Testimony of Ari S. Lewis, MS
Regarding H.R. 1391, A Bill "To prohibit the Environmental Protection Agency from regulating fossil fuel combustion waste under subtitle C of the Solid Waste Disposal Act."

Prepared for the
Subcommittee on Energy and the Environment
April 14, 2011
at the
House of Representatives Committee on Energy and Commerce
2322 Rayburn HOB
Washington, DC 20515

Prepared by
Ari S. Lewis, MS
Gradient
20 University Road
Cambridge, MA 02138
April 14, 2011

Testimony Summary

The United States Environmental Protection Agency (US EPA) has performed several analyses that evaluate the potential human health risks associated with the disposal of coal combustion products (CCPs). These risk evaluations, in part, form the basis of the recent Proposed Rule regarding potential regulatory options for coal ash disposal and its beneficial use. One of the regulatory options in the Proposed Rule is to regulate CCPs as hazardous waste under Resource Conservation and Recovery Act (RCRA) Subtitle C.

I am providing testimony regarding the Bill H.R. 1391, which is a bill that would prohibit US EPA from regulating CCPs under Subtitle C of The Solid Waste Disposal Act (US Congress, 2011).[1] My testimony relates to how US EPA risk assessment information on CCPs is best used to support regulatory options related to the disposal of CCPs and, specifically, whether the regulation of CCPs as hazardous waste is warranted. This will include a discussion of the results of US EPA's most recent (2010) risk assessment and the interpretation of these results in light of the risk assessment's strengths and limitations. Also addressed will be how health-based information from the risk assessment was used in the cost-benefit analysis presented Regulatory Impact Analysis (RIA). Based on my review of the 2010 risk assessment and RIA, I have reached the following conclusions:

- Overall, the results of the 2010 risk assessment demonstrate that, under typical existing waste disposal practices, CCPs are not associated with an elevated health risk.
- The elevated risk estimates that have been reported in the most recent US EPA risk assessment are uncertain and reflect more atypical exposure scenarios that do not necessarily reflect conditions at actual disposal sites. As a result, quantitative risk estimates cannot be used reliably to distinguish among different regulatory options.
- The results of the RIA, and considerations of the uncertainty in that analysis, demonstrate that there is very little public health benefit to be derived from regulating CCPs as hazardous waste.
- In view of these results, regulation of CCPs as hazardous waste (RCRA Subtitle C) by US EPA lacks a sound scientific basis and is not warranted.

[1] RCRA is the amended version of the Solid Waste Disposal Act.

Introduction

My name is Ari Lewis. I am a toxicologist and risk assessor at Gradient, which is an environmental consulting firm in Cambridge, Massachusetts. The majority of my graduate studies and professional career has focused on metals toxicology and risk assessment. In particular, I have been involved with the toxicology on arsenic and how human, animal, and cell culture data related to arsenic should be used in risk assessment. Although arsenic has been my key area of research over the past decade, I have also conducted analyses on other metals, including selenium, lead, mercury, thallium, molybdenum, and chromium. The toxicology and risk assessment of these metals, especially arsenic, are critical to an evaluation of the potential human health effects associated with exposure to CCPs.

My specific experience with CCPs began in 2007 when I conducted an in-depth analysis of US EPA's Human Health and Ecological Risk Assessment of Coal Combustion Waste (US EPA, 2007). At that time, I was part of a group that pointed out some of the limitations and uncertainties associated with that analysis and provided oral and written comments on what US EPA could do make its risk assessments more informative (EPRI, 2008). Since 2007, I have been actively involved in evaluating many issues related to CCPs and public health, including evaluation of potential health effects associated with CCP beneficial use, such as in concrete and wallboard (*e.g.*, Long *et al*., 2009). I have also conducted independent analyses on the potential risks to populations living in the vicinity of coal combustion waste management units (WMUs). In an ongoing effort to understand potential hazards, I have evaluated the technical merit of analyses that recommend use of Subtitle C to regulate of CCPs, *i.e.*, as a hazardous waste. Most recently, I conducted an in-depth analysis of US EPA's updated 2010 CCP risk assessment, which was conducted to support the hazardous waste regulatory determination (EPRI, 2010; US EPA, 2010a; US EPA, 2010b). As part of this effort, I also examined how information in the risk assessment was used in cost-benefit analysis presented in US EPA's RIA (US EPA, 2010c).

