

2-3-15

Members of the Air Toxics Science Advisory Committee,

Re: Review of ABC for Lead (CAS# 7439-92-1)

Submitted by James T. Lubischer MD
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A) Summary of Chronic Inhalation Exposure Values for Lead, Non-Cancer Effects

<i>EPA/IRIS:</i>	No value listed as “essentially without a threshold”.
<i>EPA/PPRTV:</i>	No value listed, defers to IRIS review.
<i>WHO/IARC:</i>	*
<i>OEHHA/ARB adopted:</i>	No value listed. Notes “no threshold” known.**
<i>OEHHA/ARB proposed:</i>	?
<i>CDC/ATSDR:</i>	No value listed as “threshold...has not been identified”.
<i>EPA/OAQPS:</i>	NAAQS = 0.15ug/m ³ . Notes, “...threshold...cannot be discerned...”

[*Lead is “probably carcinogenic to humans”. **The Consolidated Table Of OEHHA/ARB Approved Risk Assessment Health Values at page 5 lists an Inhalation Unit Risk (ug/m³)⁻¹ for cancer of 1.2E-05 TAC
http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/documents/contable.pdf]

B) Comments

Lowering Oregon’s ABC for lead is justified and necessary.¹

A lower ABC is necessary because Oregon has 512 facility sources that continue to release lead into our air. According to the National Emissions Inventory two of these sources are estimated to emit over one-half tons per year (tpy). The highest facility source of lead in Oregon is the Hillsboro Airport with estimated emissions of 0.68 tpy in 2008, 0.58 tpy in 2011 and is forecast to emit 0.9 tpy by the year 2016 due to an additional runway.² About 10 tons of lead are estimated to be released into Oregon’s air each year.³

“With regard to our understanding of the relationship between exposure or blood Pb levels in young children and neurocognitive effects, the evidence in this review, as in the last, does not establish a threshold blood Pb level for neurocognitive effects in young children (ISA, sections 1.9.4 and 4.3.12)”

EPA Policy Assessment for the Review of the Lead National Ambient Air Quality Standards May 2014 EPA-452/R-14-001, p 4-17
http://www.epa.gov/ttn/naaqs/standards/pb/data/140501_pa_pb_fin.pdf

A lower ABC is justified because no threshold for the neurotoxic effects of lead on the developing child’s brain has been found. My understanding is that an ABC is a concentration (of an air toxin) below which there results no adverse health effects over a lifetime.⁴ Unless a threshold can be established for lead’s neurotoxicity the ABC for lead must be zero or perhaps equivalent to what the EPA has considered “the average pristine ambient background concentration of 0.5 ng/m³...”⁵ (0.5 ng/m³ = 0.0005 ug/m³)

I strongly recommend ATSAC review the “Risk Assessment” analysis starting at page 4-28 of the 2007 Policy Assessment OAQPS Staff Paper which discusses expected IQ losses for various air quality scenarios. Starting at page 4-34, tables 4-3 through 4-8 show the IQ loss expected and numbers of children affected even at the lowest level examined, 0.02 ug/m³.⁶ (Per page 4-30, when looking at these tables the focus is on the LLL model values.)

As noted above, IRIS, OEHHA/ARB, and CDC/ATSDR do not give chronic inhalation exposure values for lead. IRIS, OEHHA/ARB, and CDC/ATSDR each cite the lack of a threshold for lead toxicity. The EPA’s Administrator also acknowledges the lack of a threshold for lead toxicity.⁷ Notwithstanding this acknowledgement the Administrator has judged that a revision of the NAAQS for lead of 0.15 ug/m³ is not requisite to protect the public health with an adequate margin of safety.

It is difficult to reconcile the Administrator’s judgement not to revise the NAAQS of 0.15 ug/m³ with the unanimous acknowledgement that there is no threshold for lead’s neurotoxicity. The Administrator is required to determine an air concentration for lead “which is necessary, with an adequate margin of safety, to protect the public health”. The judgement by the Administrator to not lower the NAAQS is framed in the recommendations by the Clean Air Advisory Committee (CASAC) in a “March 2007 letter”, which stated,

*“...a population loss of 1-2 IQ points is highly significant from a public health perspective”
and that “the primary lead standard should be set so as to protect 99.5% of the
population from exceeding that IQ”⁸*

[an IQ loss of 1-2 points should be] *“prevented in all but a small percentile of the population”⁹*

So the NAAQS allows some IQ loss for some children. Therefore, the Administrator did not specify a standard that is “likely to be without an appreciable risk of deleterious effects during a lifetime” for all children. Also, please note that in 2008 the Administrator stated, “Ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur” (73 FR 22998, November 12, 2008).¹⁰ In short, the current proposed rule to not lower the NAAQS for lead of 0.15 ug/m³ allows for some loss of IQ in some children. Basing Oregon’s ABC on the NAAQS will leave some children at risk. We can do better.

