UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

JUN - 8 2017

OFFICE OF
GENERAL COUNSEL

MEMORANDUM

SUBJECT: Participation in Specific Party Matters Involving Your Former Employer, the American Chemistry Council

FROM: Kevin S. Minoli
Designated Agency Ethics Official and
Acting General Counsel

TO: Nancy Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention

Effective April 30, 2017, you joined the United States Environmental Protection Agency (EPA) in an Administratively Determined (AD) position as the Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (OCSPP). In this position, you are responsible for advising the Acting Assistant Administrator in matters pertaining to chemical safety, pollution prevention, pesticides and toxic substances, including implementation of rulemaking under applicable federal statutes. Previous to your selection, you served as the Senior Director of Regulatory Science Policy at the American Chemistry Council (ACC), which represents companies that are directly regulated by EPA. You seek permission to participate in specific party matters involving your former employer.

In providing my advice, I have taken into consideration the fact that, as an AD appointment, you are not required to sign the Trump ethics pledge because this type of appointment falls outside the definition of "appointee" set forth at Executive Order 13,770 at Section 2(b).[1] You do not have any financial conflict of interest with your former employer, so the ethics rules to be applied to you are set forth in the Standards of Ethical Conduct for Employees of the Executive Branch, 5 C.F.R. Part 2635, specifically Subpart E, "Impartiality in Performing Official Duty." Pursuant to 5 C.F.R. § 2635.502(b)(1)(iv), you have a "covered relationship" with ACC as your former employer. For one year from the time you resigned from ACC, absent an impartiality determination from me, you cannot participate in any specific party matter in which ACC is a party or represents a party if that matter is likely to have a direct and predictable financial effect upon the ACC or if the circumstances would cause a reasonable

[1] *See* Office of Government Ethics advisories entitled "Guidance on Executive Order 13770," LA-17-03 (3/20/27) and Executive Order 13770," LA-17-02 (2/6/17), which apply the following OGE advisories from the last administration in full: "Who Must Sign the Ethics Pledge?" DO-09-010 (3/16/09); and "Signing the Ethics Pledge," DO-09-005 (2/10/09).

person with knowledge of the relevant facts to question your impartiality. *See* 5 C.F.R. § 2635.502(a).

It is important to note that the ethical restriction applies only to particular matters involving specific parties, not to particular matters of general applicability. Generally speaking, a "specific party" matter is a "proceeding affecting the legal rights of parties, or an isolatable transaction or related set of transactions between identified parties." *See* 5 C.F.R. § 2640.102(l). Rulemaking is not usually a "specific party" matter but rather a matter of general applicability, which involves "deliberation, decision, or action that is focused upon the interests of specific persons, or a discrete and identifiable class of persons." *See* 5 C.F.R. § 2640.103(a)(1). Therefore, under the ethics regulations, you may participate in rulemaking, even if that rulemaking may affect the members of your former employer. While you can ethically work on rulemaking in general, you have been advised -- and understand – that you cannot participate in any meetings, discussions or decisions that relate to any individual ACC comment nor attend any meeting at which ACC is present.

As provided by the ethics regulations, however, federal ethics officials can nonetheless permit employees to participate in matters that might raise impartiality concerns when the interest of the federal government in that employee's participation outweighs concern over the questioning of the "integrity of the agency's programs and operations." *See* 5 C.F.R. § 2635.502(d). The factors that we can take into consideration are:

(1) the nature of the relationship involved;
(2) the effect that resolution of the matter will have upon the financial interest of the person affected in the relationship;
(3) the nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter;
(4) the sensitivity of the matter;
(5) the difficulty of reassigning the matter to another employee; and
(6) adjustments that may be made in the employee's duties that would reduce or eliminate the likelihood that a reasonable person would question the employee's impartiality.

In reviewing these factors, I have decided to allow you to participate fully in matters of general applicability, including rulemaking, including consideration of any comments that were made by ACC. In making this determination, I have taken the following factors into consideration:

- While at ACC, you served as the Senior Director of Regulatory Science Policy and worked extensively on risk assessment, science policy and rulemaking issues;
- As ACC's leading expert for ensuring sound implementation of risk assessment practices in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, you have valuable expertise to share as the Agency considers how to implement this new statute;
- You have extensive prior expertise with the regulated industry's perspective and are already familiar with (and may well have authored) ACC comments now under consideration. Because your prior knowledge is inherently part of your expertise, it is impractical to excise that knowledge from how you carry out your Agency duties;

- While you still participate in an ACC defined contribution plan, neither you nor your former employer continues to make contributions. Pursuant to federal ethics regulations, this type of employee benefit plan does not present any financial conflict of interest. *See* 5 C.F.R. § 2640.201(c);
- Your unique expertise, knowledge and prior experience will ensure that the Agency is able to consider all perspectives, including that of the regulated industry's major trade association;
- Although your type of appointment at EPA is not a political one, you currently serve in the only non-career position in the Office of Chemical Safety and Pollution Prevention. As such, you have a unique role in advising political staff, including the Administrator, and need to be able to be able to consider as many perspectives as you can; and
- Participation in rulemaking matters is integral to your position, so the Agency has a strong and compelling interest in ensuring that you are able to advise the Administrator, the Acting Assistant Administrator and career staff to the maximum extent possible.

Under the federal ethics regulations, you are permitted to participate in matters of general applicability (such as rulemaking) even if individual members of your former employer will be affected by that particular matter. Until now, you have recused yourself from participating personally and substantially in those comments to rulemaking that were offered by ACC. This impartiality determination confirms that you are permitted to participate in any discussions or consideration of comments submitted by ACC to rulemaking or other matters of general applicability. You may also attend meetings at which ACC is present or represented, but only if the following conditions are met: (a) the subject matter of the discussion is a particular matter of general applicability, (b) other interested non-federal entities are present besides only ACC, and (c) you are not the only Agency official at the meeting. This authorization will remain in effect for the remainder of your cooling off period. After April 21, 2018, you will no longer have a covered relationship with ACC under the impartiality standards and will no longer require this determination. I am attaching a recusal statement for you to sign and issue to your staff.

If you have any questions regarding this determination, or if a situation arises in which you need advice or clarification, please contact Justina Fugh at fugh.justina@epa.gov or (202) 564-1786.

Attachment

cc: Wendy Cleland-Hamnett, Acting Assistant Administrator
Justina Fugh, Senior Counsel for Ethics

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 26 2017

OFFICE OF
ADMINISTRATION
AND RESOURCES
MANAGEMENT

Nancy Beck
[redacted]

Dear Ms. Beck:

Congratulations! You have been selected for an appointment with the U.S. Environmental Protection Agency (EPA). This is to officially inform you of your position as Deputy Assistant Administrator for Toxics, located in the Office of Chemical Safety and Pollution Prevention; Washington, DC.

This position is an Excepted Service Administratively Determined (AD) position. Pursuant to the authority vested in the Administrator under Public Law 95-190, your compensation for this position has been set at $161,900 per annum. Your acceptance of this position means that: (1) your position is not in the competitive service; (2) you will serve at the pleasure of the Administrator; and (3) termination of your appointment may occur at anytime upon notice thereof. During a change in Administration, each position is generally reviewed on a case-by-case basis to determine if they meet the needs of the new Administration's goals and objectives for the Agency.

Information About Your Position

- Your annual salary will be $161,900;
- Your immediate supervisor will be Wendy Cleland-Hamnett, Acting Assistant Administrator for Chemical Safety and Pollution Prevention; your second level supervisor will be E. Scott Pruitt, Administrator;
- You will work a full-time schedule;
- You will be subject to a pre-employment drug test. If your test results are not favorable, your appointment will be terminated; and
- Your position has been designated by our Personnel Security Office as a High Risk position. This designation will require your position to be subject to random drug testing procedures.

The effective date of your appointment is April 30, 2017. We ask that you report for employee orientation on **Monday, May 1, 2017 at 8:30 am**. You will be met at the William Jefferson Clinton North guard station. When you arrive at the guard station, please call Charles Munoz on 202-564-3097 or Sharnett Willis on 202-564-7866. One of them will meet you at the guard's station in order to sign you into the building.

You can reach the Agency by taking the Metro Commuter Rail. Board the Blue or Orange line train and get off at the Federal Triangle Metro Stop. Enter the U.S. Environmental Protection Agency William Jefferson Clinton North Building on your immediate right.