Much my work related to the potential human health effects of CCPs was conducted under contracts with the Electric Power Research Institute (EPRI). The expressed purpose of EPRI's comments was to provide technical and scientific information that can be used by US EPA and others to develop regulations based on the best data available. The EPRI comments, which do not endorse any particular regulatory option put forth by US EPA, can be downloaded at epri.com/ccp. While my comments today will also be largely focused on technical and scientific issues, any opinions I express or conclusions I draw regarding the various regulatory options of CCPs are my own. I am not being compensated for my travel expenses or any of the time I have spent preparing for or attending today's hearing.

Overall Testimony

My testimony will be focused mainly on how information in US EPA's 2010 risk assessment is best used to support regulatory options related to the disposal of CCPs. This discussion will cover the results of US EPA's most recent risk assessment and the interpretation of these results in light of the risk assessment's strengths and limitations. Also addressed will be how health-based information from the risk assessment was used in the RIA. Understanding the risk assessment results and how these results were used to support cost-benefit calculations allows one to evaluate the potential public health impact of Subtitle C *vs.* Subtitle D regulation.

The Role of Risk Assessment

Risk assessment is a tool that can be used to examine whether certain defined exposures will result in a human health risk. In general, the aim of a risk assessment is to determine the likelihood (or probability) of adverse health effects in an individual or population by estimating potential chemical exposures and relating these exposures to information on chemical toxicity. Conducting a risk assessment is important because the mere presence of a chemical in the environment or a product does not mean that

people will be exposed in a manner or at a level sufficient to cause a health problem. In this regard, saying that coal ash contains "poisonous" or "harmful" chemicals is misleading in the absence of specific exposure information; in fact, most of the constituents in coal ash occur naturally in food, water, and soil.

The quantitative information generated in risk assessments is often used by federal and state agencies to set cleanup standards at contaminated sites, evaluate product safety, develop safe occupational exposure levels, and support health-based regulations. Site-specific risk assessments often involve more definitive information on the chemicals that people could be exposed to and the amount of that exposure. Thus, site-specific risk assessments often produce more refined risk estimates that allow for targeted remediation interventions. In contrast, risk assessments that support health-based national regulations (such as the proposed national scale regulations for coal ash) tend to use more variable assumptions about exposure in an attempt to characterize a wide range of potential risks. Trying to generalize potential risks on the national level necessarily requires simplifying assumptions that can introduce substantial uncertainty into the assessment. In the face of uncertainty, assumptions are often biased to ensure that "uncertain" information does not lead to an underestimate of risk. If this uncertainty is not properly recognized or characterized, risk estimates become unreliable.

It is extremely important to note that, in order to ensure adequate health protection, risk assessments by design tend to use toxicity and exposure assumptions that *overestimate* risks. Because of this goal, risk assessments are most useful for identifying *potential* health risks. Importantly, risk exceedances cannot be used to demonstrate that a particular person or group of people became sick as a result of an evaluated exposure. To conclude that a specific exposure caused a specific health effects, a causation analysis that considers all available epidemiological and toxicological information, as well as personal risk factors, is needed.

US EPA's Human Health and Ecological Risk Assessment

Over the past 15 years, US EPA has conducted several risk assessments evaluating the potential health risks associated with CCPs. In two separate screening risk assessments, US EPA concluded that non-groundwater pathways did not pose a public health concern (US EPA, 2002; US EPA, 1998). These pathways of exposure included inhalation, soil ingestion, and ingestion of contaminated produce, beef, and milk.

While the 1998 and 2002 risk assessments were able to "rule out" many potential CCP exposure pathways as a public health concern, both risk assessments determined that the leaching of certain metals in CCPs from landfills and surface impoundments to groundwater could pose a potential concern under certain conditions. These findings prompted the full-scale risk assessment that was conducted in 2007 and updated in 2010. The Proposed Rule issued in June 2010 was not specific on how the results of the risk assessment should be used in a Subtitle C *vs.* Subtitle D determination under RCRA and, in fact, US EPA solicited public input on how risk assessment information should be used. Nonetheless, the 2010 risk assessment results were used in the RIA as a basis, in part, to calculate the costs and benefits associated with different regulatory options. Additionally, the Proposed Rule implies that the risk assessment results could be used quantitatively to demonstrate that CCPs are "capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed" – which is one criterion for listing a substance as hazardous waste.

