exposure concentration given that effects in the lung (particularly those associated with particulate matter) are often concentration-related.

**Response:** TCEQ appreciates the positive feedback in the first paragraph. The primary reason that exposure concentration was not used is because the only dose metric available for the Painesville data is cumulative exposure. Furthermore, cumulative exposure is the dose metric most commonly used in epidemiological studies and it has the advantage that it combines both exposure intensity and exposure duration

**Reviewer #4:** This exposure metric is appropriate.

**Response:** TCEQ appreciates this positive feedback.

## ***2.5 The Most Appropriate Human Epidemiological Studies***

**Were the most appropriate human epidemiological studies (Painesville Ohio and Baltimore Maryland cohorts; Crump et al. [2003] and Gibb et al. [2000]) selected for the dose-response assessment and was their selection sufficiently described and justified? Are there any other published epidemiological studies of inhaled hexavalent chromium exposures with sufficient data that should and could have been considered by TCEQ in deriving the URF?**

**Reviewer #1:** Clearly these two cohorts are the key ones for risk assessment. There are no other epidemiologic studies, apart from the supportive 4 low exposure cohorts, of which I am aware. The approach of re-analysis of the Baltimore cohort data, restricted to those with 1+ years of employment, is reasonable. It is comforting that results from this analysis do not differ much from the entire Baltimore cohort.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** Two human epidemiological studies were selected for the dose-response assessment in the DSD (Painesville, Ohio, Crump et al., 2003 and Baltimore, Maryland, Gibb et al., 2000). The choice of the selection of these two studies was sufficiently described and justified in the DSD. No other studies appear to be justified for the derivation of the URF.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** Based on the rationale provided in the DSD (relatively large with most extensive follow up and historical CrVI levels), these appear to be the most appropriate human epidemiological studies for dose-response assessment. Additional analyses for the supporting cohorts contribute additionally to the defensibility of focus on those specified above.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #4:** The Painesville and Baltimore cohorts are the best for use in a dose-response assessment due to their large sample sizes, extensive follow-up, and detailed exposure estimates. I am not aware of any other epidemiological studies that would be more appropriate. I have some concerns regarding the Baltimore data, specifically due to extremely high percentage of employees who worked for less than one year. Although removal of these workers from the analysis reduces the potential for bias due to an unhealthy lifestyle (and is ultimately necessary for this analysis), there is the risk of introducing selection bias, especially since over 40% of the original population is not considered in the analysis. I also find it interesting that there is not much difference in slope estimates based on the data including only workers with > 0.5 years of employment and >1 year of employment (Table 7).

Ultimately, for the purposes of this assessment and the meta-approach used in the final URF derivation, it is best to use only workers exposed for a year or more, which is also part of the selection criteria for Crump et al. (2003). Thus, I agree with the TCEQ approach.

**Response:** TCEQ appreciates this positive feedback.

## ***2.6 Data from Supporting Cohorts***

**Were the data from supporting cohorts (Leverkusen and Uerdingen, Germany; Corpus Christi, Texas; and Castle Hayne, North Carolina) and Applied Epidemiology (2002) used appropriately? Additionally, were the reasons for excluding the URF based on the data from these supporting cohorts (Leverkusen and Uerdingen, Germany; Corpus Christi, Texas; and Castle Hayne, North Carolina) and Applied Epidemiology (2002) appropriate and sufficiently described?**

**Reviewer #1:** Yes, the data were used appropriately. The four low exposure cohorts supply supplemental but not key information. Their exclusion from the URF calculation is appropriate given the lesser follow-up time for these 4 low exposure cohorts.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** Data from the four supporting cohorts are adequately described in Section 4.2.3. These studies support the presence of a dose response relationship between lung cancer and CrVI exposure in the low-dose region. Because of the shorter follow-up times, numerical estimates of the URF from these studies appropriately were excluded.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** The additional analyses for the low dose cohorts are helpful in characterizing risks in the range of interest with relevant limitations being appropriately described and taken into account. Consistent with the response for part c) above, focus on the critical epidemiological studies mentioned there based on articulated considerations seems appropriate.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #4:** Yes, these data were used appropriately as supporting evidence. Due to the relatively short follow-up period, these data should not be considered as primary studies.

