September 29, 2014

U.S. House of Representatives
Committee on Science, Space, and Technology
2321 Rayburn House Office Building
Washington, DC 20515

Re: Questions for the Hearing Record, "Status of Reforms to EPA's Integrated Risk Information System"

Chairmen Broun and Schweikert, Ranking Members Maffei and Bonamici:

Thank you, again, for the opportunity to testify before your committees at the July 16, 2014 hearing titled, "Status of Reforms to EPA's Integrated Risk Information System." Enclosed are my responses to your questions for the record. I look forward to the opportunity to work with you and your staffs again in the future.

I have also reviewed the transcript of the hearing and would request just four changes:

On page 27, line 513, "weight" should be "wait."

On page 27, line 517, correct to read "The final **problem** is the decision by EPA…"

On page 27, line 522, the last word should be "naïve" not "na ve."

On page 36, line 703, correct to read "**such as** the Clean Air Act **or** the Safe Drinking Water Act."

Sincerely,

Rena Steinzor

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Enclosure

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Questions submitted by Chairman Broun and Chairman Schweikert

1. To what extent does having multiple toxicity assessment sources for the same chemical present challenges for ensuring consistent risk management across the nation, and what steps should EPA take to either minimize or explain reasons for any differences?

A number of different offices within the federal government, at the state government level, and at the international level produce hazard- and risk-assessment documents that factor into risk management decisions. It is important that each of these programs operate independently, for a variety of reasons. Each is developed through a unique process, looking at different evidence bases, and developed by a unique set of experts for a specific purpose.

The following chart highlights a few reasons why a handful of federal programs each have value-added for risk managers:

Program	*Value-added*
IRIS	• Carcinogen hazard identification and dose-response assessments most useful to EPA program offices • IRIS profiles present actionable numbers (inhalation RfDs, oral RfCs) • Assessments used by state and federal regulatory officials
Report on Carcinogens	• Simplified assessment of carcinogenic potential – good starting point for the general public (including businesses seeking to "green" their production – see www.chemhat.org)
ATSDR	• Provides exposure assessments for environmental toxins • Site-based assessments that address multiple hazards • Public health advisories (e.g., case of contaminated groundwater flooding basements and leaving Cr(VI) deposits – does not rise to top of Superfund priorities, but ATSDR provided helpful advice) (see attached InsideEPA article)
NIOSH	• Specific focus on workers' exposures, so priority chemicals are different than those in the programs listed above • All NIOSHA risk assessments are conducted according to agency's "Research to Practice" mission, so publications include Recommended Exposure Levels (aimed at reducing significant risks over a working lifetime) and practical information about hazard elimination and reduction through a hierarchy of controls.

No one group—be it EPA or the World Health Organization or California's Office of Environmental Health Hazard Assessment —should be forced to align its assessment with ones done by a different agency or department for different purposes. In fact, such outcome-focused review of the evidence would contradict principles of good science. While an organization's explanation of the difference between its assessment and others' assessments may provide some value in terms of accessibility to lay readers, it is far more important that these groups clearly describe their methods and information sources (as IRIS does), so that experts can reach their own conclusions about the relative strengths and weaknesses of the different assessments.

2. As you know, Dr. Ken Olden at EPA has implemented a standing set of bi-monthly meetings to address chemical-specific scientific issues as well as to have discussions about problem formulation. At the most recent June meeting, it appeared that many NGOs boycotted the meeting due to concerns they said were related to not knowing about the meetings and concerns regarding too much industry representation. It is our understanding that these meetings have all been announced on the IRIS webpage, registration is open to everyone, and anyone who wishes to speak can get a slot on the agenda. Do you support the NGOs' call for a boycott?

Dr. Olden has significantly expanded the IRIS program's stakeholder engagement. However, increased stakeholder engagement is not good public policy, per se. As the NRC committee noted in its recent report on the IRIS program,[1] simply increasing the number of opportunities for stakeholder involvement favors the stakeholders with the greatest resources. This notion is backed by empirical research regarding other EPA programs.[2] Professor Wendy Wagner conducted such research and concluded:

> a number of doctrinal refinements [to administrative law], originally intended to ensure that executive branch decisions are made in the sunlight, inadvertently create incentives for participants to overwhelm the administrative system with complex information, causing many of the decisionmaking processes to remain, for all practical purposes, in the dark. As these agency decisions become increasingly obscure to all but the most well-informed insiders, administrative accountability is undermined as entire sectors of affected parties find they can no longer afford to participate in this expensive system. Pluralistic oversight, productive judicial review, and opportunities for intelligent agency decisionmaking are all put under significant strain in a system that refuses to manage—and indeed tends to encourage—excessive information.[3]

The toxicologists and environmental scientists who wrote an open letter to the IRIS program's top management to express their views about the June 2014 inorganic arsenic and hexavalent chromium meeting did a great service by shining a light on the measurable impacts of simply increasing the number of opportunities for stakeholders to engage in the IRIS process without actively engaging a broad set of interested parties. The NRC committee that reviewed the IRIS process made a valuable recommendation that would address these problems in the IRIS program and deserves Congress's

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[1] National Research Council of the National Academies, REVIEW OF EPA'S INTEGRATED RISK INFORMATION SYSTEM (IRIS) PROCESS (May 2014).

