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Before the

House of Representatives
Committee on Energy & Commerce
Subcommittee on Oversight & Investigations

Regarding

"Science Under Siege: Scientific Integrity at the Environmental Protection Agency"

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Introduction

Good morning Chairman Stupak, Ranking Member Shimkus, and members of the Subcommittee. My name is Sharon Kneiss and I am the Vice President of Products Divisions at the American Chemistry Council. I appreciate the opportunity to testify today regarding the flawed process that EPA used recently to revise an important health effects value for a life-saving chemical manufactured by several ACC member companies.

At the outset, I'd like to emphasize how crucial the integrity of EPA's scientific processes is to the integrity of EPA's scientific databases. Fundamentally if you don't have confidence in the process, you can't have confidence in the result. In this case, EPA's stated procedures – on paper – are appropriate. In particular, its *Peer Review Handbook* is a clearly written summary of the principles that should govern an agency peer review. It lays out the criteria for selection of peer reviewers, and it also describes the process for making those selections. The *Handbook* recommends:

- soliciting nominations from stakeholders, and
- giving notice to stakeholders of proposed panelists, *before* the panel is constituted.

The *Handbook* adds that panel members should:

- include world class scientists, since expertise is paramount;
- be sufficiently diverse to fairly represent relevant perspectives and fields of knowledge;

- represent a balanced range of technically legitimate points of view;
- not have current financial conflicts; and -- importantly,
- be open minded and be able to take an impartial approach to data examination. This means that panelists should not have made statements or taken other actions that would lead a reasonable person to conclude they had 'taken sides' on the issue in question.

The National Academies and NGOs endorse these procedures. Had EPA *followed* them, we would not be here today.

This June, EPA concluded the process of revising the oral reference dose or "RfD" for decabromodiphenyl ether (deca-BDE), a crucial flame-retardant. The many ways in which EPA failed to follow its own processes for scientific standard-setting, have resulted in an RfD in which EPA itself says it has "low confidence." The process was seriously flawed and the credibility of the outcome was its victim. If these shortcomings are widespread, they could seriously undermine the transparency and integrity of the Integrated Risk Information System, or "IRIS," EPA's hugely influential database of health effects data and dose-response values. The hearing presents a timely and important opportunity to highlight and investigate these failings in EPA's processes and their potential consequences for the integrity of science at EPA.

Background

The American Chemistry Council is the trade association that represents the leading companies in the business of chemistry. Established over a century ago, ACC is committed to improved environmental, health and safety performance through its Responsible Care® program, common sense advocacy, and health and environmental research and product testing. The business of chemistry is a $664 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. A significant part of ACC's work over the last decade has been to improve the quality and reliability of IRIS. ACC initiated and has actively supported bipartisan and successful efforts to increase the financial and personnel resources available to IRIS, without any quid pro quo or guarantee. ACC members are also among the nation's largest investors in scientific research and development. Through ACC's Long-Range Research Initiative and several voluntary testing programs, they have contributed tremendous amounts of technical expertise and experimental data to understanding and progress in the fields of toxicology and risk assessment that underlie the IRIS effort.

Deca-BDE is the most studied flame retardant on the market, having been the subject of an extensive 10-year evaluation by the European Union, as well as other major studies performed by the US EPA and the National Academy of Sciences, and has been found to present no significant risks to human health or the environment. Deca-BDE is used in plastics for electrical and electronic equipment, in the automotive and aviation industry,

and in construction and building projects. It is also used as a flame retardant in furniture applications to comply with fire safety standards. Fabric and upholstery treated with flame retardants can help prevent fires from starting and can slow the spread of fires that have already ignited. Escape times can be up to 15 times longer when flame retardants are present, providing increased survival chances for those in close proximity to fire. A prime example is the Air France jet that skidded off the runway in Toronto in 2005 and burst into flames. The flame retardant materials used in the airplane's construction were credited with providing the extended escape time needed for all 309 passengers and crew to escape. Thus, it is important to remember the reliability of this scientific review is not an academic exercise, but poses real risk/risk tradeoffs involving human lives.

EPA's Flawed Process for Revising the Deca-BDE Oral Reference Dose

EPA's recent health assessment of deca-BDE is the story of important scientific and due process procedures that were not followed and the resulting adverse consequences for the integrity and transparency of EPA's scientific resources and for the public that relies on them. For the record, ACC also notes that industry did not benefit from the ultimate outcome of the deca-BDE assessment. From ACC's perspective, the revised RfD is improperly based on an unreliable study and is three orders of magnitude lower than it would be if based on the best available science. With a properly constructed process and panel, we would not be here today. Panel composition concerns could and should have been addressed prior to constituting the panel. Concerns with the science being relied upon could have been included in the panel's charge before the panel was even

assembled. Instead, EPA's actions undermined the confidence that anyone, including the Agency itself, can have in either the process it followed or the resulting RfD.