**Response:** TCEQ appreciates this positive feedback.

## ***2.7 Statistical and Modeling Approaches***

**Were the statistical and modeling approaches used to calculate the slope ( $\beta$ ) estimates (Section 4.2.3.1.4) and URFs (Section 4.2.3.1.6) for the selected data sets appropriate?**

**Reviewer #1:** Yes the modeling approaches were appropriate. One thing that need to be made clear (assuming I am right here) is that in the Cox regression analyses of the Baltimore data an excess RR model was used. This is not made explicit in the document. Most standard Cox models use a log-linear model, not an ERR model. I would like to know the software used for Cox ERR models. Was this Epicure? This can be done in SAS via PROC NLP (Langholz and Richardson 2010).

**Response:** TCEQ appreciates the positive feedback and clarifying text regarding the Cox modeling was added to the DSD.

**Reviewer #2:** Poisson Regression Modeling and Cox Proportional Hazards Modeling are described in Section 4.2.3.1.4. These two statistical models are appropriate and commonly used to estimate the slope ( $\beta$ ) for epidemiological data. Calculation of the Unit Risk Factors (URFs) is correctly described in Section 4.2.3.1.6.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** While this is not my area of expertise, rationales for choice of the statistical and modeling approaches used to calculate the slope estimates and URFs appear to be based on thoughtful and well articulated consideration of a range of relevant factors.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #4:** The modeling approaches were appropriate. Although I am not familiar with Cox proportional hazards modeling, it seemed to be a sophisticated approach to dealing with multiplicative risk factors associated with lung cancer mortality.

I understand that this approach was used to mitigate some of the uncertainties associated with the Baltimore cohort, but could it also be utilized for the Crump et al. (2003) cohort? I assume that this approach is not possible due to the lack of availability of the individual exposure estimates and cofactor information, but TCEQ should state why they did not use this approach with this cohort, especially since they state that “Cox modeling is superior than Poisson regression modeling...”

**Response:** TCEQ appreciates the positive feedback in the first paragraph. The reviewer is correct that Cox proportional hazards modeling cannot be performed for the Crump et al. (2003) cohort due to the lack of required information. Clarifying text was added to the DSD.

## **2.8 Central Estimate of the URFs**

### **Is use of the central estimate of the URFs sufficiently discussed and justified?**

**Reviewer #1:** Yes.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** The central estimate of the slope parameter is discussed sufficiently in Sec. 4.2.3.1.4 for the Poisson regression model and the Cox proportional hazards model. These models are used to estimate the CrVI concentration corresponding to a lung cancer risk of 10% (EC<sub>10</sub>). The lower confidence limit (LEC<sub>10</sub>) is calculated to account for inherent variation in the concentration-response data in the epidemiology studies. Calculation of the URF = 0.10 / LEC<sub>10</sub> as shown on page 20 for low dose linear extrapolation is sufficiently justified.

**Response:** This reviewer appears to have misinterpreted the charge question and/or approach utilized in the DSD. Regardless, TCEQ agrees with Reviewers #1 and #4 that clearly indicated use of the central estimates is justified. The text in the DSD was revised to indicate more clearly that the URF was calculated using the central estimate of the concentration corresponding to an excess lung cancer risk of 1% (i.e., URF = 1/EC<sub>001</sub>) consistent with the TCEQ (2012) guidelines.

**Reviewer #3:** I wondered if factors other than those mentioned (i.e., where the number of responses – i.e., observed and expected cases is known) as a basis for justification of use of the central estimates should be considered.

The potential appropriate use of central estimates versus those at lower confidence intervals should, in my view, be considered in all cases, rather than relying on recommended defaults, taking into account a number of other factors including the nature of the estimates of exposure with which hazard levels are likely to be compared (depending on the problem formulation), the

stability of the data on which the central estimates are based and the desired degree of conservatism, based on the purpose of the assessment.

**Response:** TCEQ agrees that the appropriate use of central estimates versus those at lower confidence intervals should be considered in all cases instead of simply relying on defaults. Relevant factors have been considered under TCEQ guidance (e.g., mortality versus incidence, meta-analysis approach), although not all may have been explicitly discussed in the DSD. Additionally, the central URF estimates utilized for the final value do not differ significantly from the upper estimates, the URFs are based on human data (see Reviewer #4 comments), and the desired degree of conservatism has been achieved. In regard to the nature of the estimates of exposure with which hazard levels are likely to be compared, although TCEQ does not consider this relevant to the determination at hand, the calculated air concentration at 1 in 100,000 excess risk is orders of magnitude higher than long-term CrVI ambient air levels monitored in Texas.