What to Bring on Your First Day Monday, May 1, 2017

►. You should go to the links below to access the forms. Please complete and bring the forms with you on Monday, May 1st.

a. Optional Form 306, Declaration for Federal Employment - https://www.opm.gov/forms/pdf_fill/of0306.pdf

b. Standard Form 144, Statement of Prior Federal Service - https://www.opm.gov/forms/pdf_fill/SF144.pdf

c. Standard Form 256, Self-Identification of Disability - https://www.opm.gov/forms/pdf_fill/sf256.pdf

d. Standard Form 181, Ethnicity and Race Identification - https://www.opm.gov/forms/pdf_fill/sf181.pdf

e. Form 2231, FastStart Direct Deposit (need a voided check) - https://www.fiscal.treasury.gov/fsservices/gov/pmt/eft/2231.pdf

f. Tax form (federal) - https://www.irs.gov/pub/irs-pdf/fw4.pdf

► Document(s) to establish your identity and employment eligibility (e.g., a current passport, certificate of U.S. citizenship, and/or a current copy of your driver's license)
► Social Security card issued by the Social Security Administration.
► Voided check (if you will be moving your direct deposit to another financial institution)

If you are unable to produce the required document(s) you must produce a receipt showing that you have applied for the document(s). You will have three days to bring the original document(s) to your local Human Resources Office.

Benefits

As a non-temporary appointee, you are entitled to the same Federal Benefits package provided to General Schedule employees including:

► 10 paid Federal Holidays per year
► 13 days of sick leave each year based on the hours earned each pay period
► 13 to 26 days of vacation, depending on your years of employment based on the hours earned each pay period
► National recognized health insurance model that offers choice and flexibility along with substantial employer contributions to premiums. Employee share of premiums can be paid with pre-tax dollars: http://opm.gov/insure/health/index.asp

- ▶ Group Term Life Insurance Program
- ▶ Long-term Care Insurance
- ▶ Federal Employees Retirement System (FERS-FRAE) based on years of service. If it is determined that you have creditable service to place you in another retirement system, we will do so after obtaining all previous service records.
- ▶ Thrift Savings Plan (TSP), a self-directed retirement savings program through multiple investment options similar to a 401(K) plan

After your orientation, please schedule an appointment with Karmel Ferebee, Executive Resources Division Benefits Specialist, on 202-564-4059 to discuss your employee benefits. It is very important that you make contact with Ms. Ferebee within your first week of employment to establish your benefits.

We are pleased that you have chosen the U.S. Environmental Protection Agency as your place of employment and look forward to welcoming you to the Agency. We hope that you will find your new assignment both challenging and rewarding. If you have questions or concerns, please feel free to call me.

Sincerely yours,

Howard Barnett
Executive Resources Staff
Office of Human Resources

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 9, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Recusal Statement

FROM: Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator

TO: Wendy Cleland-Hamnett
Acting Assistant Administrator

Because I am in an Administratively Determined position, I have been advised by the Office of General Counsel/Ethics (OGC/Ethics) that I am not subject to Executive Order 13770 and therefore not required to sign the Trump ethics pledge. But as an executive branch employee, I have always understood that I am subject to the conflict of interest statutes codified at Title 18 of the United States Code and the Standards of Ethical Conduct for Employees of the Executive Branch, 5 C.F.R. Part 2635. Pursuant to the federal impartiality standards, I have understood that I have a "covered relationship" with my former employer, the American Chemistry Council (ACC), and have recused myself from participating personally and substantially in any particular matter involving specific parties in which ACC is a party or represents a party. I was advised by OGC/Ethics that my recusal period commenced the day that I left ACC and would remain in effect for one year unless I was authorized by the Office of General Counsel/Ethics (OGC/Ethics) to participate pursuant to 5 C.F.R. 2635.502(d).

I have sought and obtained confirmation from OGC/Ethics that I can participate in particular matters of general applicability, such as rulemaking, even if my former employer has an interest, and that I can participate personally and substantially in any discussions or consideration of comments that ACC submitted with regard to rulemaking or other matters of general applicability. *See* attached. I am also now authorized to attend meetings at which ACC is present or represented, provided that the subject matter of the meeting is a matter of general applicability, if other interested non-federal parties are present, and other EPA personnel attend. For the remainder of my cooling off period, until April 21, 2018, however, I understand that I cannot otherwise participate in any specific party matter involving ACC unless I first seek approval from OGC/Ethics.

I am issuing this recusal statement to ensure that our staff assist me by directing any ACC specific party matter to you instead of me, without my knowledge or involvement, until after April 21, 2018. In consultation with OGC/Ethics, I will revise and update my recusal statement whenever warranted by changed circumstances, including changes in my financial interests or in my personal or business relationships.

cc: OCSPP senior staff
Justina Fugh, Senior Counsel for Ethics

Nancy Beth Beck PhD, DABT

(b) (6)
[redacted]

SCIENCE & REGULATORY POLICY EXPERT

Ph.D. Toxicologist with over eighteen years of applied public health experience. Specialized ability to provide a broad policy perspective as well as detailed technical input. Deep understanding of scientific issues, risk assessment, and U.S. regulatory process. Accomplished in bringing a scientific dialogue to the policy discussion to inform critical decision-making. Skilled in leading and directing interagency negotiations to improve policy. Successful collaborations have involved partnerships with senior staff and policy officials throughout the Executive Office of the President and Federal agencies.

Education & Certification:

Diplomat American Board of Toxicology (DABT), November 2002, recertified Aug 2016
Ph.D. Environmental Health, *University of Washington*, Seattle, WA, 1998
M.S. Environmental Health, *University of Washington*, Seattle, WA, 1992
B.S. Microbiology (minor economics), *Cornell University*, Ithaca, NY, 1988

APPLIED TOXICOLOGY & PUBLIC HEALTH EXPERIENCE:

American Chemistry Council (ACC), Washington DC

Senior Director of Regulatory Science Policy
January 2012- present

- Leading expert for ensuring sound implementation of risk assessment practices within the Frank R. Lautenberg Chemical Safety for the 21st Century Act (signed into law June 2016).
- Develop technical and policy materials to develop sound scientific policies on science and health critical for the government assessment of chemicals.
- Oversee funding and development of projects to advance risk assessment methodologies and practices.
- Review and provide comment on various scientific assessments including EPA IRIS assessments, OPPT Risk Assessments, Report on Carcinogens documents, and international assessments to inform industry engagement with Federal Agencies.
- Serve as an expert technical and strategy resource to committees and self-funded groups on the development and improvement of scientific documents related to specific chemical assessments.
- Analyze scientific documents to identify critical scientific issues relating to improving the scientific basis to support decisions making. Provide technical assistance in protocol development, monitoring, auditing and communication of results.
- Co-lead ACC panel on advancing risk assessment and science policy regarding issues related to characterizing uncertainty, systematic review, and weight of evidence evaluations.
- Work to resolve member company concerns and problems related to chemical assessments
- Monitor, analyze, and track emerging issues, developments and trends on science policy and chemical assessment and management.
- Serve as spokesperson on behalf of ACC in front of federal agencies, congressional staff, press, international groups, scientific societies and other organizations.

Executive Office of the President, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC
TOXICOLOGIST/RISK ASSESSOR/POLICY ANALYST
AUG. 2002-January 2012

• Utilized toxicology expertise to bridge the science and policy gap by framing and identifying scientific issues for an active policy debate.
• Led expert for international regulatory discussions with the EU, Canada and Mexico on risk assessment and nanotechnology policy.
• Managed and led the scientific review of the toxicological/scientific analyses and risk assessments upon which rulemakings, proposals, notices, guidance documents, and information collection requests rely as part of the review by the Executive Office of the President (EOP). Included review of IRIS assessments.
• Supervised the oversight of federal agency implementation of the Information Quality Law and OMB Information Quality Guidelines.
• Coordinated and led OMB risk assessment initiatives, including oversight, authorship, coordination of working group, shepherding of draft documents through peer review and public comment, and culmination into a final OMB/OSTP Memorandum on Risk Analysis.
• Monitored and analyzed human health, environmental and safety information which appears in legislative testimony through the legislative review clearance process within the EOP.
• Provided direct scientific, risk assessment, toxicological, and environmental health assistance and interpretation to White House political appointees and senior leaders. Prepared and conducted various briefing papers and talks.