Because the 2010 risk assessment appears to be informing potential regulatory options for CCP disposal, it is important to understand the risk assessment results and the limitations of the risk estimates. Overall, the risk assessment was a very complex undertaking that attempted to capture a wide range of scenarios involved with the storage of CCPs under a full range of environmental conditions and waste

characteristics. Because US EPA's modeling approach encompasses a vast number of variables and ranges of conditions due to its large geographical and chronological spans, the modeling by necessity requires considerable simplification. This, as explained in more depth below, has led to a quantitative estimate of risk from CCPs that lack reliability, particularly when estimating high-end or low-end risks. Additionally, the overall approach used to assess risks associated with hypothetical waste management scenarios, using the full range of possible site and exposure conditions, will produce highly variable results that likely do not reflect the actual risks around any given site.

Risk Assessment Results

Based on a probabilistic approach,[2] the 2010 risk assessment ultimately presented 50th and 90th percentile risks for unlined, clay-lined, and composite-lined landfills and surface impoundments. The 50th percentile reflects conditions that are more typical of waste management operations, while the 90th percentile relies on more extreme assumptions that are not only less certain but combine assumptions that may be implausible and may not reflect real-life conditions.

The overall results of the risk assessment show that, under typical scenarios, metal constituents in CCPs do not pose a health concern. Under more extreme scenarios, overall, landfills still do not pose a substantial public health concern, but arsenic leaching from surface impoundments does require further considerations for unlined and clay-lined units. Also, any reported risk exceedances were for CCPs stored in unlined or clay-lined units. The use of a composite liner effectively eliminated any potential risk for all compounds. A more detailed summary of the 2010 risk assessment results is presented below.

[2] A probabilistic risk assessment uses distribution of assumption estimates as opposed point estimates to calculate risk estimates. Under a probabilistic approach, the values from the individual input distributions are used to create a an overall risk distribution.

For the risk estimate that reflects more typical industry conditions (*i.e.*, 50th percentile estimates), the only reported risk exceedances were from arsenic exposure in unlined and clay-lined waste management units. However, arsenic risk assessment is unique because, using current toxicity criteria, background exposure to arsenic (*i.e.*, arsenic that naturally occurs in food, water, soil, and air) is associated with cancer risks above 1×10^{-5} (the target cancer risk used in the risk assessment). The 50th percentile risks calculated arsenic for both landfills and surface impoundment storage of CCPs were similar to or less than the risks from background exposures to arsenic or from drinking water at the federal drinking water standard. For surface impoundments at the 50th percentile, in addition to arsenic, there was also an exceedance for cobalt, but only under the scenario that considered the combined storage of conventional CCPs and coal refuse. Cobalt risks, however, were based on only two data points, one of which was significantly higher than all other leachate concentrations reported for other wastes stored in surface impoundments and landfills and may represent a unique waste stream or one that was generated under very site-specific conditions that is not representative of industry-wide conditions.

At the 90th percentile, several other metals were above risk target, but the exceedances were relatively small, especially for CCPs stored in landfills (no hazard index exceeded 4); arsenic risks from landfills, even at this high-end range, were still in the range of typical background exposures and drinking water at the maximum contaminant level (MCL). Surface impoundments, however, were associated risks from cobalt and arsenic. As discussed earlier, the cobalt risks are highly unreliable.

Because arsenic risks from surface impoundments at the 90th percentile show clear risk exceedences, it is worthwhile to gain a better understanding of what these high-end risk mean and how they should be interpreted in the context of the hazardous waste determination. Although it is not possible to deconstruct exactly what assumptions went into the calculation of the high-end risk estimates we know that some of the data used to calculate the upper-bound risks were unrealistic. For example, in

the distributions that were used, an adult could weigh as little as 33 pounds and could live as close as 2 feet from a waste management unit. Many other conservative assumptions, particularly with regard to how the fate and transport of constituents were modeled, were also incorporated into risk estimates (*e.g.*, a 10,000-year modeling duration, use of data with high detection limits, environmental conditions that favor contaminant leaching and transport). Although risk assessments often use worst-case assumptions to be health protective, information should still be plausible. Also, the use of overly conservative distributions is not appropriate in a probabilistic model because the compounding effect of multiple conservative input distributions can skew the final risk percentiles significantly, making the high-end estimates unrealistically high.