**Reviewer #4:** Yes. The use of the central estimate is commonly done in other dose response assessments where human data form the basis of the assessment. This is because the uncertainty in the extrapolation of experimental animal data to humans is avoided, and the added conservatism through the use of the upper bound is not needed.

**Response:** TCEQ appreciates this positive feedback.

## ***2.9 Calculation of the Final URF***

**Are the most appropriate URFs from each study used to calculate the final URF? That is, was the choice of URFs for decision making the best choice – properly adjusted for covariates, based on the optimal exposure lag, and based on the inclusion of workers with a minimum length of employment?**

**Reviewer #1:** I would just use the 5 yr lag in the Baltimore data. The difference between the optimal lag (7 some years vs. 5 years) for the Baltimore data is imperceptible. For consistency with Crump et al. I would use the 5 years lag.

**Response:** As the reviewer states, the difference between the optimal lag and 5-year lag for the Baltimore data is “imperceptible.” Since the optimal lag provides the best model fit, TCEQ believes this is most predictive and represents the best dose-response modeling, which is considered by TCEQ as more important than consistency in exposure lag time between the two key studies. However, text was added to the DSD to indicate that an identical final weighted URF would result from use of the 5-year lag URF for the Baltimore cohort.

**Reviewer #2:** The most appropriate URF from each study was used to calculate the final URF. The URFs were properly adjusted for covariates, e.g., smoking. The optimal exposure lag is recommended. Inclusion of workers with a minimum length of employment is important.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** Rationales for the choice of the URFs from each study appear to be based on thoughtful and well articulated consideration of a range of relevant factors. In addition, analyses for a number of alternative options are also presented as a basis for comparison.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #4:** I am not convinced that the 7.4 year lag estimate is the best choice for calculating the final URF. Although it is the MLE of the lag for workers with a minimum of 1 year of employment, the model fit with a 7.4 year lag is not convincingly different than that with a 5 year lag based on the deviance shown in Table 6. When using a meta-analysis, you want to reduce inter-study variability as much as possible.

Maintaining the same lag time (5 years) and minimum length of employment (1 year) between both cohorts may be best. I recommend that TCEQ consider doing this.

**Response:** TCEQ did consider maintaining the same lag time (5 years) and minimum length of employment (1 year) between both cohorts. Reviewer #1 states the difference between the optimal lag and 5-year lag for the Baltimore data is “imperceptible.” Since the optimal lag provides the best model fit, TCEQ believes this is most predictive and represents the best dose-response modeling, which is considered by TCEQ as more important than consistency in exposure lag time between the two key studies. However, text was added to the DSD to indicate that an identical final weighted URF would result from use of the 5-year lag URF for the Baltimore cohort.

## ***2.10 Age-Dependent Adjustment Factors***

**Was the decision not to apply age-dependent adjustment factors (ADAFs) to the URF, to account for potential increased sensitivity of children, justified and properly considered given TCEQ guidance on evaluating the carcinogenic MOA (see Section 5.7.5 of TCEQ 2012)?**

**Reviewer #1:** Yes.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** Since CrVI has not been demonstrated to have a mutagenic MOA for lung carcinogenicity, it is reasonable not to apply an age-dependent adjustment factor (ADAF) to the URF to account for potential increased sensitivity of children.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** See comments above regarding the need for a stronger rationale for the conclusion that “CrVI has not been demonstrated to have a mutagenic MOA for lung carcinogenicity considering the reasonably scientifically-rigorous standard set under TCEQ guidelines” (Question 5). In my view this necessarily requires additional analysis of the cited relevant references.

**Response:** As indicated previously, additional text has been added to the DSD regarding considerations relevant to TCEQ's conclusion that a mutagenic MOA has not been adequately demonstrated.

**Reviewer #4:** The decision not to apply the age dependent adjustment factor appears to be justified, primarily because the most likely MOA for lung tumors is the formation of reactive oxygen species that is expected to have a threshold for adverse effect due to the lung's innate capacity to reduce CrVI extracellularly. This capacity for reduction is physiologically-based and not likely to vary significantly among individuals of different ages. Thus, the use of a linear default, or even bi-modal MOA with a linear component, is highly conservative. Multiplying this conservative URF by an ADAF does not make physiological sense.