[2] *See*, Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 DUKE L. J. 1321 (2010)

[3] *Id.*

support. The committee suggested:

> One way to ensure broad stakeholder input would be to provide technical assistance to enable under-resourced stakeholders to develop and provide input to the IRIS program; this could be modeled after other EPA technical-assistance programs. For example, EPA's Superfund program has a long history of providing technical assistance in the form of grants and more recently direct consultation to neighbors of sites on the National Priorities List. The grants generally improve the process of remedial decision-making by ensuring that the affected public understands both the characterization and the remediation of hazardous-waste contamination and by making it easier for such people to provide constructive input.[4]

Questions Submitted by Environment Subcommittee Ranking Member Suzanne Bonamici

1) On January 9th of this year, approximately 10,000 gallons of Methylcyclohexane-Methanol (MCHM) began spilling into the Elk River in West Virginia. About 300,000 people were left without access to clean drinking water for days. It took the company that developed the chemical more than a week to publicly release toxicology studies. Another five days passed before regulators discovered that a new chemical, propylene glycol phenyl ether (PPH), was also present in the tanks. Far from an isolated incident, spills within the last two years in Ohio, Texas, North Dakota, Wisconsin, Oklahoma, and Georgia highlight two important considerations: It is critically important that state agencies and the public have information to inform response decisions to chemical spills. It is also clear that industry is in no hurry to provide that information freely.

    a) Does continued secrecy from industry regarding the safety of their products endanger the public?

As I noted in my written and oral testimony, the Freedom Industries spill is a striking example of all that can go wrong when we shrink government public health functions and rely on private industry to protect us from harm. The company's failure to release immediately all toxicology studies on the chemicals that it stored at the facility is deplorable. Unfortunately, such behavior is effectively condoned, given the yawning gap in protections under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Toxic Substance Control Act (TSCA). TSCA, as implemented by EPA, requires chemical manufacturers to disclose some basic toxicological information about chemicals before they go on the market. However, tens of thousands of chemicals, including crude MCHM, were already in commerce and "grandfathered in" when Congress passed TSCA in 1976. In other words, the companies that produce and use the chemical had no obligation to develop toxicity studies when TSCA took effect—crude MCHM was presumed safe enough. Similarly, EPCRA established some protections against public health threats, but does not cover crude MCHM. Any company that stores crude MCHM (or any of thousands of other chemicals) must report to local authorities how much of that chemical they have stored, and where. But since crude MCHM was not previously identified as "extremely hazardous" by federal officials, local officials did not have to develop plans for a potential leak.

This situation points up the other critical factor in city of Charleston's public health emergency

[4] National Research Council of the National Academies, REVIEW OF EPA'S INTEGRATED RISK INFORMATION SYSTEM (IRIS) PROCESS, 23 (May 2014).

following the Freedom Industries spill. The state public health department (the West Virginia Bureau of Public Health) is underfunded and understaffed. A recent assessment of the department's capacity by federal experts from the Centers for Disease Control includes several striking points:

- Five of the 34 epidemiology positions (15 percent) at the Bureau of Public Health (BPH) are currently vacant.
- BPH has failed to adequately plan for the many types of natural and man-made disasters that could potentially affect West Virginia residents.
- The epidemiologic investigation of the Freedom Industries spill took over six weeks, involved over a dozen staff, and required hundreds of hours of their time.
- BPH employs no epidemiologists in positions assigned to respond to acute chemical or radiological releases, or specifically tasked with natural disaster response.
- BPH has no programs to enhance occupational safety and health of responders.[5]

In this context, industry secrecy regarding basic toxicological information is a major public health threat.

b) Does the lack of transparency by industry make an even stronger case for a functioning IRIS?