ACC was pleased when EPA announced in 2003 that it would revise the IRIS file for deca-BDE. The existing RfD – the estimated amount of a substance that can be ingested daily for a lifetime without an appreciable risk of deleterious effects[1] -- dated from the late 1980s and was based on a study from 1975 on a commercial product that was significantly different from the product in commerce today. In the meantime, the National Toxicology Program – the federal government's flagship project for conducting animal testing to protect human health – had completed a pair of comprehensive, top-quality studies of deca-BDE exposure in rats and mice. In turn, the National Academy of Sciences' National Research Council – the federal gold standard for scientific peer collaboration in this area – had derived a human RfD using the two NTP studies. Finally, a well-conducted study from 2002 had evaluated the potential for deca-BDE to affect fetal development (and had discerned no ill effects). It seemed obvious that EPA would base the new RfD on this high-quality dataset.

Thus, ACC was surprised and alarmed to discover in December 2006 that EPA's draft toxicological assessment for deca-BDE (the technical support document underlying the IRIS file for a chemical) proposed to base the RfD on a highly questionable study from Sweden (the "Viberg" study). ACC was equally distressed to learn in February 2007 that EPA (through a contractor) had already convened an external panel to peer review the

[1] http://www.epa.gov/ncea/iris/help_ques.htm#rfd.

toxicological assessment. Finally, and exacerbating our concerns with the credibility of the panel and its processes, ACC was dismayed to read around the same time of statements made by the chair of the panel, statements that reasonably led it to conclude that the chair had made up her mind regarding deca-BDE before the panel had even met or concluded its evaluation.

The Viberg Study's Inadequacies

The Viberg study purported to demonstrate that a single dose of deca-BDE administered to young mice caused a neurological deficit, "disruption of habituation," as determined by a measuring device called a "Rat-O-Matic." Reliance on this study was highly inappropriate for a host of reasons:

- The study did not follow EPA "Good Laboratory Practices," or their European Union ("EU") equivalent, as any study would have to do if was being submitted to EPA by industry under the Toxic Substances Control Act ("TSCA") or the federal pesticide statute ("FIFRA"). "GLPs" provide quality assurance for laboratory data and allow full auditing of laboratory analysis to help ensure its scientific integrity.
- The study did not follow EPA's study protocols for developmental neurotoxicity testing, again as would be required for any study being submitted to EPA under TSCA or FIFRA. Indeed, in its review of the study for purposes of EPA's Voluntary Children's Chemical Evaluation Program, the Agency's Office of

Pollution Prevention & Toxics (OPPT) has stated that Viberg did not follow accepted methodologies for assessing neurological effects.[2]

- The methodology that Viberg did follow had numerous shortcomings. Most notably, OPPT determined that the study had a "fundamental flaw": it treated pups from the same litter as independent from each other, when a proper developmental study regards the litter as the basic analytical unit, because siblings tend to be similar to each other.[3]
- Perhaps most troubling, the study's author repeatedly refused requests from EPA, EU and industry officials for additional data that might answer their many questions about the study. A failure to supply sufficient data to allow others to reproduce a study renders the study unreproducible, and hence not "objective" within the meaning of Office of Management and Budget's (OMB)[4] and EPA's Information Quality Guidelines.[5] Both of these guidelines recognize that transparency about data and methods is an indispensable element of influential scientific information such as an IRIS file. Such transparency is not just a concern of industry or government, moreover; NGO groups widely endorse a

[2] EPA Voluntary Children's Chemical Evaluation Program (VCCEP), *Data Summary: Update from the Original VCCEP Submission Dated Dec. 17, 2002 and the Peer Consultation Meeting in April 2003 – Decabromodiphenyl Ether* (Feb. 29, 2008), p. 47, available at http://www.epa.gov/oppt/vccep/pubs/sum22908.pdf.
[3] *Id*. at 42.
[4] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8460 (Feb. 22, 2002).
[5] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, EPA/260R-02-008 (Oct. 2002), pp. 20-21, available at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

requirement that, in order for a study to be relied upon by EPA, the study's author must supply underlying data upon request.[6]

Both EPA and EU regulators have concluded that the Viberg study was not adequate for use in supporting quantitative risk assessment; such as setting health effects values like an RfD.[7] More bluntly, EPA's Voluntary Childrens Chemical Evaluation Program (VCCEP) concluded just this February that "Viberg et al.'s results do not provide substantive evidence of a developmental neurotoxic effect due to decabromodiphenyl ether."[8] Remarkably, the very EPA scientists who considered the peer review report for purposes of conducting the IRIS review of deca-BDE state on their website that they have "low" confidence in the Viberg study.[9]

Failures in EPA's Peer Review of Deca-BDE

A key reason that the IRIS file for deca-BDE is substantively flawed is the process by which its underlying assessment was peer reviewed. As discussed below, serious failures of transparency and integrity render the entire process unreliable.