B C) Review of relevant sources

Integrated Risk Information System (IRIS)

IRIS concludes it is “inappropriate” to estimate an RfD (and by extension an RfC) for lead because RfDs and RfCs are estimates of “daily exposure to the human population (including sensitive subgroups) that is [are] likely to be without an appreciable risk of deleterious effects during a lifetime.”

IRIS concludes such estimates would be “inappropriate” because no threshold for lead’s toxicity has been established. To the contrary, IRIS states, “It appears that some of these effects [of lead], particularly changes in the levels of certain blood enzymes and in aspects of children’s neurobehavioral development, may occur at blood lead levels so low as to be essentially without a threshold.”¹¹

IRIS states lead is a “probable human carcinogen” [<http://www.epa.gov/iris/subst/0277.htm#refinhal> see II.A.1]

IRIS: “I.A.1. Oral RfD Summary... Lead bioaccumulates in the body, primarily in the skeleton.” [The IRIS report is available @ <http://www.epa.gov/iris/subst/0277.htm#refinhal> see fifth paragraph of I.A.1]

IRIS: “II.A.4. Supporting Data for Carcinogenicity... Under certain conditions lead compounds are capable of inducing chromosomal aberrations in vivo and in tissue cultures. Grandjean et al. (1983) showed a relationship between sister chromatid exchange and lead exposure in exposed workers. Lead has been shown, in a number of DNA structure and function assays, to affect the molecular processes associated with the regulation of gene expression (U.S. EPA, 1986b).” [The IRIS report is available @ <http://www.epa.gov/iris/subst/0277.htm#refinhal> see second paragraph of II.A.4]

Provisional Peer Review Toxicity Values (PPRTVs)

The PPRTVs has no listing for lead. [<http://hhpprtv.ornl.gov/quickview/pprtv.php> and http://hhpprtv.ornl.gov/quickview/pprtv_compare.php]

“The PPRTV electronic library summarizes provisional toxicity values for contaminants in the table, when no IRIS value on that contaminant is available.” [<http://hhpprtv.ornl.gov/> > User’s Guide, **first sentence**] IRIS has reviewed lead as noted above.

“Once an IRIS value for a specific chemical becomes available for Agency review, the analogous PPRTV for that same chemical is retired.” http://hhpprtv.ornl.gov/issue_papers/Ammonia.pdf p 1, **last paragraph**.

International Agency for Research on Cancer (IARC)

“Inorganic lead compounds are probably carcinogenic to humans.” <http://apps.who.int/bookorders/MDIbookPDF/Book/17200087.pdf> , **on right, second paragraph, line 12**.

Office of Environmental Health Hazard Assessment / Air Resources Board (OEHHA/ARB)

OEHHA does not include lead in their Acute, 8-hour and Chronic Reference Exposure Level (REL) Summary. <http://www.oehha.ca.gov/air/allrels.html> June 2014 [Non-cancer Health Effects (RELs) <http://www.oehha.ca.gov/> > home > Air > then at menu on far right choose “Non-cancer health effects (RELs) > “View the Table of OEHHA Acute, 8-hour and Chronic Reference Exposure Level (RELs)”]

The Consolidated Table Of OEHHA/ARB Approved Risk Assessment Health Values contains no listing for non-cancer chronic inhalation effects. p5 @ http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/documents/contable.pdf

“The ARB has identified lead and vinyl chloride as 'toxic air contaminants' with no threshold level of exposure for adverse health effects determined. These actions allow for the implementation of control measures at levels below the ambient concentrations specified for these pollutants. <http://www.arb.ca.gov/research/aaqs/aaqs2.pdf> > **second page, footnote #11 6-4-13** California Air Resources Board (6-4-13)

A 1996 Executive Summary by the Staff of the ARB / OEHHA Report “**Proposed Identification of Inorganic Lead as a Toxic Air Contaminant**” stated, “...the OEHHA staff concurs with the U.S. EPA, the CDC, and the National Academy of Sciences that 10 micrograms per deciliter should be regarded as the level of concern for children. A no observed adverse effect level (NOAEL) has not yet been clearly identified, and an analysis, specifically focusing on the determination of a threshold, was unable to detect one.” <http://www.arb.ca.gov/toxics/id/summary/leadsum.pdf> , p 10, **last paragraph**.

