

#	Author and Title	Salient information	Regulatory implications for the industry	Source/link
Environmental publications				
1	OECD, 2016. Guidance on the Incorporation of Bioavailability Concepts for Assessing the Chemical Ecological Risk and/or Environmental Threshold Values of Metals and Inorganic Metal Compounds.	This is a technical guidance document aimed for uses as a reference by regulators, policy makers and scientists in the OECD countries. The document provides an overarching framework on how to apply bioavailability methods, models and tools developed in the US and Europe for ecological risk assessment of metals including lead in aquatic and terrestrial environments. It further calls for harmonization of the approaches and methodology, where appropriate, in OECD countries.	The document may serve as a global reference to bioavailability methods and models developed for lead by the lead industry through its environmental research programs. Worldwide application and the mutual acceptance of data and approaches among various jurisdictions may result in significant resource savings.	OECD Environment, Health and Safety Publications, Series on Testing & Assessment No 259. ENV/JM/MONO(2016)66 .
2	Li et al. 2016. Quality Decline and oxidative damage in sperm of freshwater crab Sinopotamon henanense exposed to lead	A laboratory study defining the effects of Pb exposure on reproductive abnormalities in a freshwater crab. Pb levels in sperm increased significantly upon exposure, resulting in decline of sperm quality due to effects on membrane, DNA and oxidative endpoints.	Reinforcing the evidence of Pb effects on male fertility in invertebrates similar to vertebrates including human, with implications on stringent Pb classification for reproductive effects.	Ecotoxicology and Environmental Safety, 30: 193 – 198.
3	Toth et al., 2016. Maps of heavy metals in the soils of	This is one of the publication series of these authors, presenting maps of metal contamination in European surface soil. This paper	Identification of a large contaminated area as a threat to soil-based ecosystem	Science of the Total Environment, 565: 1054 – 1062.

#	Author and Title	Salient information	Regulatory implications for the industry	Source/link
	the European Union and proposed priority areas for detailed assessment.	includes maps of As, Cd, Cr, Cu, Hg, Pb, Zn, Sb, Co and Ni concentrations in the topsoil and more importantly, unlike their report on agricultural soils (6.24%), identifies a large area (1.2 M km ² or 28.3%) in Europe for further assessment because of threat from metal contamination to soil ecosystem services including food and feed production. The paper particularly highlights Pb and a few other metals (AS, Cd and Hg) because of elevated levels in industrial and mining areas.	services with hotspots in Western Central Europe, Central Italy, Greece and South-East Ireland may trigger regulatory measures including remediation activities requiring industry resources.	
4	Hernout et al., 2016. A national level assessment of metal contamination in bats.	This is a monitoring study suggesting that metal contamination is an environmental stressor affecting bat populations in UK and Wales. Pb was found to pose the greatest risk to bats among other metals monitored. The paper calls for further research to explore the direct links between metal contamination and bat population declines worldwide.	Weight of evidence to provoke regulatory limits and restrictions on lead uses.	Environmental Pollution, 214: 847 – 858.
5	McCumbera and Strevett, 2017. A geospatial analysis of soil lead concentrations around regional Oklahoma airports	Airports are now one of the greatest sources of Pb air emission in the US. Soil samples collected from runways and the vicinity of three low volume airports used by aircrafts operated with leaded aviation gasoline (avgas) reveal that soil Pb concentrations correlate with the direction of prevailing winds and soil organic matter. Pb “hot spots” were found near the avgas fueling stations but the soil Pb levels ranged from 10 to 170 ppm, i.e., none were above the USEPA recommended action level for remediation (400 ppm).	Limited use of avgas at the current rate may not pose concern to public and the study can be used as an evidence that there is no remedial action needed for airports allowing avgas operated aircrafts.	Chemosphere 167: 62 – 70.