The IRIS program could partially bridge the gap between EPCRA and TSCA, if it were properly funded. IRIS staff has broad authority to develop hazard assessments for any chemical in commerce. In an ideal world, where the IRIS program has unlimited resources, IRIS staff would collect and assess the available information on the tens of thousands of chemicals that have not undergone TSCA-based reviews and publish those assessments in its widely accessible web database. In the real world, however, the IRIS program operates under significant resource constraints. With its available resources, most of the IRIS agenda centers on developing assessments for EPA's regulatory program offices (e.g., the Office of Water or the Superfund program), with little room for assessing emerging public health threats. Nevertheless, the IRIS program has the flexibility to prioritize assessments for chemicals that are stored, used, produced, or transported in significant quantities in communities that are overburdened by toxic chemicals and socioeconomic stressors. For one approach to that kind of agenda-setting process, please refer to the Center for Progressive Reform paper, *Setting Priorities for IRIS: 47 Chemicals that Should Move to the Head of the Risk-Assessment Line*,[6] which is attached to my written testimony.

2) You have written reports on the tactics used by industry to stall the publication of IRIS health assessments. What kind of tactics have you seen employed by industry in this area? What conclusions have you reached regarding the willingness of industry to

[5] Letter from Mary Anne Duncan, DVM, MPH, Epidemiologist and Assessment of Chemical Exposures (ACE) Program Coordinator, Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, to Loretta E. Haddy, PhD, MS, West Virginia State Epidemiologist and Director of Office of Epidemiology and Prevention Services (Aug. 18, 2014), *available at* http://media.wvgazette.com/static/watchdog/CDC%20Training%20Memo.pdf.

[6] *Available at* http://www.progressivereform.org/articles/IRIS_Priorities_1010.pdf.

spend millions of dollars to delay and discredit IRIS assessments?

The chemical industry's advocates are skilled, knowledgeable, and well-connected—and they completely outgun public interest advocates. The two overarching strategies that I have observed the chemical industry employ for years are (1) fund research to increase uncertainty about each facet of a chemical risk assessment, and (2) foster a sense of distrust about the programs and processes for developing those risk assessments. Some examples of the chemical industry's efforts to pursue these strategies include:

- IRIS staff have been working on new hazard assessments for hexavalent chromium (Cr(VI)) for a number of years. After they set their work in motion, the American Chemistry Council started a multi-year research program dedicated to exploring issues related to the mode of action for chromium toxicity. A better understanding of toxicological modes of action is helpful, to be sure, but ACC has used this ongoing research program as an excuse to demand that the IRIS program slow down its development of new hazard assessments for Cr(VI). Meanwhile, millions of U.S. residents are exposed to the chemical in drinking water or through food, driving home the need for solid risk assessments that will enable risk managers to do their jobs.
- A constant stream of reports from the Government Accountability Office (GAO) and the National Academies' National Research Council (NRC) maintain a sense that the IRIS program is scuffling and struggling to develop high quality assessments. The people who write these reports are respectable professionals, so their assessments of the IRIS program are fair and balanced, generally noting both the strengths and weaknesses of the IRIS program. However, the criticisms in the reports get the most attention and help the chemical industry build a case for constantly revising the processes by which IRIS staff develop new assessments. While IRIS leadership profess that program and management changes are designed to have little effect on output, the results are clear. Production of final assessments has dropped dramatically in recent years.

The chemical industry can—and does—spend millions of dollars on research and advocacy to slow the IRIS process. Without new assessments, the public, policymakers, and risk managers are left without adequate information to properly control the chemicals that pervade our lives.

GROUNDWATER 'INTRUSION' SPURS EPA TO WEIGH EXPANDED NPL LISTING POLICY
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HEADLINE: GROUNDWATER 'INTRUSION' SPURS EPA TO WEIGH EXPANDED NPL LISTING POLICY

BODY:

EPA officials are weighing whether to expand the scope of their proposed changes to the Superfund Hazard Ranking System (HRS) to allow sites that have toxic liquids and solids seeping into buildings from groundwater to be eligible for Superfund listing -- in addition to listing sites where toxic vapors may be a source of concern.

The proposition is being sparked by a unique case in New Jersey where groundwater flooding into local basements is leaving behind hexavalent chromium (Cr6) crystals, but officials are unable to place the site on the Superfund National Priorities List (NPL) because of the agency's current policy preference for weighing exposure to contaminated drinking water sources.

But officials may have to be careful about how they frame any additions to the potential rulemaking since it may encourage other groups to push for changes to the HRS -- the scoring system that evaluates whether sites should be placed on the NPL and made eligible for federal cleanup funding -- such as including explosive materials as a pathway to listing. The HRS is a numerically based screening system that uses information from preliminary assessment and site inspections to assess the relative potential of sites to pose a threat to human health or the environment.