US EPA CAREER DEVELOPMENT DETAIL
US EPA, Office of the Assistant Administrator for the Office of Research and Development, Washington DC. Feb.2006-May 2006

- Reviewed and provided comments on strategies and draft documents for the EPA Assistant Administrator
- Assessed differences and similarities of risk assessment procedures among different EPA program offices, with a specific emphasis on pesticides and the IRIS processes.
- Gained critical understanding of the Office of Research and Development and its role in regulations.

AAAS (American Association for the Advancement of Science) Science and Technology Policy Fellow, Washington DC ***FELLOW--US EPA, National Center for Environmental Assessment***
Sept. 2000-Aug. 2002

• Worked on toxicology projects focused on identifying health issues related to childhood susceptibilities, human variability, childrens toxicokinetics and toxicodynamics, and susceptible populations.

Washington State Department of Health, Office of Environmental Assessments, Olympia, WA
TOXICOLOGIST/PUBLIC HEALTH ADVISOR Feb. 1999-July 2000

• Prepared health and exposure assessments, including site specific risk assessments, for ATSDR and the Washington State Department of Health.
• Evaluated human health risks using knowledge, risk assessment tools, air modeling programs, hydrogeology knowledge, and a strong understanding of the fate and transport of compounds in the environment and the body.
• Interacted regularly with other regulators and the general public at public meetings.

Publications, awards, and other leadership activities available upon request

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

May 30, 2017

MEMORANDUM

SUBJECT: Concur with Comment
Expedited Final Agency Review – Final Rule: Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances (Tier 2; SAN 5947; RIN 2070-AK20)

FROM: Michael Shapiro
Acting Assistant Administrator, Office of Water

TO: Wendy Cleland-Hamnett
Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention

The Office of Water (OW) concurs with comments on the above referenced Risk Evaluation rule, in which EPA describes a process to conduct risk evaluations on High Priority chemicals and on chemicals whose evaluation is requested by manufacturers.

Understanding the Administrator's direction to meet the tight deadline to promulgate a final rule by June 22, 2017, OW has conducted an expedited 2-day review of the rule and preamble. If there is any extension of time provided as a result of OMB's review process or if the rule is changed after FAR, the OW requests that OCSPP reengage the workgroup.

The OW understands that changes have been made to the final prioritization rule (in a separate rulemaking) and the risk evaluation rule that result in prioritization and risk evaluation for one or more "conditions of use" of a chemical, as determined by the Administrator, rather than for a chemical substance in its entirety for all conditions of use. OW recommends that OCSPP remove references in the Risk Evaluation rule to evaluating *single* conditions of use or *subsets* of conditions of use and instead adopt a chemical substance-based approach. If only a portion of conditions of use of a chemical are included in the scope, it is not clear how a risk-based prioritization approach will be conducted and how aggregate risk (under all conditions of use) to human health or the environment will be assessed. OW's concern is whether a chemical may occur in drinking water or ambient water above a level of concern for human health or the environment regardless of the condition(s) of use that led to its occurrence.

Of particular concern is the revised preamble language in the section *Exclusions from the Definition of Conditions of Use*. Under this new paradigm, "legacy uses," "associated disposal (e.g., the future disposal of insulation that contains a chemical substance that is no longer manufactured, processed, or distributed for use in insulation)," and "legacy disposal (e.g., a chemical substance currently in a landfill or in groundwater plumes)" may be excluded from conditions of use. These important chemical

exposure pathways may not be included as part of the chemical prioritization or risk evaluation process, which would result in underestimation of the potential risks to human health and the environment. For example, one industrial chemical that has drawn OW's attention recently is perfluorooctanoic acid (PFOA), which has contaminated surface water and groundwater from manufacturing sites, industrial use, fire/crash training areas, and industrial or municipal waste sites where products are disposed of or applied. Although the 2010/2015 PFOA Stewardship Program has worked toward eliminating PFOA emissions and product content, there are still some ongoing uses of this highly persistent and bioaccumulative chemical. There is also potential PFOA exposure from use on products that are recycled (e.g., carpets). Under the revised prioritization and risk evaluation processes, some important conditions of use (e.g., legacy use, disposal, groundwater contamination) may not be considered, as determined by the Administrator.

OW recommends that OCSPP revise the rule to avoid any suggestion that the agency will not evaluate entire categories of conditions of use such as those described above as well as this blanket statement, which leaves open the possibility for additional exclusions: "As EPA gains experience in conducting risk evaluations, EPA will likely also determine that other activities do not constitute conditions of use, based on the same types of analysis of Congressional intent."

In addition, one of the key criteria for prioritizing and evaluating risk of chemical substances as stated in the Lautenberg Chemical Safety for the 21st Century Act is "…consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of…storage near significant sources of drinking water)..." It is unclear how the chemical storage facilities for specific conditions of use will be identified for prioritization and subsequent exposure assessments. PFOA is an excellent example of why it is important to evaluate all conditions of use of the chemical, including storage facilities, to protect significant sources of surface and drinking water.

If you have any questions, please contact Colleen Flaherty at (202) 564-5939.

cc: Sandy Evalenko, RSC Representative for Water
Nicole Owens, OPEI, RSC Chair
Nathaniel Jutras, OPEI
Peter J. Smith, OCSPP
Susanna Blair, Workgroup Chair
Angela F. Hofmann, Director, OCSPP Regulatory Coordination Staff

From: Celeste, Laurel
Sent: Tuesday, May 30, 2017 5:55 PM
To: Hofmann, Angela <Hofmann.Angela@epa.gov>; Jutras, Nathaniel <Jutras.Nathaniel@epa.gov>; Figueroa, Zaida <Figueroa.Zaida@epa.gov>; Presler, Amos <presler.amos@epa.gov>; Bernota, Carolyn <Bernota.Carolyn@epa.gov>; Strickland, Ann <Strickland.Ann@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Foster, Stiven <Foster.Stiven@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; McQueen, Jacqueline <McQueen.Jacqueline@epa.gov>; Cybulski, Walter <Cybulski.Walter@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Som, Kushal <som.kushal@epa.gov>; Grams, Bradley <grams.bradley@epa.gov>; Williams, Pat <Williams.Pat@epa.gov>; Kerwin, Courtney <Kerwin.Courtney@epa.gov>; Fegley, Robert <Fegley.Robert@epa.gov>; Simons, Andrew <Simons.Andrew@epa.gov>; Corrales, Mark <Corrales.Mark@epa.gov>; Miles-McLean, Stuart <Miles-Mclean.Stuart@epa.gov>; Bartlett, Keith <Bartlett.Keith@epa.gov>; Folkemer, Nathaniel <Folkemer.Nathaniel@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>; Cogliano, Gerain <Cogliano.Gerain@epa.gov>; Noggle, William <Noggle.William@epa.gov>; Evalenko, Sandy <Evalenko.Sandy@epa.gov>; Maldonado, Mayra <maldonado.mayra@epa.gov>; Jencius, Morgan <jencius.morgan@epa.gov>
Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>; Smith, Peterj <Smith.Peterj@epa.gov>; Chun, Melissa <Chun.Melissa@epa.gov>; Green, Teresa <Green.Teresa@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Mottley, Tanya <Mottley.Tanya@epa.gov>; Cunningham-HQ, Barbara <Cunningham-HQ.Barbara@epa.gov>; Blunck, Christopher <Blunck.Chris@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Canavan, Sheila <Canavan.Sheila@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Barone, Stan <Barone.Stan@epa.gov>; Mclean, Kevin <Mclean.Kevin@epa.gov>; Grant, Brian <Grant.Brian@epa.gov>; Owens, Nicole <Owens.Nicole@epa.gov>; Curry, Bridgid <Curry.Bridgid@epa.gov>; Cooperstein, Sharon <Cooperstein.Sharon@epa.gov>; OP ADP Calendar <OP_ADP_Calendar@epa.gov>; OCSPP-RCS <OCSPP-RCS@epa.gov>
Subject: RE: 5/30/17: EXPEDITED Tier 2 Final Agency Review (SAN 5947) - Final Rule: Procedures for Chemical Risk Evaluation under Amended TSCA

Confidential Attorney Client Communication
Do Not Release Under FOIA

OGC concurs with comment on the FAR package for Final Agency Review (SAN 5947) - Final Rule: Procedures for Chemical Risk Evaluation under Amended TSCA.

As we have discussed, we have concerns that several provisions of the final rule – most significantly, the definition of "best available science" -- are vulnerable to challenge on the ground that they differ so greatly from the proposal that they cannot be considered to be the "logical outgrowth" of the proposal and the comments.