Also, as acknowledged by US EPA, many other uncertain assumptions were used in the risk assessment. This uncertainty, although acknowledged, was not sufficiently characterized, such that risk estimates (and regulatory benefits based on those risk estimates, see below) are unreliable and should not be used quantitatively to inform regulatory decision. Because of the uncertainties in the quantitative risk estimates presented in the risk assessment, it is most appropriate to use information qualitatively to understand the relative risks among different waste management units and waste types, as well as key exposure pathways. More specifically, the collective risk assessments are useful for confirming that the groundwater pathway is a key exposure route, surface impoundments have a greater *potential* to constitute an unacceptable health risk than landfills *via* leaching to groundwater, composite liners effectively reduce risks, and arsenic is a key constituent that should be carefully monitored.

The Use of Risk Assessment Data in the Regulatory Impact Analysis

To evaluate different regulatory options, US EPA conducted a cost-benefit analysis (RIA, US EPA, 2010c) in which benefits, in part, were based on a reduction in potential cancer cases associated

with different waste management options. To quantify the number of cancer cases that could be avoided under different regulatory options, US EPA conducted a population risk assessment.

Given that the arsenic risk estimates as presented in the 2010 risk assessment, particularly at the high end, are uncertain, the cancer cases avoided analysis is also necessarily uncertain. Additionally, there were several elements of the RIA itself that compound this uncertainty. Because the uncertainty is not sufficiently characterized, the risk estimates are not bounded; confidence in the estimates cannot be evaluated and should not serve as a basis for determining among regulatory options.

Moreover, there are several assumptions used in the RIA that likely lead to an over estimate of cancer cases avoided under Subtitle C *vs.* Subtitle D regulation. Some of these key assumptions are summarized briefly below:

- The RIA relies on a cancer slope factor (CSF) for arsenic that is over 17 times more potent than the value used in the 2010 risk assessment. While it is recognized that the CSF used for arsenic in the risk assessment is outdated, a revised slope factor is currently being reviewed by US EPA and by a scientific advisory panels. There are several outstanding scientific issues, many of which relate to the CSF used in the RIA. Until the CSF assessment is finalized, it is not appropriate to use a value that lacks a scientific consensus. Using the currently accepted slope factor for arsenic (i.e., the value that was used in the 2010 risk assessment), the number of cancer cases avoided under Subtitle C vs. Subtitle D would have been considerably less (i.e., .the hypothetical cancer cases would be 17 times lower).
- Regardless of the arsenic slope factor used, it is important to appreciate that both values are derived using health-protective assumptions that overestimate risks (and, in this case, cancer cases). Specifically, the CSF is developed by defining an upper-bound risk estimate at a given exposure and using linear extrapolation to assume proportional risk at lower exposure levels; this assumes any increase in arsenic exposure leads to some increase in risk. It is important to realize, however, that using a linear slope factor to assess arsenic risks is a conventional, but conservative, approach. There is substantial evidence, however, suggesting that arsenic carcinogenicity has a threshold and that arsenic exposures below a certain level may be associated with zero risk (see for example, Petito Boyce *et al.*, 2008). Thus, excess cancer cases calculated in the RIA analysis should also be considered a conservative, hypothetical estimate. Determining any actual increase in disease rates in communities living within the vicinity of CCP waste management units would require a properly designed epidemiological study. To my knowledge, however, there are no epidemiological studies that report a link between CCP exposure in communities living near waste management units (from the drinking water exposure route or other pathways) and disease.

- Arsenic can exist in the environment in several different forms. The cancer cases avoided analysis assumed that all arsenic exists in groundwater as trivalent arsenic (AsIII), which is the more mobile form of arsenic. In reality, it is likely that a large portion of the arsenic leaching from surface impoundments and traveling through ground water is in a less mobile form (*i.e.*, pentavalent arsenic, AsV). If the RIA had assumed that arsenic was present in groundwater as AsV, the number of cancer cases calculated over a 75-year period would be about 25 times lower.
- When determining the population that could be potentially exposed to CCPs in groundwater, the RIA made some generic assumptions. I was part of an independent assessment that engaged in a more refined estimate of the number of people in the US that live in the vicinity of a CCP waste management unit. That analysis determined the RIA overestimated the potentially exposed population. If the more refined population estimate were used, cancer cases avoided under Subtitle C *vs.* Subtitle D would have been about 2-fold lower.

In light of the overestimates documented above, the number of cancer cases avoided under Subtitle C *vs.* Subtitle D regulations is negligible. In fact, given the magnitude of the potential overestimate of arsenic-related cancer cases and the fact that there is no epidemiological evidence establishing a link between CCPs in drinking water and cancer, it is plausible that regulating CCPs under RCRA Subtitle C *vs.* Subtitle D offers no measurable public health benefit.