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[6] *See, e.g.*, Center for Progressive Reform, *Saving Science from Politics* (July 2008), p. 7, available at http://www.progressivereform.org/articles/SavingScience805.pdf.
[7] EPA, *VCCEP Data Needs Decision Document of Decabromodiphenyl Ether* (June 2005), p. 15, available at http://www.epa.gov/oppt/vccep/pubs/finaldeca.pdf.
[8] VCCEP Data Summary, supra note 2, at 47. The IRIS database began as an EPA consensus process, but in the case of deca-BDE, it is clear that the IRIS file does not reflect such a consensus.
[9] http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showQuickView&substance_nmbr=0035.

Scientific peer reviews at EPA are governed by EPA's *Peer Review Handbook*.[10] This publication – which is widely endorsed across the spectrum, from ACC to environmental NGOs – cogently describes a deliberative process for conducting agency peer reviews of scientific and technical studies. If the process for the peer review of the deca-BDE toxicological assessment had followed recommendations of the *Handbook*, very likely the problems described above and below would not have occurred. Unfortunately, the deca-BDE peer review failed to follow several key recommendations of the *Handbook*:

- The public was not notified before the peer review panel was formed, and thus was unable to nominate proposed reviewers. The *Handbook* states that EPA staff managing peer reviews "should . . . consider requesting that the public, including scientific and professional societies, nominate peer reviewers.[11] It also notes that EPA's Science Advisory Board (SAB) routinely solicits such nominations to make sure that it gets the best possible reviewers.[12]
- The public was not provided with a list of proposed reviewers upon which it could have commented. Again, the *Handbook* notes that the SAB solicits nominations on a draft slate of reviewers so that interested persons can express support for or concerns about them.[13]
- The peer review panel was chaired by an individual who had not been adequately vetted, and who in fact had made public statements declaring her commitment to banning deca-BDE without waiting for any more scientific results. This major failing is discussed below.

[10] EPA Science Policy Council, PEER REVIEW HANDBOOK (3d ed. May 2006).
[11] *Id*. at 60.
[12] *Id*. at 61.
[13] *Id*.

EPA's Process for Evaluating Potential Peer Reviewers

The *Handbook* is clear that "[t]he choice of peer reviewers should be based primarily upon the reviewers' expertise, knowledge, skills, and experience . . . . The group of reviewers should be sufficiently broad and diverse to fairly represent a balanced range of technically legitimate points of view."[14] The Handbook frankly recognizes that "experts with a stake in the outcome – and therefore a conflict or appearance issue – may be some of the most knowledgeable and up-to-date experts because they have concrete reasons to maintain their expertise."[15] On the other hand, federal statutes prevent EPA from using as peer reviewers either (i) individuals with current financial conflicts of interest or (ii) individuals who appear to lack impartiality.[16] The Handbook admits that decisions regarding impartiality are "not . . . clear cut" and "a judgment" call, due to the fact just noted that knowledgeable experts generally have views regarding the issues on which they are expert.[17] However, it states that, "[a]s a general rule, experts . . . *who have clearly 'taken sides,'* may have an appearance of a lack of partiality . . . and should be avoided."[18] The National Academies and NGO groups draw a similar line.[19]

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[14] *Id*. at 60.
[15] *Id*. at 70.
[16] When EPA conducts the peer review itself, the bar arises from rules implementing the Ethics in Government Act, 5 C.F.R. Part 2635, Subparts D & E; when EPA uses a contractor, as in the case of deca-BDE, the bar arises from the federal acquisition regulations, 48 C.F.R. § 9.505 (Federal Acquisition Regulations) & Subpart 1509.5 (EPA Acquisition Regulations); *see generally* EPA's *Peer Review Handbook* at 63-68. EPA can waive conflicts or partiality if they are outweighed by the need for the person's expertise.
[17] *Handbook* at 64.
[18] *Id*. at 63.