We are also concerned that, as currently drafted, the preamble lacks an adequate rationale for a number of final rule provisions that have changed significantly from the proposal. These are identified in the attached redline. We will continue to work with your office while the rule is at OMB to try to

develop better explanations in the preamble or response to comments document, and to overall bolster the defensibility of the package.

Additional comments and edits are contained in the attached files in track changes.

Laurel Celeste
Office of General Counsel
(202) 564-1751

MEMORANDUM

SUBJECT: Final Agency Review-Proposed Rule: Procedures for Chemical Risk Evaluation Pursuant to the Amended TSCA Section 6(b)(4) (Tier 2; SAN 5947; RIN 2070-AK20)

FROM: Gregory Sullivan, Director
Waste and Chemical Enforcement Division
Office of Enforcement and Compliance Assurance

TO: Angela F. Hofmann, Director
Regulatory Coordination Staff
Office of Assistant Administrator
Office of Chemical Safety and Pollution Prevention

The Office of Enforcement and Compliance Assurance (OECA) concurs with comments on the above-referenced Risk Evaluation rule, in which EPA proposes a process to conduct risk evaluations on High Priority chemicals and on chemicals whose evaluation is requested by manufacturers.

Understanding the Administrator's direction to meet the tight statutory deadline established by the amended TSCA to promulgate a final rule by June 22, 2017, we have to the best of our ability conducted an expedited review of the rule. Having had only two working days to review the preamble and rule impacted our ability to fully assess the rule's legal and policy impacts, track the Agency's consideration of certain comments, and understand the Agency's decision to change certain language in the final rule. If there is any extension of time provided as a result of OMB's review process, including questions raised, we request OCSPP reengage the workgroup members to rework any comments or language of the rule. If the rule is changed after FAR, we would like the opportunity to review those changes.

OECA Supports Revisions to Enforcement and Certification Provisions

OECA appreciates OCSPP's incorporation of revisions to 40 C.F.R. § 702.31(d), *see* Final Agency Review Draft: Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (May 25, 2017) ("FAR Draft"), 1707-1715, and the submitter certification statement in § 702.37(b)(6), *id.* 1848-1860, that manufacturers requesting a risk evaluation must sign. The revised provision at 40 C.F.R. § 702.31(d) appropriately preserves TSCA civil remedies by distinguishing the civil standard from the criminal standard. The revised certification statement is a marked improvement that brings this rule in line with the latest Department of Justice guidelines for proving knowing violations.

The Exclusion of Specific Conditions of Use Makes the Rule Challenging to Implement for EPA and Regulated Community

OECA recommends that OCSPP revise the rule to avoid any suggestion that the Agency will not evaluate "legacy" chemical substances, including their continued use and disposal.[1] As currently drafted, the preamble states that the Agency will implement the rule in a way that may exclude certain conditions of use, including the continued use and disposal of "legacy" chemical substances—i.e., those not manufactured on a current/ongoing basis—from risk evaluation. FAR Draft, 293-294, 345-359. At the FAR meeting on May 30, 2017, the Office of General Counsel confirmed that the regulatory text does not prevent the Agency from changing course to evaluate such uses and disposals in future risk evaluations, notwithstanding text in the preamble that justifies a more constrained interpretation. The preamble's exclusionary approach creates uncertainty in the regulated community regarding compliance with TSCA section 6(a) rules promulgated after risk determinations.

For example, chemical substances may, at any given time, be both continuing and "legacy", i.e., have current continuing conditions of use as well as "legacy" conditions of use. In such cases, the exclusionary approach in the preamble creates the potential for the same chemical to be evaluated for disposal (and regulated) for the non-legacy conditions of use but not the legacy conditions of use. In both cases—legacy and non-legacy conditions of use—the same chemical could be used for commercial purposes yet be managed differently even though the exposure and hazard potential is the same and necessitates similar regulatory restrictions. OECA sees two challenges with the exclusionary approach. First, the section 6(a) restrictions would affect some users and disposers, but not those engaged in a legacy condition of use, potentially creating an unequal playing field. Second, companies engaged in processing, distributing, or using a chemical for a non-legacy use would have an incentive to mischaracterize the use so as to evade section 6(a) restrictions, particularly with regard to disposal. This result would undermine the agency's interest in ensuring compliance with these rules and in supporting the purpose/outcomes of OCSPP's risk evaluation.

Risk Determinations Based on Subsets of Conditions of Use Could Cause Federal-State Conflict and Barriers to Compliance

OECA recommends that OCSPP adopt the chemical substance-based approach of the Risk Prioritization rule and remove references in the Risk Evaluation rule to evaluating *single* conditions of use or *subsets* of conditions use. OECA notes that TSCA requires prioritizations and risk determinations to be made for a "chemical substance," not for a limited subset of that substance's conditions of use. 15 U.S.C. §§ 2605(b)(1)(B), 2605(i). If EPA prioritizes an entire chemical substance but subsequently evaluates and makes risk determinations on a subset of the conditions of use, the Agency may create potential regulatory compliance conflicts and uncertainty.

For example, the Risk Prioritization rule requires chemical substance-based prioritizations, but the Risk Evaluation rule will allow subsequent evaluations and determinations for individual conditions of use or subsets of conditions of use to the exclusion of others, including those that were prioritized. *Compare*

[1] OECA shares the concerns voiced by other offices at the May 30, 2017 FAR meeting—including OLEM, OW, and OP—about categorically excluding disposal of legacy chemicals from evaluation. Additionally, OECA recommends that the agency should preserve the newly amended TSCA section 6(a) as a risk management tool for such disposals that are not addressed by RCRA, including substances that are not listed or do not meet the characteristics of hazardous waste under RCRA Subtitle C, and substances whose risk to health or the environment would not be sufficiently minimized by treatment as solid waste under Subtitle D.

Risk Evaluation FAR FR Document, 2009-2024, 40 C.F.R. § 702.41(a)(7) ("In general" EPA will make determinations for "individual" and "categories" of conditions of use rather than for "chemical substances") *with* Risk Prioritization FAR FR Document, 786-788, 40 C.F.R. § 702.1(b) ("EPA will make priority designations . . . for a chemical substance, not for a specific condition or conditions of use of a chemical substance."). The Risk Evaluation rule's use-based approach conflicts with section 6(i) of the statute and may result in a patchwork of overlapping federal and state regulations that Congress sought to avoid in amending TSCA. Federal preemption only applies to those conditions of use included within the scope of risk evaluation. States may regulate conditions of use not considered and thereby increase the compliance burden on regulated entities seeking to determine the applicability of federal and/or state requirements. Similarly, these potential conflicts and the lack regulatory certainty are barriers to efficient and effective compliance monitoring and enforcement programs at both the state and federal levels.

Incorporate Section 8(a) and 8(d) Authorities into the Risk Evaluation Rule.

OECA appreciates that OCSPP requested public comment on utilizing TSCA section 8 authorities in general and continues to recommend directly incorporating section 8 authorities into this rule to ensure relevant manufacturer information is submitted upon EPA's notice of a risk evaluation in the Federal Register. By explicitly incorporating section 8 into this rulemaking, EPA could efficiently obtain needed information and avoid the inevitable delays and resource burdens associated with undertaking separate sections 8(a) or 8(d) rulemakings each time it is necessary to fill information gaps in a risk evaluation. To achieve this, OECA suggests the following modifications:

- Add to the end of the sentence at 40 C.F.R. § 702.31(b) ("Scope") (line 1704): "and in information gathering incident to such risk evaluations pursuant to sections 8(a) and 8(d) of the Toxic Substances Control Act (15 U.S.C. §§ 2607(a), 2607(d))."
- Add to 40 C.F. R. § 702.41(b) ("Information and information sources") a subsection (3) following § 702.41(b)(2) (line 2038): "(3) Pursuant to 15 U.S.C. § 2607(a) and § 2607(d), EPA may require, by notice in the Federal Register, manufacturers with information subject to § 2607(a)(2) and § 2607(d) to submit that information to EPA for use in a risk evaluation."

The Rule Should Replace "Weight of Evidence" in the Regulatory Text and Preamble with the "Weight of Scientific Evidence."

OCSPP has added direct references in the final rule to acknowledge the Agency's commitment to implementing the best available science and weight of the scientific evidence provisions from section 26 of TSCA. Risk Evaluation FAR FR Document, 1769, 2000, 2104, 2132. OECA stresses the importance of referring to the "weight of scientific evidence" rather than the "weight of evidence." The statute requires the "weight of scientific evidence" to guide section 6 decisions, not a broader category that is susceptible to inclusion of non-scientific evidence. 15 U.S.C. § 2625(i).