#	Author and Title	Salient information	Regulatory implications for the industry	Source/link
6	Mariet et al., 2016. Palaeo-pollution from mining activities in the Vosges Mountains: 1000 years and still bioavailable	A combination of chemical approaches and microcosm studies with soil samples suggest that metals (Pb, Cd, As, Ag, Co, Sb) in mine wastes from the historical mining districts of Vosges Mountains in France are bioavailable to local vegetation and snails. Pb appeared to be the most bioavailable metal to snail. EDTA is the best extractant for evaluating trace metal bioavailability to snails.	Historical mine wastes remain to be a problem after centuries as contamination sources for biota, asking for stringent risk assessment and management policies that may have implications on the today's industry.	Environmental Pollution 214: 575 – 584.
7	Dong et al. 2016. A meta-analysis to correlate lead bioavailability and bioaccessibility and predict lead bioavailability	This meta-analysis used a large number of datasets to establish correlation between <i>in vitro</i> bioaccessibility (BAc) and <i>in vivo</i> relative bioavailability (RBA) and presents a generic and soil/tissue-type specific models to estimate RBA (%) used in developing site-specific soil clean-up goals for Pb. An overall estimation of Pb RBA is $49 \pm 25\%$. The RBA in the residential land was the highest ($58 \pm 19\%$), followed by house dust ($46 \pm 20\%$) and mining/smelting soils ($45 \pm 31\%$).	A seminal paper for the industry, scientists and regulators to estimate site-specific soil risks and clean-up goals aimed at contamination site management and remediation.	Environmental International 92-93: 139-145.
8	Beyer et al. 2016. Bioaccessibility tests accurately estimate bioavailability of lead to quail	This article is a US Government work, characterizing <i>in vivo</i> relative bioavailability (RBA) of Pb to Japanese quail fed diets containing soils from five Superfunds sites in the US. The relative bioavailabilities ranged from 33% to 63%, with a mean of approximately 50% and were correlated with 6 <i>in vitro</i> bioaccessibility tests. The paper provides guidance on accurately using bioaccessibility data for ecological risk assessment of Pb in soil.	A seminal paper for the industry, scientists and regulators to assess risks of Pb to wildlife in Superfund sites and to estimate their clean-up goals.	Environmental Toxicology and Chemistry, 35(9): 2311–2319

#	Author and Title	Salient information	Regulatory implications for the industry	Source/link
Health publications				
1	Bennett et al., 2016 Project TENDR: Targeting Environmental Neuro-Developmental Risks. The TENDR Consensus Statement.	A consensus statement authored by more than 50 scientists, health professionals and providers, children’s health and disabilities advocates, and organizations including David Bellinger, Linda Birnbaum, Bruce Lanphear, Philip Landrigan, the American College of Obstetricians and Gynecologists, the Child Neurology Society, the Endocrine Society, and the International Neurotoxicology Association, asserted that the current system in the United States for evaluating scientific evidence and making health-based decisions about environmental chemicals, including Pb, is fundamentally broken. They asserted that to help reduce the unacceptably high prevalence of neuro-developmental disorders in children, exposures to chemicals that contribute to these conditions, including Pb, must be reduced. In addition, a new framework must be adopted for assessing chemicals that have the potential to disrupt brain development and prevent the use of those that may pose a risk. This consensus statement lays the foundation for developing recommendations to monitor, assess, and reduce exposures	Although this consensus statement’s sole focus is not on Pb but rather includes other neurotoxic chemicals such as organophosphate (OP) pesticides, PBDE flame retardants, PAHs, nitrogen dioxide, particulate matter, mercury, and PCBs, this statement could still be highly influential in guiding regulations for Pb. The present statement may be laying the groundwork for regulatory decisions to lower Pb exposures for workers and in communities.	Environmental Health Perspectives 124(7):A118-A122