“If the Board [Air Resources Board] has found that there is not sufficient available scientific evidence to support the identification of a threshold exposure level, the "Threshold" column specifies "None identified.” Lead’s “Threshold Determination” is “None identified”. 2011 <http://www.arb.ca.gov/toxics/id/taclist.htm>

“In 1996, the ARB established a cancer potency value of 1.2×10^{-5} per $\mu\text{g}/\text{m}^3$ for inorganic lead exposure. This value also applies to lead acetate, lead phosphate and lead subacetate.” <http://www.arb.ca.gov/research/aaqs/caaqs/pb-1/pb-1.htm> > **History of Lead Quality Standard**

The Consolidated Table Of OEHHA/ARB Approved Risk Assessment Health Values at page 5 lists an Inhalation Unit Risk $(\text{ug}/\text{m}^3)^{-1}$ for cancer of $1.2\text{E}-05$ TAC http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/documents/contable.pdf

Substances and Disease Registry (ATSDR)

The December 2014 ATSDR Minimal Risk Level list has no listing for lead.

http://www.atsdr.cdc.gov/mrls/pdfs/atsdr_mrls_december_2014.pdf

“MRLs (Minimal Risk Levels) were not derived for lead because a clear threshold for some of the more sensitive effects in humans has not been identified.” <http://www.atsdr.cdc.gov/toxguides/toxguide-13.pdf>
> scroll down to “Minimal Risk Levels (MRLs)”

“The body accumulates lead over a lifetime and normally releases it very slowly.”

[<http://www.atsdr.cdc.gov/csem/csem.asp?csem=7&po=9> May need to download PDF and see page 29, “Key Points”; or click on :”Biological Fate” in menu on left of initial page, then go down to “Key Points”.]

For the references to “[Toxicological Profile for Lead](#)” cited below go to

<http://www.atsdr.cdc.gov/ToxProfiles/TP.asp?id=96&tid=22> > click on “PDF Version”.

“...elemental lead cannot be broken down...” p4 “[Toxicological Profile for Lead](#)”, US Department of Health and Human Services, Public Health Service Agency for Toxic Substances and Disease Registry, August 2007.

“Fetuses exposed to lead in the womb...may be born *prematurely* and have *lower weights* at birth. Exposure in the womb, in infancy, or in early childhood also may *slow mental development* and cause *lower intelligence* later in childhood. There is evidence that these effects may persist beyond childhood...” p10, **last 3 sentences of second paragraph**, “[Toxicological Profile for Lead](#)”, US Department of Health and Human Services, Public Health Service Agency for Toxic Substances and Disease Registry, August 2007.

“Lead can be transferred from the mother to the fetus and also from the mother to infants via maternal milk.” p156, **line 12 in** “[Toxicological Profile for Lead](#)”, US Department of Health and Human Services, Public Health Service Agency for Toxic Substances and Disease Registry, August 2007.

“...several other population groups at risk for potential exposure to high levels of lead can be identified: preschool-age children and fetuses...” p374, **last paragraph first sentence**, “[Toxicological Profile for Lead](#)”, US Department of Health and Human Services, Public Health Service Agency for Toxic Substances and Disease Registry, August 2007.

~~“Lead can be transferred from mother to the fetus and also from the mother to infants via maternal milk.” p156, line 12 in “[Toxicological Profile for Lead](#)”, US Department of Health and Human Services, Public Health Service Agency for Toxic Substances and Disease Registry, August 2007. duplicate~~

“The most important step parents, doctors, and others can take is to prevent lead exposure before it occurs. CDC recommends focusing on primary prevention of lead exposure.”

[http://www.atsdr.cdc.gov/sites/toxzine/lead_toxzine.html > scroll down to “Governmental Regulations and Recommendations” **close to the end; first sentence of fifth paragraph.**]

Guidelines For The Identification And Management Of Lead Exposure In Pregnant And Lactating Women, November 2010. U.S. Department of Health and Human Services, Atlanta, GA: “**Because there is no apparent threshold below which adverse effects of lead do not occur**,...[the] CDC has not identified an allowable exposure level, level of concern, or any other bright line intended to connote a safe or unsafe level of exposure for either mother or fetus.” (page iv, **line 2**); “Lead readily crosses the placenta by passive diffusion and has been measured in the fetal brain as early as the end of the first trimester, so primary prevention of exposure is particularly important to reduce risk.” (page 27, **fourth “Key Points”**)
<http://www.cdc.gov/nceh/lead/publications/LeadandPregnancy2010.pdf>

Office of Air Quality Planning and Standards (OAQPS)

The National Ambient Air Quality Standard for Lead is 0.15 ug/m³ with a rolling 3 month average.