EPA is weighing whether to launch a rulemaking to amend the HRS to account for exposure to "vapor intrusion" from underground sources of contamination. EPA is considering the issue at the recommendation of the Government Accountability Office (GAO), which encouraged the agency to address the issue in a report released last year. Among other things, GAO found that an additional 37 sites would be added to the Superfund list if vapor intrusion was added to the HRS, although it did not say which sites those were.

The agency published a notice in the Federal Register Jan. 31 asking for comment on the "Potential Addition of Vapor Intrusion Component to the Hazard Ranking System," saying EPA is only considering "a proposed rulemaking to add a vapor intrusion component to the HRS" and is seeking comment on if and how it should do so. Intrusion of solids and liquids is not mentioned

in the notice.

But at a Feb. 24 listening session on the agency's plan to add vapor intrusion to the HRS, Dennis Munhall of EPA Region II told Inside EPA that the agency is also weighing exposure pathways to liquids and solids in an attempt to head off what could be an "emerging problem."

The proposed expansion stems from a groundwater plume under Garfield, NJ, which is contaminated with Cr6, the result of a 1983 discharge of roughly 5,441 pounds of the metal from the E.C. Electroplating site. Despite monitoring, the plume was never fully cleaned up.

In recent years, yellow dust began appearing in local basements, deposited there by flooding groundwater. Last September, the Agency for Toxic Substances & Disease Registry (ATSDR) issued a public health advisory recommending "that U.S. EPA take short- and long-term measures to dissociate persons -- whether in residential or commercial properties in the area of the contaminant plume -- from hexavalent chromium exposures resulting from infiltration of contaminated groundwater into the basements of these properties."

ASTDR further recommends that EPA in the long term "remediate permanently" the groundwater plume. "In the absence of a permanent solution, all residents within that groundwater contamination plume could continue to be exposed to hexavalent chromium," according to the health advisory. "And that exposure could be at levels that present an immediate and significant health threat."

Region II's Office of Emergency Response is addressing the most immediate contamination as officials grapple with a long-term solution.

The region is now looking at listing the site on the NPL, Munhall said, but is having trouble determining how to rank it through the existing pathways. Since residents are all on a public water system, which is piped in from uncontaminated wells, and the groundwater isn't being used, Region II officials are unclear if the site can be added to the NPL on that pathway.

One lawyer familiar with the Superfund program says that it’s likely that the site would not score high enough on the HRS through the groundwater pathway to land on the Superfund list because drinking water supplies aren't being threatened. The HRS is heavily weighted towards protecting drinking water and since residents are on a clean public water supply, the potential for exposure as laid out in the current scoring system is minimal.

When the HRS was being drafted, officials "never considered people getting in contact with groundwater" other than through drinking it, the source says. "Because everything is focused on drinking water, the presence of public water changes things enormously," the source adds, noting that sites with vapor intrusion are blocked from the NPL for largely similar reasons.

While the agency could use ASTDR's public health advisory and recommendation to seek listing -- a rarely used method for placing sites on the NPL -- that would not help similar sites in the future. Munhall said he did not know of any other site where intrusion of solids or liquids is threatening public health, but added "if it's happening here, my guess is it's happening elsewhere."

Munhall said the region is looking into all options including the potential rulemaking to add vapor

intrusion to the HRS -- the first time the regulation has been amended in 20 years -- for possible relief.

At the Feb. 24 listening session, agency officials insisted that no decisions have been made on how or whether to move forward with the rulemaking or make changes through guidance, if anything issued would include solids and liquids or what such language would look like.

The seven commenters at the meeting -- comprising representatives from the Edison Wetlands Association, Center for Health, Environment and Justice and residents of Pompton Lakes, NJ, and Ashville, NC -- all supported the addition of vapor intrusion on the HRS, arguing that the change would "put some teeth" into addressing affected sites and ensure better protection of human health.

However, the lawyer familiar with Superfund issues says EPA would be better off issuing a guidance document that allows for sites to be ranked on vapor intrusion through the air and groundwater pathways in order to avoid the "scrutiny" of a formal rulemaking and political pressure from Congress. Furthermore, the source adds, the agency should set a national toxicity standard for the chlorinated hydrocarbons most often associated with vapor intrusion and require evaluations to be done as a criteria for funding for state Superfund response programs.

In addition, a rule would likely not be ready until 2012, an election year when politicians will be reluctant to push through a potentially controversial regulation, that is if the rulemaking does not loose funding from regulation-leery Republicans before a final rule is prepared.

EPA is accepting comments until April 16 and will hold two more listening sessions, the first March 16 in San Francisco and the second March 30 in Albuquerque, NM. -- Jenny Hopkinson