#	Author and Title	Salient information	Regulatory implications for the industry	Source/link
		to neurotoxic chemicals. It is concluded that these measures are urgently needed if healthy brain development is to be protected.		
2	<p>Dash et al., 2016 Developmental exposure to lead (Pb) alters the expression of the human tau gene and its products in a transgenic animal model.</p>	<p>A study of whether Pb exposure plays a significant role in tau pathogenesis (e.g., Alzheimer’s Disease, or AD). Used a double mutant mouse model that expressed the human tau gene and lacked the gene for murine tau. Mouse pups were developmentally exposed to Pb from postnatal day (PND) 1-20 with 0.2% Pb acetate. Mice were then sacrificed at PND 20, 30, 40 and 60. Protein and mRNA levels for tau and CDK5 as well as tau phosphorylation at Ser396 were determined. In addition, the potential role of miRNA in tau expression was investigated by measuring levels of miR-34c, a miRNA that targets the mRNA for human tau, at PND20 and 50. The expression of the human tau transgene was altered by developmental exposure to Pb. This exposure also altered the expression of miR-34c.</p>	<p>While the existing literature does not provide clear evidence that Pb exposure is related to AD or other tauopathies, the identification of relationships between Pb exposure and cognitive decline has surfaced in several longitudinal and cross-sectional studies performed on the elderly (e.g., the Normative Aging Study). As the findings in Dash et al. are purported to be the first to test the responsiveness of the human tau gene to Pb and to examine an epigenetic mechanism that may be involved in the regulation of this gene’s expression, future regulatory deliberations may more seriously consider an association between Pb and degenerative neurological conditions such as AD as the basis for future bans or restrictions of Pb.</p>	<p>Neuro Toxicology 55:154-159</p>
3	<p>Evans et al. 2016 End-stage renal disease after occupational lead exposure: 20 years of follow-up.</p>	<p>A study to investigate if low-level occupational exposure to Pb was associated with increased incidence of end-stage renal disease (ESRD) in a cohort of 10,303 Pb-workers who had controlled blood Pb concentrations due to a compulsory occupational health surveillance program in</p>	<p>This study of workers with documented occupational Pb exposures followed for 20 years showed no statistically significant association between Pb exposure (following the current occupational recommendations for Sweden) and ESRD. This</p>	<p>Occup Environ Med. doi:10.1136/oemed-2016-103876 [Epub ahead of print]</p>

#	Author and Title	Salient information	Regulatory implications for the industry	Source/link
		<p>Sweden from 1977 to 1990. The ESRD incidence among the Pb-exposed workers was compared with the age, sex, and calendar period-adjusted expected incidence based on data from the Swedish renal registry. Dose-response association was evaluated in external (general population) and internal (within the occupational cohort) comparisons by highest achieved blood Pb level. Authors reported 30 (0.29%) individuals in the cohort who developed ESRD during the median follow-up period of 26.3 years. The standardized incidence ratio (SIR) for ESRD incidence was 0.79 (95% CI 0.54 to 1.13). Among those who achieved the highest blood Pb (>41.4 µg/dL), the SIR was 1.01 (0.44 to 1.99). There was no evidence of a dose-response relationship between the maximum achieved blood Pb or the cumulative blood Pb exposure and ESRD in external or internal comparisons.</p>	<p>study could be cited in the event OEL setting were to be based wholly or in part on kidney effects of Pb.</p>	
4	<p>Eida and Zawiaa, 2016 Consequences of lead exposure, and it's emerging role as an epigenetic modifier in the aging brain.</p>	<p>A review of studies reporting "classical outcomes" as a result of Pb exposure, with a focus on the role of Pb in neurodegenerative and adult disease, and an introduction of the role Pb may have in regulating gene expression via epigenetic mechanisms. Authors stated that Pb has been shown to induce latent changes in the aging brain, has</p>	<p>This review could be cited in regulatory deliberations as further evidence for an associated between Pb exposure and neurodegenerative diseases, as well as providing mechanistic evidence for such diseases.</p>	<p>Neuro Toxicology 56:254-261</p>