**Response:** TCEQ appreciates this positive feedback.

## 2.11 Meta-Analysis Approach

**The final URF was derived using a meta-analysis approach that combined the two preferred URFs using a weighting based on inverse variance. Was this appropriate and does it result in a better URF and chronicESLnonthreshold(c)?**

**Reviewer #1:** Yes it was appropriate to combine the two preferred URFs as done.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** A meta-analysis approach that combines the two preferred URFs is appropriate. Inverse variance provides a measure of the precision of an estimate. That is, the smaller the variance of an estimate the better the precision and a higher weight (based on the reciprocal of the variance) is assigned to that estimate. This provides a better estimate of the URF and effect screening level (ESL).

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** Given the variations between the design of the two studies and populations examined, I wondered if any thought had been given to consideration at least semi-quantitatively of the relative uncertainty of study specific URFs as a basis for selection of an optimum value, rather than the combined approach weighted only on the basis of inverse variance (See comments below on uncertainty analysis).

**Response:** As indicated in the draft DSD, variance in the  $\beta$  values used to derive the study-specific URFs reflects uncertainty in the  $\beta$  estimates, is a standard statistical procedure used in meta-analyses, and was used as an appropriate and objective weighting factor. Both of the study URFs utilized and their associated variances are very similar. Additionally, upper bound estimates of the URFs are not significantly different from central estimates. These facts are indicative of good inter-study agreement as well as relatively low uncertainty in the slope parameter values. Thus, whatever differences may exist between these studies potentially related to uncertainty, such differences ultimately

do not result in the studies providing appreciably different answers. The inverse-variance weighting resulted in a final URF of 2.28E-03 per  $\mu\text{g}/\text{m}^3$  (rounded to 2.3E-03 per  $\mu\text{g}/\text{m}^3$ ). Had any alternative weighting method been used, the final URF would have been between 1.94E-03 and 2.56E-03 per  $\mu\text{g}/\text{m}^3$ . That is, the final URF resulting from combining the two individual URFs for the Painesville and Baltimore studies cannot be more than 17.5% lower or 12% higher than the final URF calculated in the DSD using the inverse-variance weighting. This circumstance does not justify an attempted analysis of study uncertainty in an attempt to select just one study, which would be tantamount to discarding a large amount of highly relevant dose-response data by assigning one study a weight of 100%, and would likely be considered by TCEQ to be less objective (and transparently quantitative) than the weighting factor employed.

**Reviewer #4:** I agree with TCEQ that neither the Baltimore nor the Painesville cohort is better than the other in terms of study design and interpretation of results. Thus, I agree with the use of TCEQ's meta-analysis approach. Since some of the glaring issues of the Baltimore cohort were corrected by limiting the minimum duration of employment and by using the Cox modeling approach, I feel comfortable that combining the two URFs is appropriate. The weighting approach used was also appropriate.

However, note that the Baltimore cohort (Gibb et al., 2000), which has more uncertainty due to study design issues, is weighed more heavily than the Painesville cohort (Crump et al. 2003) (55.6% of the weight versus 44.4%, respectively) for the derivation of the final URF. This appears to be counter-intuitive, TCEQ might recheck this weighting.

**Response:** TCEQ appreciates the positive feedback in the first paragraph. In regard to the second paragraph comment on uncertainty associated with the Baltimore cohort study, whatever differences may exist between these studies potentially related to uncertainty, such differences ultimately do not result in studies providing appreciably different answers. Additionally, both the URFs and the weighting factors for the two studies are very similar. Use of variance in the  $\beta$  values used to derive the study-specific URFs as a weighting factor is an objective measure that takes into account the uncertainty and variability present in the epidemiological data, a standard statistical procedure used in meta-analyses, and is appropriate. In addition, any other weighting scheme would have resulted in a final URF that is between 1.94E-03 and 2.56E-03 per  $\mu\text{g}/\text{m}^3$ . That is, the final URF resulting from combining the two individual URFs for the Painesville and Baltimore studies cannot be more than 17.5% lower or 12% higher than the final URF calculated using the inverse-variance weighting. This circumstance does not justify a reevaluation or altering of the weighting procedure.

### **3. Other Questions**

#### **3.1 Uncertainty Analysis**

**Appendix E presents an uncertainty analysis. Have all the key uncertainties been identified? Are the conclusions regarding these uncertainty issues and their impact on the URFs correct and discussed?**



**Reviewer #1:** I think Appendix F presents a reasonable uncertainty analysis.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #2:** The key uncertainties have been identified. The conclusions regarding the uncertainty issues and their impact on the URFs are adequately discussed and appear to be correct.