Public statements made by the person appointed to chair the deca-BDE peer review panel could reasonably lead to the perception that she had clearly taken sides and was unwilling to consider other perspectives. The chair:

- Was reported as saying "there is no question in [my] mind that deca-BDE should be eliminated because it is a persistent toxin that accumulates in the food chain."[20]
- Testified before the Maine legislature in support of a report specifically advocating that the state mandate a phase-out of deca-BDE.[21]
- Was quoted as saying she would support use of an equally toxic alternative to deca-BDE because "[t]he reason we are in this bind is because the industry doesn't

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[19] The National Academies state: "Potential sources of bias are not necessarily disqualifying for purposes of committee service. Indeed, it is often necessary, in order to ensure that a committee is fully competent, to appoint members in such a way as to represent a balance of potentially biasing backgrounds or professional or organizational perspectives. For example, an individual may be selected to serve on a committee conducting a broad study of proposed new scientific missions in space, although the individual is a consultant or an employee of an aerospace company that has a general business interest in such matters. . . . Some potential sources of bias, however, may be so substantial that they preclude committee service (e.g., where one is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary)." *National Academies' Policy on Committee Composition and Balance and Conflicts of Interest* (May 12, 2003), available at http://www.nationalacademies.org/coi/bi-coi_form-0.pdf. NGO groups agree: "As the [National Academies'] guidelines recognize, some degree of bias is unavoidable. . . . On the other hand, when biases become so strong that they impinge on an individual's ability to objectively answer new questions, that person should not be given the institutional power of an advisory committee member." *Saving Science from Politics, supra* note 6, at 27.

[20] *DEP Urges Legislative Ban on Fire Retardant*, BANGOR DAILY NEWS, Feb. 16, 2007, at B4.

[21] *Brominated Flame Retardants, Third Annual Report to the Maine Legislature* (Jan. 2007), available at http://maine.gov/dep/rwm/publications/legislativereports/pdf/finalrptjan07.pdf.

have to collect any data about the compounds they are putting into commerce."[22]

This bias was confirmed by a later discovery: the chair was quoted in the SEATTLE POST INTELLIGENCER as saying "[w]e know enough now to ban deca. . . . because of bioaccumulation, because of the persistence, and I think we have enough hints of its toxicity. We don't need to wait another five years or even another two years and let an increase in the environment, while we nail down every possible question we have."[23]

ACC wrote and met with EPA to express its concerns when ACC learned about the chair selected for the toxicological assessment of deca-BPE. At this late date (the panel submitted its final report to EPA in April 2007), there really was no satisfactory way to undo the damage caused by the flawed process, including the chair's leadership role in the panel. Convening an entirely new panel was the best action EPA could take, but ACC doubted that such a request would be considered seriously. As a result, ACC was reduced to stating that, in light of the "policy predisposition" revealed by the chair's actions and statements, "ACC believes that the Agency must base its final Toxicological Review on data, opinions, and conclusions other than the Chairperson's. Otherwise, the

[22] *Id*. The statement is incorrect, by the way. The kinds of information that TSCA requires industry to provide, or authorize EPA to require, are summarized in EPA, OVERVIEW: OFFICE OF POLLUTION PREVENTION & TOXICS PROGRAMS (April 2007) at 3-20, available at http://www.epa.gov/oppt/pubs/oppt101-042007.pdf.
[23] *PBDEs: They are everywhere, they accumulate and they spread*, SEATTLE POST INTELLIGENCER, March 28, 2007, available at http://seattlepi.nwsource.com/local/309169_pbde28.html.

integrity of this peer review will be further compromised – which ultimately calls into question the overall integrity of the entire IRIS database."[24]

Notably, ACC advised EPA of this information and the positions the chair previously had taken. ACC did not call for Dr. Rice to be ousted as chair and did not "argue that scientific expertise with regard to a particular chemical and its human health effects is a basis for disqualification from a peer review board."[25] To the contrary, the chair's academic credentials are not in dispute and we appreciate her public service. Furthermore, ACC agrees with the *Peer Review Handbook* that "[t]he choice of peer reviewers should be based primarily upon the reviewers' expertise . . . ."[26] But it also agrees with the Handbook's statements about lack of impartiality. ACC also notes that NGOs have asked EPA to strike knowledgeable industry reviewers from peer review panels for the very same concerns about partiality.[27]

NGOs also weighed in, expressing concern in March regarding another member of the deca-BDE peer review panel. The letter from NRDC and six other NGOs objected to the service of Richard Bull on the grounds that he had previously been asked to resign from a

[24] Letter from Sharon H. Kneiss, ACC to George M. Gray, EPA (May 3, 2007), at 6.
[25] Letter from Chairmen Dingell and Stupak to EPA Administrator Johnson (March 13, 2008), at 1.
[26] *See* note 14 *supra*.
[27] The March 13 letter sent in this investigation by Chairmen Dingell and Stupak to EPA Administrator Johnson was derived in part from a June 2006 letter from NRDC, EWG, CSPI and 22 other NGOs to EPA that sought to keep nine industry scientists off an SAB panel on ethylene oxide. The NGOs objected to three individuals because they "have *publicly taken a position* on the quantitative cancer risk of [ethylene oxide]." They concluded: "Committees whose members have . . . *a strong bias* . . . undermine the credibility of the EPA."