OECA wishes to recognize the stewardship of this rule by OCSPP's workgroup chair, Susanna Blair. It has been a pleasure for OECA to work with Ms. Blair and with the other staff and managers of OCSSPP.

If you have any questions concerning this memorandum, please contact OECA staff members Amos Presler at (202) 564-1076 and Jessica Goldstein at (202) 564-1493.

United States Senate
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510–6175

August 18, 2017

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dodaro:

The Environmental Protection Agency (EPA) and Council on Environmental Quality (CEQ) use various authorities to hire political appointees. It has come to our attention that the ethics requirements for political appointees vary by the authority under which the appointment was made. Some of the appointees are in high-level positions, managing staff and making consequential decisions, yet they were hired in a manner that exempts them from compliance with Executive Order 13,770: Ethics Commitments by Executive Branch Appointees (otherwise known as the Trump Ethics Pledge). We are additionally concerned that the authorities are being abused and that non-confirmed political appointees may not be complying with the ethics requirements that do apply to them in a timely or complete manner.

For example, EPA is authorized under the Safe Drinking Water Act (SDWA, at 42 U.S.C. § 300j-10) to appoint "not more than thirty scientific, engineering, professional, legal, and administrative positions within the Environmental Protection Agency without regard to the civil service laws." The Office of Government Ethics (OGE) has advised that individuals employed pursuant to this authority are exempted from certain other Executive Branch requirements, including the Trump Ethics Pledge, although they remain subject to other ethics requirements such as 5 CFR Part 2635, Subpart E entitled "Impartiality in Performing Official Duties." In contrast, other political appointees are often hired as Schedule C or non-career Senior Executive Service employees, both of which are subject to Executive Order 13,770 and other ethics requirements such as 5 CFR Part 2635, Subpart E.

EPA has utilized its SDWA authority to hire a number of non-Senate-confirmed political appointees, some of whom are serving in supervisory positions and in roles that raise ethical questions. Various entities, including OGE, Office of Personnel Management, and the Designated Agency Ethics Officials, play differing roles in implementing and overseeing compliance with ethics requirements depending on the authority. When we have made inquiries directed to these entities regarding these matters, we have often been told the specific entity does not handle the particular aspect we asked about and get unclear answers about which entity does.

Our written requests to EPA for specific information regarding political appointees have thus far gone almost entirely unanswered. We write to request that GAO examine the authorities, policies, practices, entities involved, and compliance with applicable ethics requirements that EPA and CEQ have followed in hiring non-confirmed political appointees. Specifically, we request that GAO undertake a review that addresses the following:

- All authorities that can be used to hire political appointees at EPA and CEQ, including the policies and procedures, any background and position requirements and limitations, ethics requirements (including but not limited to compliance with the Trump Ethics Pledge), the agency charged with implementation and oversight of each requirement, and which, if any, civil services laws are permitted to be disregarded.
- Historical and current use of the authorities to employ non-Senate-confirmed political employees, including the types of roles such employees have been hired to perform, the length of service, whether the roles and responsibilities are consistent with the authority and its use during the Obama Administration, and any abuse of the hiring authorities. This should include a review of the initial authority used to hire an appointee.
- For non-Senate-confirmed appointees who are required to comply with the Trump Ethics Pledge, please note at what point following their date of hire or date on which they subsequently became subject to the Pledge because their employment status changed; At what point did they agree to comply, receive a written ethics determination regarding any recusals or other measures they needed to take in order to assure compliance; and, if applicable, at what point a waiver was granted.
- Whether non-Senate-confirmed political appointees who were not subject to Executive Order 13,770 on the date of hire underwent a process to assure their compliance with other applicable ethics regulations. Please detail at what point such a process was completed; at what point they received a written ethical determination regarding any recusals or other measures they needed to take in order to assure compliance; and, if applicable, at what point was a public interest or other determination made regarding their continued work on particular subject matter or participation in certain meetings.
- For any lag time between the date of hire or transition into a position with different ethics requirements and the date that written ethics analysis or recusal agreements are signed, the extent to which retrospective reviews were conducted to ensure appointees did not violate ethics Executive Order 13,770 or other requirements. Further, determine whether non-confirmed political appointees have been found to have worked on subject matter, communicated with outside groups, or participated in certain meetings that were later determined by the Designated Agency Ethics Official or any other entity to require recusals or other measures.

Thank you very much for your consideration of this important matter. If you or members of your staff have any questions or concerns with the contents of this letter, please ask them to contact Michal Freedhoff on the Environment and Public Works Committee staff at 202-224-8832 and Emily Enderle on Senator Whitehouse's staff at 202-224-2921.

Sincerely,

Tom Carper
U.S. Senator

Sheldon Whitehouse
U.S. Senator

OFFICE OF MANAGEMENT AND BUDGET

Proposed Risk Assessment Bulletin

SUMMARY: As part of an ongoing effort to improve the quality, objectivity, utility, and integrity of information disseminated by the federal government to the public, the Office of Management and Budget (OMB), in consultation with the Office of Science and Technology Policy (OSTP), proposes to issue new technical guidance on risk assessments produced by the federal government.

DATES: Interested parties should submit comments to OMB's Office of Information and Regulatory Affairs on or before June 15, 2006.

ADDRESSES: Because of potential delays in OMB's receipt and processing of mail, respondents are strongly encouraged to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic comments may be submitted to: OMB_RAbulletin@omb.eop.gov. Please put the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number and e-mail address in the text of the message. Please be aware that all comments are available for public inspection. Accordingly, please do not submit comments containing trade secrets, confidential or proprietary commercial or financial information, or other information that you do not want to be made available to the public. Comments also may be submitted via facsimile to (202) 395-7245.

FOR FURTHER INFORMATION CONTACT: Dr. Nancy Beck, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, N.W., New Executive Office Building, Room 10201, Washington, DC, 20503. Telephone (202) 395-3093.

SUPPLEMENTARY INFORMATION:

Introduction

Risk assessment is a useful tool for estimating the likelihood and severity of risks to human health, safety and the environment and for informing decisions about how to manage those risks. For the purposes of this Bulletin, the term "risk assessment" refers to a document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment.

The acceptance of risk assessment in health, safety, and environmental policy was enhanced by the seminal report issued by the National Academy of Sciences (NAS) in 1983: *Risk*

Assessment in the Federal Government: Managing the Process. The report presented a logical approach to assessing environmental, health and safety risk that was widely accepted and used by government agencies.

Over twenty years after publication of the NAS report, there is general agreement that the risk assessment process can be improved. The process should be better understood, more transparent and more objective. Risk assessment can be most useful when those who rely on it to inform the risk management process understand its value, nature and limitations, and use it accordingly.

Many studies have supported the use of risk assessment and recommended improvements. For example, in 1993 the Carnegie Commission on Science, Technology, and Government issued "Risk and the Environment: Improving Regulatory Decision-making."[1] In 1994, the NAS issued "Science and Judgment in Risk Assessment" to review and evaluate the risk assessment methods of EPA.[2] In 1995, the Harvard Center for Risk Analysis issued "Reform of Risk Regulation: Achieving More Protection at Less Cost."[3] In 1997, the Presidential/Congressional Commission on Risk Assessment and Risk Management issued "Risk Assessment and Risk Management in Regulatory Decision-Making."[4] A series of NAS reports over the past 10 years have made useful recommendations on specific aspects and applications of risk assessment.[5] The findings in these reports informed the development of this Bulletin.

OMB, in collaboration with OSTP, has a strong interest in the technical quality of agency risk assessments because these assessments play an important role in the development of public policies at the national, international, state and local levels. The increasing importance of risk assessment in the development of public policy, regulation, and decision making requires that the

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[1] Carnegie Commission on Science, Technology and Government, *Risk and the Environment: Improving Regulatory Decision Making*, New York, NY, June 1993.

[2] National Research Council *Science and Judgment in Risk Assessment*, Washington DC: National Academy Press, 1994.

[3] Harvard Group on Risk Management Reform, *Reform of Risk Regulation: Achieving More Protection at Less Cost*, Human and Ecological Risk Assessment, vol. 183, 1995, pp. 183-206.

[4] Presidential/Congressional Commission on Risk Assessment and Risk Management, Vol. 2, *Risk Assessment and Risk Management in Regulatory Decision-Making,* hereinafter "*Risk Commission Report*," 1997.