**Response:** TCEQ appreciates this positive feedback.

**Reviewer #3:** The authors appropriately note that many of the presented uncertainties are common to risk assessments based on epidemiological studies. I wondered if there had been any thought given to providing more specific figurative representation of the calculated URFs with visual “bounding” based on consideration of their relative uncertainty. The objective is to additionally clarify confidence in the various outputs, based on at least semi-quantitative assessment of the impact of stated uncertainties, in a relative context.

**Response:** As indicated in a previous response, both of the study URFs utilized and their associated variances are very similar, and upper bound estimates of the URFs are not significantly different from central estimates. These facts are indicative of good inter-study agreement as well as relatively low uncertainty in the slope parameter values. Thus, whatever the studies relative uncertainties may be, such differences ultimately do not result in appreciably different answers or significant consequence for the final URF. This circumstance does not justify an attempted analysis of study uncertainty beyond what is already presented in the DSD, which Reviewers #1 and #2 agree is a reasonable uncertainty analysis identifying key uncertainties and their impact on the URFs are adequately discussed.

**Reviewer #4:** I think some of the key uncertainties have been identified in Appendix E. Section E.2 is particularly important since the URF is intended for the general population, not just healthy workers. Uncertainties due to sex, age (i.e., children, adolescents, and/or elderly), and race need to be carefully considered and TCEQ appears to have done this in its evaluation of the ADAF.

However, I would like to see some information on susceptibility and sensitivity beyond TCEQ’s assertion that background lung cancer rates are similar (or lessened) among these groups than among workers.

**Response:** TCEQ appreciates the positive feedback in the first paragraph. In regard to the second paragraph comment on susceptibility and sensitivity, TCEQ agrees with the reviewer’s comment that, “Uncertainties due to sex, age (i.e., children, adolescents, and/or elderly), and race need to be carefully considered and TCEQ appears to have done this...” Furthermore, TCEQ agrees with Reviewers #1 and #2 that the uncertainty analysis is reasonable, identifies key uncertainties, and adequately discusses their impact on the URFs.

### **3.2 Other Relevant Issues or Questions**

**Please identify any other relevant issues or questions that are important for the review of this assessment.**

**Reviewer #1:** I have no substantive issues with the risk assessment. One formatting issue: the Table numbers in the text do not seem to correspond to the relevant Tables.

**Response:** TCEQ appreciates the positive feedback. The mismatched table numbers were an artifact of omitting other sections not the subject of this review and have been corrected.

**Reviewer #2:** The Table numbers in the text do not match the actual Table numbers.

**Response:** The mismatched table numbers were an artifact of omitting other sections not the subject of this review and have been corrected.

**Reviewer #3:** Justification for the dosimetric adjustment (Section 4.2.3.1.5) should be included since many effects on the lung are concentration – related.

**Response:** The occupational-to-environmental concentration dosimetric adjustment in Section 4.2.3.1.5 is consistent with TCEQ guidance and a standard adjustment when using occupational data in a carcinogenic dose-response assessment. Because the exposure-response models used by TCEQ used cumulative exposure as the dose metric, the occupational-to-environmental dosimetric adjustments used in the CrVI DSD assumes that the dose metric is cumulative exposure to CrVI. This same occupational-to-environmental dosimetric adjustment would apply if average daily concentration had been used as the dose metric.

**Reviewer #4:** I was surprised at the frequent use of inappropriate precision throughout the text. As TCEQ knows well, the wrought risk assessment values are generally no more precise than one digit. Listing these values with two digits of precision is problematic since managers will then consider these values appropriate at two digits. Using three digits of precision is scientifically incorrect.

**Response:** TCEQ has previously determined, as outlined in guidance which underwent an external expert peer review organized by TERA, that it will not round numbers until the final toxicity factor is calculated. The final toxicity factor will be rounded to two significant figures, as has been historically done by TCEQ and was done in the DSD.

Several marginal comments are listed in the table below for consideration.