#	Author and Title	Salient information	Regulatory implications for the industry	Source/link
		<p>been implicated in the pathogenesis of neurodegenerative diseases, particularly Alzheimer's Disease and Parkinson's, and has the ability to alter DNA methylation, histone modifications, and miRNA expression in experimental models and in humans, thus implicating epigenetics in Pb-induced toxicity and long term changes in individuals.</p>		
5	<p>McClure et al., 2016 Blood lead levels in young children: US, 2009-2015.</p>	<p>A 6-year retrospective study (May 2009 to April 2015) based on >5 million blood Pb level results (including >3.8 million venous results) from children <6 years old living in all 50 states and the District of Columbia. Compared to a similar study by Tsoi et al. (2016) (see ILA's January-July 2016 Science Developments communication), this study utilized a much larger data set for a slightly longer time period (2009 to 2015), giving it stronger statistical power compared to Tsoi et al.; however, it included ages up to <6 years old, which is not same range as Tsoi et al. (<5 years). McClure et al. reported that the top 2.5% blood Pb level threshold (i.e., 97.5th percentile) was 5.1 µg/dL for every year of the study, in contrast to the 3.48 µg/dL value reported in Tsoi et al. The results of McClure et al., using a more statistically robust data set, indicate a 97.5th percentile reference</p>	<p>On December 30, 2016, Reuters (http://www.reuters.com/article/us-usa-lead-cdc-idUSKBN14J160) reported that the U.S. Centers for Disease Control and Prevention is considering lowering its blood Pb reference level by 30 percent – from 5 micrograms per deciliter (µg/dL) to 3.5 µg/dL – for children under age 6, in the coming months. The measure will come up for discussion at a CDC meeting January 17 in Atlanta. This study may have been considered in CDC's deliberations regarding a revised reference level, but it is likely that the proposed reference level modification will be more influenced by the Tsoi et al. (2016) study described in ILA's January-July (2016) Science Developments communication.</p>	<p>J Pediatr. 175:173-181</p>

#	Author and Title	Salient information	Regulatory implications for the industry	Source/link
		value closer to 5 µg/dL instead of 3.5 µg/dL, even though the McClure et al. results may be conservatively biased by including six-year-olds.		
6	Wu et al., 2016 Dose-response relationship between cumulative occupational lead exposure and the associated health damages: A 20-year cohort study of a smelter in china.	A retrospective cohort study of 1,832 smelting workers from 1988 to 2008 in China who were in continuous contact with Pb at work for >3 months. The dose-response relationship between occupational cumulative Pb exposure and Pb “poisoning”, abnormal blood Pb, urinary Pb, and erythrocyte zinc protoporphyrin (ZPP) were analyzed and benchmark dose lower-bound confidence limits (BMDLs) calculated. Authors reported statistically significant positive correlations between cumulative Pb dust and Pb fume exposures and workplace seniority, blood Pb, urinary Pb and ZPP values. A dose-response relationship was observed between cumulative Pb dust or Pb fume exposure and Pb poisoning (p <0.01). The BMDLs of the cumulative occupational Pb dust and fume doses were 0.68 mg-year/m ³ and 0.30 mg-year/m ³ for Pb poisoning, respectively. The BMDLs of workplace airborne Pb concentrations associated with Pb poisoning were 0.02 mg/m ³ and 0.01 mg/m ³ for occupational exposure Pb dust and Pb fume, respectively.	Although the methodology of using a large cohort and benchmark dosing to establish a BMDL for cumulative airborne Pb levels and health effects is acceptable, a poorly defined description of Pb “poisoning” in the study compromises the authors’ conclusions. Nonetheless, this study may influence OEL setting as it is one of the first to attempt to establish a BMD in a large occupationally-exposed cohort; in fact, the study’s BMDL for Pb fume (0.01 mg/m ³ , or 10 µg/m ³) is consistent with the proposed Cal/OSHA PEL.	Int. J. Environ. Res. Public Health 13(3):E328