[5] See, e.g., National Research Council, *Health Implications of Perchlorate Ingestion,*, Washington DC: National Academy Press, 2005; National Research Council, *Arsenic in Drinking Water 2001 Update*, Washington DC: National Academy Press, 2001; National Research Council, *Toxicological Effects of Methylmercury*, Washington DC: National Academy Press, 2000; National Research Council, *Health Effects of Exposure to Radon, BEIR VI*, Washington DC: National Academy Press, 1999; National Research Council, *Science and the Endangered Species Act*, Washington, DC: National Academy Press, 1995; National Research Council, *Science and Judgment in Risk Assessment*, Washington DC: National Academy Press, 1994; National Research Council, *Issues in Risk Assessment I: Use of the Maximum Tolerated Dose in Animal Bioassays for Carcinogenicity*, Washington DC: National Academy Press, 1993; National Research Council, *Issues in Risk Assessment II: The Two Stage Model of Carcinogenesis*, Washington DC: National Academy Press, 1993; National Research Council, *Issues in Risk Assessment III: A Paradigm for Ecological Risk Assessment*, Washington DC: National Academy Press, 1993; National Research Council, *Pesticides in the Diet of Infants and Children*, Washington DC: National Academy Press, 1993; National Academy of Engineering, *Keeping Pace with Science and Engineering: Case Studies in Environmental Regulation*, Washington DC: National Academy Press, 1993; National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, Washington DC: National Academy Press, 1983.

technical quality and transparency of agency risk assessments meet high quality standards. Moreover, a risk assessment prepared by one federal agency may inform the policy decisions of another federal agency, or a risk assessment prepared by one or more federal agencies may inform decisions made by legislators or the judiciary. This Bulletin builds upon the historic interest that both OMB and OSTP have expressed in advancing the state of the art of risk assessment.[6]

The purpose of this Bulletin is to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards. Federal agencies should implement the technical guidance provided in this Bulletin, recognizing that the purposes and types of risk assessments vary. The Bulletin builds on OMB's Information Quality Guidelines and Information Quality Bulletin on Peer Review and is intended as a companion to OMB Circular A-4 (2003), which was designed to enhance the technical quality of regulatory impact analyses, especially benefit-cost analysis and cost-effectiveness analysis. Like OMB Circular A-4, this Bulletin will need to be updated periodically as agency practices and the peer-reviewed literature on risk assessment progress.

The audience for the Bulletin includes analysts and managers in federal agencies with responsibilities for assessing and managing risk or conducting research on improved approaches to risk assessment. The Bulletin should also be of interest to the broad range of specialists in the private and public sectors involved in or affected by risk assessments and/or decisions about risk and safety.

Although this Bulletin addresses certain technical aspects of risk assessment, it does not address in any detail the important processes of risk management and risk communication.[7] The technical guidance provided here addresses the development of the underlying documents that may help inform risk management and communication, but the scope of this document does not encompass how federal agencies should manage or communicate risk.

Uses of Risk Assessments

Risk assessment is used for many purposes by the Federal Government. At a broad level, risk assessments can be used for priority setting, managing risk, and informing the public and other audiences. The purpose of the assessment may influence the scope of the analytic work, the type of data collected, the choice of analytic methods, and the approach taken to reporting the findings. Accordingly, the purpose of an assessment should be made clear before the analytical work begins.

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[6] See U.S. Office of Science and Technology Policy, *Chemical Carcinogens: A Review of the Science and Its Associated Principles*, 50 FR10371 (1985); and, U.S. Office of Management and Budget, Memorandum for the Regulatory Working Group, *Principles for Risk Analysis,* Jan 12, 1995.

[7] National Research Council *Understanding Risk: Informing Decisions in a Democratic Society*, Washington DC: National Academy Press, 1996; Risk Commission Report, Volume 2, 1997; National Research Council, *Improving Risk Communication,* Washington DC: National Academy Press, 1989.

Priority Setting

Risk assessment is sometimes used as a tool to compare risks for priority-setting purposes.[8] For example, in 1975 the Department of Transportation prepared a comparative assessment of traffic safety hazards related to highway and vehicle design as well as driver behavior.[9] A wide range of countermeasures were compared to determine which measures would be most effective in saving lives and reducing injuries. Similarly, risk assessment models relating to food safety and agricultural health concerns may be used to rank relative risks from different hazards, diseases, or pests. In 1987 and again in 1990, the Environmental Protection Agency (EPA) prepared a comparative assessment of environmental hazards – both risks to human health and the environment – to inform the Agency's priority setting.[10] This work demonstrated that the environmental risks of greatest concern to the public often were not ranked as the greatest risks by agency managers and scientists.

Screening-level risk assessments are sometimes used as a first step in priority setting. The purpose of the "screen" is to determine, using conservative (or worst-case) assumptions, whether a risk could exist, and whether the risk could be sufficiently serious to justify agency action. If the screening-level assessment indicates that a potential hazard is not of concern, the agency may decide not to undertake a more comprehensive assessment. If the screening-level assessment indicates that the potential hazard may be of concern, then the agency may proceed to undertake a more comprehensive assessment to estimate the risk more accurately.[11]

Informing Risk Management Decisions

Often, a risk assessment is conducted to help determine whether to reduce risk and, if so, to establish the appropriate level of stringency. A wide set of standards derived from statutes, regulations, and/or case law guide regulatory agencies in making risk management decisions. In such situations, the risk management standard is known a priori based on "acceptable risk" considerations.[12]

Risk assessments may be used to look at risk reduction under various policy alternatives to determine if these alternatives are effective in reducing risks. In some agency programs, the

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[8] Davies, J. C. (ed), *Comparing Environmental Risks: Tools for Setting Government Priorities*, Resources for the Future, Washington, DC, 1996; Minard, R, *State Comparative Risk Projects: A Force for Change*, Northeast Center for Comparative Risk, South Royalton, Vermont, March 1993.

[9] U.S. Department of Transportation, *National Highway Safety Needs Report*, Washington, DC, April 1976.

[10] U.S. Environmental Protection Agency, *Unfinished Business: A Comparative Assessment of Environmental Protection*, Washington, DC, 1987; U.S. Environmental Protection Agency, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, Science Advisory Board, Washington, DC, 1990.

[11] National Research Council, *Science and Judgment in Risk Assessment*, Washington DC: National Academy Press, 1994.

[12] Douglas, M, *Risk Acceptability According to the Social Sciences*, Russell Sage Foundation, New York, NY, 1985; Fischhoff, B, S Lichtenstein, P Slovic, SL Derby, RL Keeney, *Acceptable Risk*, Cambridge University Press, UK, 1981.

results of risk assessments are an important technical input to benefit-cost analyses, which are then used to inform risk management decisions in rulemakings.[13]

Informing the Public

In some circumstances, risk assessments are undertaken to inform the public through education and informational programs.[14] Such programs can help citizens make informed decisions in their personal lives. For example, Federal agencies alert the public about the risks of living in a home with elevated levels of radon gas, of purchasing a sport utility vehicle with a certain height-to-width ratio, and taking long-term estrogen therapy. The dissemination of public risk information, even if it is not accompanied by a regulation, can induce changes in the behavior of consumers, patients, workers, and businesses.

Sometimes, Federal agencies undertake large-scale risk assessments that are designed to inform multiple audiences. For example, the Surgeon General's Report on Smoking and Health has, over the years, contained a wide variety of health risk estimates. These estimates have been adopted in programs and documents disseminated by local and state governments, Federal agencies, private companies, and the public at large. In some cases, Federal scientists participate in an international effort to develop risk models that can be used to educate the public and inform decisions throughout the world.[15]

Types of Risk Assessments

Risk assessment is a broad term that encompasses a variety of analytic techniques that are used in different situations, depending upon the nature of the hazard, the available data, and needs of decision makers.[16] The different techniques were developed by specialists from many disciplines, including toxicology, epidemiology, medicine, chemistry, biology, engineering, physics, statistics, management science, economics and the social sciences. Most risk assessments are performed by teams of specialists representing multiple disciplines. They are often prepared by government scientists or contractors to the government.

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[13] Breyer, S., *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Harvard University Press, Cambridge, MA 1993; Hahn, RW (ed), *Risks, Costs and Lives Saved: Getting Better Results from Regulation*, Oxford University Press, New York, NY, 1996; Viscusi, WK, *Rational Risk Policy*, Clarendon Press, Oxford, UK, 1998; National Research Council, *Valuing Health Risks, Costs, and Benefits for Environmental Decisionmaking*, Washington, DC: National Academy Press, 1990.