The Risk Assessment, the RIA, and Overall Implications CCP Regulatory Options

Providing the most significant public health benefit should be the primary goal of any regulation affecting CCP disposal. Based on the 2010 risk assessment results, which showed minimal risk at the 50th percentile (*i.e.*, under the more typical conditions), CCP disposal does not pose a public health concern. Under more extreme scenarios where waste concentrations may be relatively high, environmental conditions favor contaminant leaching and transport, and individuals have unusually high exposures, there may be a potential for CCPs to pose a human health risk. However, these high-end exposure risk results are highly uncertain and cannot be used quantitatively to distinguish among appropriate risk management options.

Based on these analyses, it is my opinion that a Subtitle C regulation, which would require federal resources to oversee all CCP disposal facilities is not warranted, mainly because the vast majority of facilities already operate under conditions that do not pose a public health concern and because the requirements of Subtitle C that will limit CCP leaching and potential risk are very similar to requirements under Subtitle D. Indeed, the result of the RIA, and considerations of the uncertainty in that analysis, show that there is very little public health benefit to be derived from a Subtitle C *vs.* Subtitle D designation.

References

Electric Power Research Institute (EPRI); Ladwig, K; Gradient; Lewis, A; Bittner, A; Natural Resource Technology, Inc.; Hensel, B; Tetra Tech, Inc.; Summers, K; Johnson, K; S.S. Papadopulos & Associates, Inc.; Vlassopoulos, D. 2008. "Comments on US Environmental Protection Agency Notice of Data Availability on the Disposal of Coal Combustion Wastes in Landfills and Surface Impoundments, Human and Ecological Risk Assessment of Coal Combustion Wastes." EPA-HQ-RCRA-2006-0796, February 11.

Electric Power Research Institute (EPRI). 2010. "Comments to US EPA re: Hazardous and Solid Waste Management System; Identification and Listing of Special Wastes; Disposal of Coal Combustion Residuals From Electric Utilities." Submitted to US EPA Docket. EPA–HQ–RCRA–2009–0640, 94p., November 18.

Long, C; Lewis, A; Sax, S. 2009. "Inhalation risks of mercury from indoor air from beneficial use of coal combustion products (CCPs) in building materials." *Toxicologist - Supplement to Toxicological Sciences* 108(1):172. Abstract No. 834, In Society of Toxicology 48th Annual Meeting, Baltimore, MD.

Petito Boyce, C; Lewis, AS; Sax, SN; Eldan, M; Cohen, SM; Beck, BD. 2008. "Probabilistic analysis of human health risks associated with background concentrations of inorganic arsenic: Use of a margin of exposure approach." Hum. Ecol. Risk Assess. 14 :1159-1201.

US Congress. 2011. "H.R. 1391: A bill to prohibit the Environmental Protection Agency from regulating fossil fuel combustion waste under subtitle C of the Solid Waste Disposal Act." 4p., April 6.

US EPA. 1998. "Draft Final Report: Non-Groundwater Pathways, Human Health and Ecological Risk Analysis for Fossil Fuel Combustion Phase 2 (FFC2)." Office of Solid Waste and Emergency Response, EPA 68-W6-0053, 139p., June 5.

US EPA. 2002. "Constituent Screening for Coal Combustion Wastes." EPA-HQ-RCRA-2006-0796-0470, 171p., October.

US EPA. 2007. "Human and Ecological Risk Assessment of Coal Combustion Wastes (Draft)." Office of Solid Waste, EPA-HQ-RCRA-2006-0796-0009, 333p., August 6.

US EPA. 2010a. "Hazardous and Solid Waste Management System; Identification and listing of special wastes; Disposal of coal combustion residuals from electric utilities (Proposed rule)." Accessed on June 02, 2010 at http://www.epa.gov/epawaste/nonhaz/industrial/special/fossil/ccr-rule/index.htm#propose, 283p.

US EPA. 2010b. "Human and Ecological Risk Assessment of Coal Combustion Wastes (Draft)." Office of Solid Waste and Emergency Response, 409p., April.

US EPA. 2010c. "Regulatory Impact Analysis for EPA's Proposed RCRA Regulation of Coal Combustion Residues (CCR) Generated by the Electric Utility Industry." Office of Resource Conservation & Recovery, 242p., April 30.