Section Number	Page Number	Comment
3.1.2	2	This is a well written section, with enough text to be convincing, even if one only has a passing understanding of chromium's toxicity.
3.1.2	2	"These reactions commonly involve intracellular species, such as ascorbate, glutathione, or amino acids." - use the word "chemicals" instead of "species"
3.1.2	3	"Cellular damage from exposure to many chromium compounds can be blocked by radical scavengers, further strengthening the hypothesis that oxygen radicals play a key role in chromium toxicity." - Well, we presume that this hypothesis has been previously stated; this is the first time it is mentioned in this section.
4.2.1	4	"Particulate forms of CrVI, relatively water insoluble compounds more specifically (e.g., moderate to low solubility), appear to be more potent lung carcinogens, with extracellular dissolution of the CrVI compound critical to activity" - It is not readily apparent from this text in which direction the dissolution of CrVI takes the toxicity: more toxic or less?
4.2.1	5	"Consistent with these WOE classifications, the TCEQ considers CrVI and CrVI compounds as a group to be carcinogenic to humans via inhalation (at least at sufficiently high long-term doses)." - I agree with the WOE classification and its application to all CrVI forms.
4.2.3	7	"More specifically, for comparison of nonlinear-threshold assessment results to the TCEQ policy-based 1 in 100,000 excess target risk air concentration calculated using the default linear low-dose URF approach" - This is not a complete sentence. Suggested revision: More specifically, these authors compared the nonlinear...
4.2.3	8	"... derives a potential cancer-based chronic ReV of 0.24 µg CrVI/m <sup>3</sup> following dosimetric adjustments and application of appropriate UFs (total UF of 30)." - non-linear ReV of 0.24 ug/m <sup>3</sup>
4.2.3.1.2	8	"Thus, the dose metric used for the dose-response assessment is cumulative CrVI exposure..." - I am ok with the choice of this dose metric.
4.2.3.1.3.1	9	All the stated risks in this paragraph are too precise.
4.2.3.1.3.1	9	"... estimated the slope of the linear relative risk model with multiplicative background as 0.636" - What are the units of the slope? Risk per person-year?
4.2.3.1.3.1	10	"... estimates based on Crump et al. (2003) are given in Table 8 below." - Table numbers throughout this text do not appear to be correct.
4.2.3.1.3.2	11	"... ≥ 5 years for the Baltimore cohort" - of the Baltimore cohort
4.2.3.1.3.2	11	"As can be seen..." - Moreover, as can be...
4.2.3.1.3.2	11	"and to increase SMRs for..." - use "have increased" instead of "to increase"

Section Number	Page Number	Comment
4.2.3.1.3.2	11	"... (important when short-term, low- dose workers are used as the referent) and the general population (important when the general population is the referent as in Gibb et al. 2000)" - These two parentheticals seem to be important, but I do not understand the context in which they are being used. Please expand the text a bit here.
4.2.3.1.3.2	11	"the exposure scenario they experienced..." - use "the Baltimore cohort" instead of "they"
4.2.3.1.3.3	14	"... are given in Table 9 below." - This is Table 2, correct?
4.2.3.1.3.3 Table 2.	14	Why is the expected value different in each group? Are these values not standardized?

**Response:** TCEQ appreciates the time required to develop these minor comments. Those which are highlighted (in gray) were addressed by TCEQ in the DSD. The last comment (regarding Table 2) is addressed in the following response. The expected number of lung cancer deaths (E) in Table 2 was back-calculated from the observed number of lung cancers (O) and the SMRs reported in Table 15 in Applied Epidemiology (2002). Cumulative exposure intervals to calculate SMRs can be defined using different criteria; for example: (a) intervals with approximately equal observed number of deaths in each group; (b) intervals with approximately equal expected number of deaths in each group; and (c) intervals with a convenient breakdown of the cumulative exposure, regardless of the number of observed and expected deaths in each group. The summary statistics given in Table 15 in Applied Epidemiology (2002) defined cumulative exposure intervals that were reasonable and that included at least some lung cancer deaths, regardless of the homogeneity in the observed and expected number of lung cancer deaths in the different groups.

## 4. Public Comments

The following addresses public written comments submitted by the City of Houston and the Ontario Ministry of the Environment and reported in Appendix C of TERA's June 17, 2013 expert panel review report.

### 4.1 City of Houston

**Comment #1:** Thank you for giving the Houston Department of Health & Human Services, Bureau of Pollution Control & Prevention the opportunity to comment on important changes to the hexavalent chromium toxicity value and associated screening levels presented in the Final Draft of the Development Support Document dated March 2013. The findings in this document indicate that the Effect Screening Level (ESL) for this chemical will be lowered from 0.01 to 0.0043 µg/m<sup>3</sup>. The deadline for filing comments in May 24, 2013. The Houston Department of Health, Bureau of Pollution Control & Prevention endorses this change with the following comments.