[14] Fischhoff, B, S Lichtenstein, P Slovic, SL Derby, RL Keeney, *Acceptable Risk*, Cambridge University Press, UK, 1981; Douglas, M, *Risk Acceptability According to the Social Sciences*, Russell Sage Foundation, New York, NY, 1985; Wilson, R, EAC Crouch, *Risk-Benefit Analysis*, Harvard University Press, Cambridge, MA, 2001.

[15] Renn, O, *White Paper on Risk Governance: Towards an Integrative Approach*, International Risk Governance Council, Geneva, Switzerland, September 2005.

[16] Haimes, YY, *Risk Modeling, Assessment, and Management*, John Wiley and Sons, New York, New York, 1998; Wilson, R, EAC Crouch, *Risk-Benefit Analysis*, Harvard University Press, Cambridge, MA, 2001.

Actuarial Analysis of Real-World Human Data

When large amounts of historic data from humans are available, an actuarial risk assessment may be performed using classical statistical tools. For example, the safety risks associated with use of motor vehicles, including the risks of a vehicle's design features, may be estimated by applying statistical tools to historic data on crashes, injuries and/or fatalities. When sufficient numbers of people have been exposed to large doses of chemicals and radiation, it may be feasible to estimate risks using health data and statistical methods. The field of epidemiology, a branch of public health and medicine, performs such assessments by combining actuarial analyses with biologic theory and medical expertise.[17] The field of radiation risk assessment has been informed by epidemiology, including studies of the World War II bombings at Hiroshima and Nagasaki and more recently the experiences of workers who were exposed to radiation on the job. Estimates of the health risks of tobacco products have been generated primarily on the basis of epidemiology.

Dose-Response Analysis Using Experimental Data

Special techniques of risk assessment have been developed for settings where humans and/or animals are exposed – intermittently or continuously – to various doses of substances.[18] The adverse effects of concern may range from different types of cancer to developmental, reproductive or neurological effects. Real-world data on adverse effects in humans or wildlife may not be available because (a) adequate data have not been collected, (b) the adverse effects (e.g., certain types of leukemia) are too rare to analyze directly, (c) the exposures of concern are associated with a new technology or product, or (d) adverse effects may occur only after a long period (e.g., several decades) of exposure.

When direct real-world data on toxicity are unavailable or are inadequate, risk assessments may be performed based on data from toxicity experiments with rodents, since rats and mice have relatively short lifetimes and are relatively inexpensive to house and feed. Toxicity experiments involving rodents, although controversial to some, have three important advantages: (1) the doses, whether administered by injection, in feed or by inhalation, can be measured precisely, (2) different doses can be applied to different groups of rodents by experimental design, and (3) pathology can be performed on rodents to make precise counts of tumors and other adverse events.

When dose-response data are available from a rodent experiment, the assessor usually faces two critical extrapolation issues: how effects observed in rodents are relevant to people or wildlife and how effects observed at the high doses used in experiments are relevant to the low doses typically found in the environment. Techniques have been developed to perform such extrapolations and to portray the resulting uncertainty in risk estimates associated with extrapolation.

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[17] Monson, R, *Occupational Epidemiology, Second Edition*, CRC Press, Boca Raton, Florida, 1990.
[18] Rodricks, JV, *Calculated Risks: The Toxicity and Human Health Risks of Chemicals in Our Environment*, Cambridge, University Press, New York, NY, 1992.

Infectious Disease and Epidemic Modeling

Risk assessments of infectious agents pose special challenges since the rate of diffusion of an infectious agent may play a critical role in determining the occurrence and severity of an epidemic. Risk assessments of the spread of the HIV virus, and the resulting cases of AIDs, were complicated by the different modes of transmission (e.g., sexual behavior, needle exchange and blood transfusion) and the analyst's need to understand the relative size and degree of mixing of these populations.[19] Scientific understanding of both biology and human behavior are critical to performing accurate risk assessments for infectious agents.

Failure Analysis of Physical Structures

One of the best known types of risk assessments addresses low-probability, high-consequence events associated with the failure of physical structures.[20] Since these events are exceedingly rare (e.g., bridge failure or a major core meltdown at a nuclear reactor), it may not be feasible to compute risks based on historic data alone. Engineers have developed alternative techniques (e.g., fault-tree analysis) that estimate both the probability of catastrophic events and the magnitude of the resulting damages to people, property and the environment. Such "probabilistic" risk assessments are now widely used in the development of safety systems for dams, nuclear and chemical plants, liquefied natural gas terminals, space shuttles and other physical structures.

Legal Authority

This Bulletin is issued under statutory authority and OMB's general authorities to oversee the quality of agency analyses, information and regulatory actions.

In the "Information Quality Act," Congress directed OMB to issue guidelines to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information" disseminated by Federal agencies. Pub. L. No. 106-554, § 515(a). The Information Quality Act was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., which requires OMB, among other things, to "develop and oversee the implementation of policies, principles, standards, and guidelines to . . . apply to Federal agency dissemination of public information." Moreover, Section 624 of the Treasury and General Government Appropriations Act of 2001, often called the "Regulatory Right-to-Know Act," (Public Law 106-554, 31 U.S.C. § 1105 note) directs OMB to "issue guidelines to agencies to standardize . . . measures of costs and benefits" of Federal rules.

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[19] Turner, CF., et al., *AIDS: Sexual Behavior and Intravenous Drug Use*, National Research Council, Washington, D.C., 1989, pp. 471-499.

[20] Pate-Cornell, ME, *Uncertainties in Risk Analysis: Six Levels of Treatment*, Reliability Engineering and System Safety, vol. 54(2-3), 1996, pp. 95-111; Haimes, YY, *Risk Modeling, Assessment, and Management*, John Wiley and Sons, New York, New York, 1998.

Executive Order 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), establishes that OIRA is "the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency," and it directs OMB to provide guidance to the agencies on regulatory planning. E.O. 12866, § 2(b). The Order requires that "[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information." E.O. 12866, § 1(b)(7). The Order also directs that "[i]n setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of risks posed by various substances or activities within its jurisdiction." E.O. 12866, § 1(b)(4). Finally, OMB has additional authorities to oversee the agencies in the administration of their programs.

All of these authorities support this Bulletin.

The Requirements of This Bulletin

This bulletin addresses quality standards for risk assessments disseminated by federal agencies.

Section I: Definitions

Section I provides definitions that are central to this Bulletin. Several terms are identical to or based on those used in OMB's government-wide information quality guidelines, 67 Fed. Reg. 8452 (Feb. 22, 2002), and the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq.

The term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA).

The term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. § 3502(1).

The term "Information Quality Act" means Section 515 of Public Law 106-554 (Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000)).

The term "risk assessment" means a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment. For the purposes of this Bulletin, this definition applies to documents that could be used for risk assessment purposes, such as an exposure or hazard assessment that might not constitute a complete risk assessment as defined by the National Research Council.[21] This definition includes documents that evaluate baseline risk as well as risk mitigation activities.

[21] National Research Council *Risk Assessment in the Federal Government: Managing the Process*, Washington DC: National Academy Press, 1983.

The term “influential risk assessment” means a risk assessment the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. The term "influential" should be interpreted consistently with OMB's government-wide Information Quality Guidelines and the Information Quality Guidelines of the relevant agency. A risk assessment can have a significant economic impact even if it is not part of a rulemaking. For instance, the economic viability of a technology can be influenced by the government’s characterization of the risks associated with the use of the technology. Alternatively, the federal government's assessment of risk can directly or indirectly influence the regulatory actions of state and local agencies or international bodies.

Examples of “influential risk assessments” include, but are not limited to, assessments that determine the level of risk regarding health (such as reference doses, reference concentrations, and minimal risk levels), safety and environment. Documents that address some but not all aspects of risk assessment are covered by this Bulletin. Specific examples of such risk assessments include: margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments which support EPA National Ambient Air Quality Standards, FDA tolerance values, ATSDR toxicological profiles, HHS/NTP substance profiles, NIOSH current intelligence bulletins and criteria documents, and risk assessments performed as part of economically significant rulemakings. Documents falling within these categories are presumed to be influential for the purposes of this Bulletin.

The term “available to the public” covers documents that are made available to the public by the agency or that are required to be disclosed under the Freedom of Information Act, 5 U.S.C. § 552.