National Academies committee for failing to disclose, during the pendency of the committee, that he had been a paid consultant to a company in litigation over the same chemical that the committee was assessing.[28] This letter raises further question about the process by which EPA assembled and conducted the deca-BDE peer review.

EPA ultimately deleted the chair's statements from the peer review panel's final report. But the damage was done – as just noted, the panel had completed its work, and EPA's IRIS staff had already reviewed the reviewers' draft report. EPA's action therefore was about as ineffective as a judge instructing a jury to disregard something they had just heard a witness say. The final toxicological report conformed to the chair's recommendations; most important, it continued to rely on the unreliable Viberg study. Symbolically, while the chair's name may have been removed from the final report of the peer reviewers, she remains listed today as chair of the panel in the final toxicological assessment.[29] And disturbingly, when EPA initially removed the chair's comments from the final document, it failed to note that the final report had been revised or the reasons for that revision. ACC wrote the Agency a letter suggesting that it explain why the peer review report had been changed.

EPA issued its revised RfD for deca-BDE on June 30 of this year. The IRIS file relies on the Viberg study, and cites the flawed peer review report as support for doing so. It gives short shrift to or ignores ACC's substantive criticisms of the Viberg study and its

[28] Letter from Richard Wiles et al. to Stephen Johnson and George Gray (March 17, 2008), available at http://docs.nrdc.org/health/hea_08031701A.pdf.
[29] *See* page xi of the toxicological assessment, available at http://www.epa.gov/ncea/iris/toxreviews/0035-tr.pdf#page=84.

procedural criticisms of the peer review process. Thus, it should be clear that EPA's attempts to "un-ring the bell" of the chair's biased stewardship of the peer review panel, whether or not sincere, had no effect on the ultimate result. Instead, EPA has posted a new IRIS file for deca-BDE which declares that EPA has "low" confidence in both the Viberg study upon which it has just relied and the RfD that it has derived from that study.[30]

Conclusion

ACC thanks the Subcommittee for initiating this inquiry. By shedding light on the numerous process failures involved in EPA's recent reassessment of deca-BDE, this hearing could be the beginning of an effort to ensure that EPA follows its own Peer Review Handbook and related process guidance more closely. Until it does so, the integrity of peer review at EPA and the integrity of the IRIS database will both be at risk, because if you don't have confidence in a process, you can't have confidence in its result. Ultimately, it is the public that will suffer the greatest loss.

Once again, I appreciate the opportunity to provide this statement to the Subcommittee, and I would be happy to answer any questions that the Subcommittee has.

[30] *See* note 9 *supra*.

Summary

The integrity of EPA's review processes are critical to the integrity of EPA's scientific databases. Fundamentally if you don't have confidence in the process, you can't have confidence in the result. In this case, EPA's stated procedures for peer reviews – on paper – are appropriate. In particular, EPA's *Peer Review Handbook* is a clearly written summary of the principles and procedures that should govern an agency peer review. It lays out the criteria for selection of peer reviewers, and it also describes the process for making those selections.

This June, EPA concluded the process of revising the oral reference dose or "RfD" for decabromodiphenyl ether (deca-BDE), a crucial flame-retardant. The many ways in which EPA failed to follow its own processes for scientific standard-setting, have resulted in an RfD in which EPA itself says it has "low confidence." The process was seriously flawed and the credibility of the outcome was its victim.

The story of the deca reassessment is a litany of processes that were not followed, and the consequences of those failures for the integrity and transparency of EPA's scientific enterprise and the public that relies on it. This flawed process resulted in two major failures. First, EPA used a completely inappropriate study to set the RfD. Second, the chair of the external peer review supporting the assessment had made numerous public statements indicating that she had made up her mind on the science and would not be willing to entertain evidence or opinions to the contrary.

The hearing presents a timely and important opportunity to highlight and investigate these failings in EPA's processes and their potential consequences for the integrity of science at EPA.