<http://www.epa.gov/oar/oaqps/> > Under “Air Quality” choose “National Ambient Air Quality Standards. (NAAQS)”.

[To find the Federal Register cited below go to

<http://www.gpo.gov/fdsys/granule/FR-2008-11-12/E8-25654> > In the “Actions” box on the left choose “Browse the Federal Register” > 2015 > January > Monday, January 5 > Environmental Protection Agency > choose “PDF” or “Text” (In the “Text” choice you can copy sentences easily).]

EPA Administrator acknowledges that no threshold has been found for the neurotoxic effects of lead. See the Federal Register / Vol. 80, No. 2 / Monday, January 5, 2015: “...within the range of blood Pb levels investigated in the available evidence base, a threshold level for neurocognitive effects was not identified (73 FR 66984, November 12, 2008; 2006 CD, p. 8-67).” p287, line 13 of “PDF” or line 7 of “Text”; “...as in the last review, a threshold blood Pb level with which nervous system effects, and specifically cognitive effects, occur in young children cannot be discerned from the currently available studies (ISA, sections 1.9.3 and 4.3.12).” p294, line 21 of “PDF”; or in “Text” go to first sentence of the paragraph beginning with “We additionally note...” ; “...the PA notes that the evidence in this review, as in the last, does not establish a threshold blood Pb level for neurocognitive effects in young children (ISA, sections 1.9.4 and 4.3.12).” p307, line 10 in “PDF” ; line 8 in “Text”; “...given the lack of identified blood Pb level threshold in the current evidence base for neurocognitive effects...”, p312, third column line 10 in “PDF”; or line 17 of paragraph beginning with “In drawing conclusions...” in the “Text” version.

EPA’s 2013 Integrated Science Assessment for Lead, page lxxxviii, last sentence of first paragraph (EPA/600/R-10/075F | June 2013 | www.epa.gov) states, “...there is no evidence of a threshold below which there are no harmful effects on cognition from Pb [lead] exposure.” [Go to <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=255721> > Downloads > Lead ISA Final Report with Errata Sheet (PDF)]

“The EPA concludes that a causal relationship is likely to exist between Pb exposure and cancer, based primarily on consistent, strong evidence from experimental animal studies, but inconsistent epidemiological evidence (ISA, section 4.10.5). Lead has also been classified as a probable human carcinogen by the International Agency for Research on Cancer, based mainly on sufficient animal evidence, and as reasonably anticipated to be a human carcinogen by the U.S. National Toxicology Program (ISA, section 4.10).”¹²

Thank you,

James T. Lubischer MD

¹ Per the Clean Air Act, Oregon has the authority to establish ambient air quality standards “which are more stringent than the national standards.” CFR Title 40, Chapter 1, Subchapter C, Part 50, Section 50.2(d) gives Oregon the authority to establish a lower standard for lead than the NAAQS. §50.2 Scope. 50.2(d): “The proposal, promulgation, or revision of national primary and secondary ambient air quality standards shall not prohibit any State or Indian country from establishing ambient air quality standards for that State or area under a tribal CAA program or any portion thereof which are more stringent than the national standards.” [See <http://www.ecfr.gov/cgi-bin/text-id.x?SID=e8d697599f0308b726c8c2c1409d9288&node=se40.2.50.12&rgn=div8>]

² See page 30, Table 6-3, of the [2/14 Hillsboro Airport Parallel Runway 12L/30R Final Supplemental Environmental Assessment.](#)

³ About 10 tons of lead are emitted in Oregon every year. According to the 2011 National Emissions Inventory [<http://www.epa.gov/ttn/chief/net/2011inventory.html>], scroll down to “Maps and Fusion Tables” > Lead Table > Filter > State > Or] there are 512 facility sites in Oregon that emit lead into the air, the overwhelming majority being airports. Oregon’s top emitting airports’ collectively emit over 3 tons of lead just in the landing-takeoff cycles at airports. (The Port of Portland estimates that Hillsboro Airport alone will emit 0.9 tons by 2016– See page 30, Table 6-3, of the [2/14 Hillsboro Airport Parallel Runway 12L/30R Final Supplemental Environmental](#)

Assessment.) In 2008 an additional 5.3 tons was emitted by aircraft during the “cruise” phase of flight. [See Calculating Piston - Engine Aircraft Airport Inventories for Lead for the 2008 National Emissions Inventory, by the Assessment and Standards Division Office of Transportation and Air Quality U.S. Environmental Protection Agency @ <http://www.epa.gov/otaq/regs/nonroad/aviation/420b10044.pdf> .