**Response:** TCEQ appreciates the City of Houston's support for the draft carcinogenicity-

based ESL, which TCEQ believes is based on the most scientifically-defensible dose-response assessment possible.

**Comment #2:** Hexavalent chromium (CrVI) is an important air toxic of concern in the City of Houston. As early as 2006 it was identified as one of twelve air pollutants posing a definite risk to Houstonians<sup>1</sup> and as recently as 2012 it has been found in the ambient air downwind of some metal recycler facilities at unhealthy levels.<sup>2</sup> Prior to the discovery of CrVI downwind of metal recyclers, it had remained un-monitored and all discussions of risk to the community from this contaminant were based on modeling. We believe that the decrease in the ESLs should be accompanied by an increase in actual monitoring of this chemical.

**Response:** The City of Houston's comment is noted. However, the technical and scientific merit of TCEQ's draft carcinogenic assessment of CrVI, as opposed to CrVI monitoring in TCEQ Region 12, was the subject of the external expert panel review and request for public comments (<http://www.tera.org/Peer/crvi/index.html>).

**Comment #3:** In addition, we have noted that no adjustments have been made for childhood exposure because there currently is not information on the differential effect on children. The TCEQ states that it will review it in the future. Because the locations where the City of Houston has found elevated risk from ambient concentrations are residential, we are anxious that TCEQ re-examine the risk to children in a timely manner so that children are adequately protected.

**Response:** This issue will be revisited by TCEQ as relevant data become available.

**Comment #4:** Finally, we remain of the opinion that a screening level is more appropriate at the 1:1,000,000 risk limit and the 1:100,000 is more correctly an action level.

**Response:** This comment on TCEQ's policy-based, risk management excess risk level of 1 in 100,000 is noted. The no significant excess risk level for a carcinogenic chemical with a nonthreshold assessment such as CrVI is defined as the concentration associated with a theoretical excess lifetime cancer risk of 1 in 100,000. This theoretical excess lifetime cancer risk level is consistent with the State of California's No Significant Risk Level (22 CCR §12703) and is ten times less than the upper end of USEPA's acceptable risk range (1 in 10,000). This risk management goal was approved by the Commissioners and Executive Director of the TCEQ and is consistent with other TCEQ programs.

Footnote 1: Sexton, K., Linder, S., Abramson, S., Bondy, M. Delclos, G, Fraser, M., Stock, T., Ward, J., (2006) "A Closer Look at Air Pollution in Houston: Identifying Priority Health Risks, Report of the Mayor's Task Force on the Health Effects of Air Pollution"; Institute for Health Policy Report ES-001-006, Prepared for the City of Houston by The Institute for Health Policy, University of Texas School of Public Health, , Health Science Center at Houston. Available at: [http://www.sph.uth.tmc.edu/uploadedFiles/Centers/IHP/Report\\_Body.pdf](http://www.sph.uth.tmc.edu/uploadedFiles/Centers/IHP/Report_Body.pdf)

Footnote 2: Raun, Loren, Karl Pepple, Dan Hoyt, Arturo Blanco, Don Richner and Jiao Li. Community scale air pollution area sources and public health: Assessing risk from an under-regulated area source of metal particulate, Environmental Impact Assessment Review, April 2013.

## 4.2 Ontario Ministry of the Environment

**Comment #1:** I felt that much of the MOA section lacks sufficient supporting evidence and raises questions. For example:

Excerpt	Comment and Response to Comment
<p><i>“However, TCEQ (2012) indicates there should be a reasonably scientifically-rigorous standard for demonstration of a mutagenic MOA and the TCEQ believes such a standard has <b>not</b> been met for CrVI (i.e., merely demonstrating plausibility is not tantamount to an adequately robust demonstration that mutagenicity is in fact THE initiating event in target tissues).”</i></p>	<p>Although certain theories of carcinogenicity are briefly mentioned (Holmes et al., 2008; Tox Strategies, 2012; Zhitkovich et al., 2011, etc.), the theories don’t appear to be reviewed in any detail. In order to lend support to the above statement (or any other MOA hypothesis), I suggest that a more detailed MOA analysis is carried out, which would be critical in in developing a more data-informed value. (I understand that the purpose of the DSD is not a comprehensive WOE paper on the MOA. However, I find the current write-up confusing. If the standard for scientific rigour has not been met for Cr(VI), why is a linear extrapolation being carried out?)</p> <p><b>Response:</b> Additional discussion and clarifying language relevant to the referenced excerpt was added to the MOA section of the DSD pursuant to the comment, consistent with its purpose for the document. A linear low-dose extrapolation was used as a conservative default in the absence of an adequately supported alternate approach with an acceptable level of scientific uncertainty for the protection of public health.</p>
<p><i>“CrVI carcinogenicity/toxicity appears to be mediated through reactive intermediates (e.g., CrIII, oxygen radicals) generated during the rapid intracellular reduction of CrVI to CrIII, which is the final product of intracellular CrVI reduction”</i></p>	<p>Although cited by TCEQ in a different sections, O’Brien 2003 and Zhitkovich 2005 suggests that radical formation is likely limited under physiological conditions, where the formation of sequential electron transfers is restricted due to millimolar ascorbate concentrations. This suggests a diminished role for radical species in Cr(VI) carcinogenicity and should be discussed in more details.</p> <p><b>Response:</b> Additional text was added to the DSD pursuant to the comment.</p>
<p><i>“These MOA concepts are consistent with ATSDR (2012) indicating that CrVI absorption into tissues may be a function of doses high enough to overwhelm CrVI reduction mechanisms and the results of a recent oral carcinogenic MOA analysis</i></p>	<p>As reviewed by Harvey Clewell for OSHA (2006) cell uptake will occur concurrently and in parallel with extracellular reduction). Thus, even at low Cr(VI) concentrations where the reductive capacity is undiminished, a fraction of Cr(VI) will still be taken up into cells, be reduced to Cr(III) and may interact with DNA. This is inconsistent with what is presented in the TCEQ document.</p> <p><b>Response:</b> Additional discussion and clarifying language was</p>

Excerpt	Comment and Response to Comment
<i>(Thompson et al. 2011).</i> ”	added to the MOA section of the DSD pursuant to the comment.

**Comment #2:** As discussed in the answer to question #3, I felt that the WOE analysis of the MOA could be examined more thoroughly and presented to the reader in more details.

Regarding whether the URF applies to all forms of Cr(VI), irrespective of solubility, for public health protection, is appropriate as insoluble compounds have slower clearance and longer residence time in the lung, which may enhance their carcinogenic potential.

**Response:** Additional discussion and clarifying language was added to the MOA section of the DSD pursuant to the first part of the comment, consistent with its purpose for the document. TCEQ appreciates the positive feedback in the last part of the comment on the TCEQ decision to apply the URF to all forms of CrVI.

**Comment #3:** As discussed in the answer to question #3, I felt that many aspects of the MOA discussion should be examined more thoroughly and presented to the reader in more details. And given that *“if data on the MOA are not sufficient to justify an alternate approach to linear low-dose extrapolation, the DSD only needs to generally summarize the primary proposed MOAs, MOA issues, and justify use of the default extrapolation methods”* why does TCEQ state: *“However, TCEQ (2012) indicates there should be a reasonably scientifically-rigorous standard for demonstration of a mutagenic MOA and the TCEQ believes such a standard has not been met for CrVI...”*? The document as written, appears biased in favour of a threshold-like analysis, yet derives a value based on linear extrapolation. This is confusing to the reader.

**Response:** Additional discussion and clarifying language was added to the MOA section of the DSD pursuant to the comment, consistent with its purpose for the document. “A reasonably scientifically-rigorous standard for demonstration of a mutagenic MOA” refers to the evaluation under TCEQ guidelines of MOA analyses (or similar studies) published in the peer-reviewed literature which purport to demonstrate a mutagenic MOA.

**Comment #4:** I do believe that at this time, linear extrapolation is the most appropriate option given that more sophisticated modelling techniques have not yet been developed to account for the non-linear kinetics (dissolution, extracellular reduction, cellular uptake as well as the homeostatic response to depletion of reductive resources) of Cr(VI). I also believe that selecting a crude point of departure and applying uncertainty factors (as carried out in Haney et al., 2012) is also an overly-simplistic approach to address this. These points have been previously mentioned by Harvey Clewell for OSHA (2006) and Lynne Haber for TERA (2008).

**Response:** TCEQ agrees that linear extrapolation is the most appropriate option at this time and believes that the approach in Haney et al. is associated with an unacceptable level of uncertainty utilizing currently available data.

## 5. References

- Haber, L. 2008. TERA. (Personal Communication). Comments on: Ontario Ministry of the Environment Science Discussion Document on Hexavalent Chromium.
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