⁴ Pursuant to OAR 340-246-0090, Oregon’s Ambient Benchmark Concentrations (ABC) are “...concentrations of air toxics that serve as goals in the Oregon Air Toxics Program. They are based on human health risk and hazard levels considering sensitive populations.” Also, “Oregon air toxics benchmarks are based on concentration levels that would result in a cancer risk of one-in-a-million additional cancers based on a lifetime of exposure. For non-carcinogens, the benchmarks are levels you could breathe for a lifetime without any non-cancer health effects.” [DEQ website @ <http://www.deq.state.or.us/qa/toxics/benchmark.htm> .]

⁵ See page 72 of EPA’s 2010 Development and Evaluation of an Air Quality Modeling Approach for Lead Emissions from Piston-Engine Aircraft Operating on Leaded Aviation Gasoline done at Santa Monica Airport in California. (EPA-420-R-10-007, February 2010): “The combined impacts from on-roadway mobile source Pb exhaust and entrained Pb emissions were shown to be less than the average pristine ambient background concentration of 0.5 ng/m³ and are therefore not expected to be a significant contributor to ambient Pb concentrations levels.”

⁶ Review of the National Ambient Air Quality Standards for Lead: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, November 2007, EPA-452/R-07-013. http://www.epa.gov/ttn/naaqs/standards/pb/data/20071101_pb_staff.pdf

⁷ Federal Register / Vol. 80, No. 2 / Monday, January 5, 2015: “...within the range of blood Pb levels investigated in the available evidence base, a threshold level for neurocognitive effects was not identified (73 FR 66984, November 12, 2008; 2006 CD, p. 8-67).” p287; “...as in the last review, a threshold blood Pb level with which nervous system effects, and specifically cognitive effects, occur in young children cannot be discerned from the currently available studies (ISA, sections 1.9.3 and 4.3.12).” p294; “...the PA notes that the evidence in this review, as in the last, does not establish a threshold blood Pb level for neurocognitive effects in young children (ISA, sections 1.9.4 and 4.3.12).” p307; “...given the lack of identified blood Pb level threshold in the current evidence base for neurocognitive effects...”, p312.

⁸ Federal Register Volume 73, Number 219 (Wednesday, November 12, 2008, page 67000. <http://www.gpo.gov/fdsys/pkg/FR-2008-11-12/pdf/E8-25654.pdf>

⁹ Ibid at page 67000. (In paragraph that starts with “In their July 2008 advice...”)

¹⁰ Ibid at page ~~289~~. 67004 (In paragraph that starts with “As noted in the proposal...”)

¹¹ EPA’s Integrated Risk Information System (IRIS) concludes it would be “inappropriate” to estimate an RfC for lead because no threshold for toxicity has been shown. See link @ <http://www.epa.gov/iris/subst/0277.htm#refinhal> IRIS states, “I.B.1 Inhalation RfC Summary. No RfC is available. See Section I.A for additional information.” Section I.A details why IRIS does not give an RfD (Reference Concentration for Chronic Oral Exposure) for lead and by extension for RfC (Reference Concentration for Chronic Inhalation Exposure). In short, no RfD (and by extension RfC) for lead is given because RfD and RfC are estimates that are “likely to be without an appreciable risk of deleterious effects during a lifetime.” The RfD and RfC are both “based on the assumption that thresholds exist for certain toxic effects”. IRIS goes on to explain, “EPA considered providing an RfD for inorganic lead in 1985, and concluded that it was inappropriate to develop an RfD, as documented online in the following statement in 1988: A great deal of information on the health effects of lead has been obtained through decades of medical observation and scientific research. This information has been assessed in the development of air and water quality criteria by the Agency’s Office of Health and Environmental Assessment (OHEA) in support of regulatory decision-making by the Office of Air Quality Planning and Standards (OAQPS) and

by the Office of Drinking Water (ODW). By comparison to most other environmental toxicants, the degree of uncertainty about the health effects of lead is quite low. It appears that some of these effects, particularly changes in the levels of certain blood enzymes and in aspects of children's neurobehavioral development, may occur at blood lead levels so low as to be essentially without a threshold. The Agency's RfD Work Group discussed inorganic lead (and lead compounds) at two meetings (07/08/1985 and 07/22/1985) and considered it inappropriate to develop an RfD for inorganic lead.” [The IRIS report is available @ <http://www.epa.gov/iris/subst/0277.htm#refinhal>]

¹² Footnote 24 at page 290 of the EPA Administrator’s Proposed Rule which may be found @ <http://www.gpo.gov/fdsys/pkg/FR-2015-01-05/pdf/2014-30681.pdf>