Section II: Applicability

Section II states that, *to the extent appropriate*, all publicly available agency risk assessments shall comply with the standards of this Bulletin. This statement recognizes that there may be situations in which it is not appropriate for a particular risk assessment to comport with one or more specific standards contained in this Bulletin, including the general standards in Section IV, which apply to both influential and non-influential risk assessments. A rule of reason should prevail in the appropriate application of the standards in this Bulletin. For example, in a screening-level risk assessment, the analyst may be seeking to define an upper limit on the unknown risk that is not likely to be exceeded. Screening-level assessments, in this situation, would not have to meet the standard of “neither minimizing nor exaggerating the nature and magnitude of risk.” On the other hand, it is expected that every risk assessment (even screening-level assessments) will comply with other standards in Section IV. For example, it is expected that every risk assessment shall describe the data, methods, and assumptions with a high degree of transparency; shall identify key scientific limitations and uncertainties; and shall place the risk in perspective/context with other risks familiar to the target audience. Similarly, every quantitative risk assessment should provide a range of plausible risk estimates, when there is scientific uncertainty or variability.

This Bulletin does not apply to risk assessments that arise in the course of individual agency adjudications or permit proceedings, unless the agency determines that: (1) compliance with the Bulletin is practical and appropriate and (2) the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities. This Bulletin also shall not apply to risk assessments performed with respect to inspections relating to health, safety, or environment.

This Bulletin also does not apply to any risk assessment performed with respect to an individual product label, or any risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use. An example of this type of risk assessment includes risk assessments performed for labeling of individual pharmaceutical products. This Bulletin does apply to risk assessments performed with respect to classes of products. An example of this type of risk assessment is the risk assessment performed by FDA in their evaluation of the labeling for products containing trans-fatty acids.

Section III: Goals

For each covered risk assessment, this Bulletin lays out five aspirational goals.

1. Goals Related to Problem Formulation

As a risk assessment is prepared, risk assessors should engage in an iterative dialogue with the agency decision maker(s) who will use the assessment. There will be many choices regarding the objectives, scope, and content of the assessment, and an iterative dialogue will help ensure that the risk assessment serves its intended purpose and is developed in a cost-effective manner. For example, a risk manager may be interested in estimates of population and/or individual risk and an iterative dialogue would ideally bring this to the attention of a risk assessor early in the process.

2. Goals Related to Completeness

There is often a tension between the desire for completeness in the scientific sense and the desire for a well-defined scope that limits the inquiry to a set of practical, tractable, and relevant questions. The scope of an assessment should reflect a balance between the desire for scientific completeness and the need to provide relevant information to decision makers. The concept of considering the benefits and cost of acquiring further information (e.g., a broader scope or better data on a more narrow scope) is presented in the OMB Information Quality Guidelines, the OMB Information Quality Bulletin for Peer Review, and OMB Circular A-4.[22]

[22] US Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 FR 8452-8460 Feb. 22, 2002; US Office of Management and Budget, *Final Information Quality Bulletin for Peer Review*, 70 FR 2664-2677, Jan 14, 2005; and

3. Goals Related to Effort Expended

The level of effort should be commensurate with the importance of the risk assessment, taking into consideration the nature of the potential hazard, the available data, and the decision needs. For instance, if an agency is only interested in a screening-level assessment, then an assessment which explores alternative dose-response models may not be warranted.

4. Goals Related to Resources Expended

Agencies should take into account the importance of the risk assessment in gauging the resources, including time and money, required to meet the requirements of this Bulletin.[23]

5. Goals Related to Peer Review and Public Participation

Agencies should consider appropriate procedures for peer review and public participation in the process of preparing the risk assessment. When a draft assessment is made publicly available for comment or peer review, the agency is required to clarify that the report does not represent the official views of the federal government. Precise disclaimer language is recommended in OMB's Information Quality Bulletin on Peer Review. Public comments can play an important role in helping to inform agency deliberations.[24] When people are engaged early in the process, the public typically has an easier time concurring with government documents and decisions which may affect them.[25]

Section IV: General Risk Assessment and Reporting Standards

Each risk assessment disseminated by a Federal agency is subject to OMB's Information Quality Guidelines and the agency's Information Quality Guidelines. These guidelines require risk assessments to meet the three key attributes of utility, objectivity, and integrity.

US Office of Management and Budget, *Circular A-4*, Sept 2003 available at: http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.

[23] See Risk Commission Report, Vol. 2, at 63 ("Deciding to go forward with a risk assessment is a risk management decision, and scaling the effort to the importance of the problem, with respect to scientific issues and regulatory impact, is crucial."); id., at 21 ("The level of detail considered in a risk assessment and included in the risk characterization should be commensurate with the problem's importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures."), 1997.

[24] Risk Commission Report, Vol. 2, at 21 ("Stakeholders play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns that they would like to see addressed." id., at 185, 1997.

[25] National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*, Washington DC: National Academy Press, 1996.

This Bulletin identifies six standards that apply to both influential and non-influential risk assessments. An additional seventh standard is also presented for risk assessments that are likely to be used in regulatory analysis.

1. Standards Relating to Informational Needs and Objectives

A risk assessment should clearly state the informational needs driving the assessment as well as the objectives of the assessment. This simple requirement will ensure that readers and users are able to understand the questions the assessment sought to answer and will help to ensure that risk assessments are used for their intended purposes. This is particularly important in cases where likely users of the risk assessment are not the original intended audience for the document. For example, an explicit statement of the ranges of chemical doses for which the assessment is relevant will inform other users as to whether or not the assessment is relevant their purposes.

2. Standards Relating to Scope

Every risk assessment should clearly summarize the scope of the assessment. The statement of scope may necessitate policy judgments made by accountable policy officials and managers as well as analysts. The scope of some assessments may be highly discretionary while others may be rigidly determined or influenced by statutory requirements, court deadlines or scarcity of available agency resources. In cases where the scope of an assessment has been restricted primarily due to external considerations beyond the agency's control, policy makers and other participants in the process should be made aware of those complicating circumstances and the technical limitations they have introduced in the agency's work product.

To begin framing the scope of a risk assessment, the first step should be to specify and describe the agent, technology and/or activity that is the subject of the assessment. The next step entails describing the hazard of concern. In order for an assessment to be complete, the assessment must address all of the factors within the intended scope of the assessment. For example, a risk assessment informing a general regulatory decision as to whether exposure to a chemical should be reduced would not be constrained to a one-disease process (e.g., cancer) when valid and relevant information about other disease processes (e.g., neurological effects or reproductive effects) are of importance to decision making.

The third step in framing the scope of the assessment entails identifying the affected entities. Affected entities can include populations, subpopulations, individuals, natural resources, animals, plants or other entities. If a risk assessment is to address only specific subpopulations, the scope should be very clear about this limitation. An analytic product may be incomplete when it addresses only risks to adults when there is information suggesting that children are more exposed and/or more susceptible to adverse effects than are adults.

Once the affected entities are defined, the assessment should define the exposure or event scenarios relevant to the purpose of the assessment as well as the type of event-consequence or dose-response relationship for the exposure or event ranges that are relevant to the objectives of the risk assessment. Although scientific completeness may entail analysis of different health

effects and multiple target populations, the search for completeness will vary depending upon the nature of the assessment. In a fault-tree analysis of nuclear power accidents, an aspect of completeness may be whether pathways to accidents based on errors in human behavior have been addressed as well as pathways to accidents based on defects in engineering design or physical processes.

When agencies ask whether a particular chemical or technology causes or contributes to a particular disease, completeness in a scientific sense may entail consideration of evidence regarding the causative role of other factors in producing the disease of interest. For example, an assessment of radon exposure and lung cancer may need to consider the role of cigarette smoking as a potential confounding factor that influences the estimated risk of radon. Alternatively, the evidence on smoking may suggest that the risks of radon are larger for smokers than non-smokers, a so-called risk-modifying or synergistic factor. The scientific process of considering confounding and/or synergistic factors may assist policy makers in developing a broader sense of how risk can be reduced significantly and the range of decision options that need to be considered if maximum risk reduction is to be achieved.

3. Standards Related to Characterization of Risk

Every risk assessment should provide a characterization of risk, qualitatively and, whenever possible, quantitatively.[26] When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided.[27] Expressing multiple estimates of risk (and the limitations associated with these estimates) is necessary in order to convey the precision associated with these estimates.

In the 1996 amendments to the Safe Drinking Water Act (SDWA), Congress adopted a basic quality standard for the dissemination of public information about risks of adverse health effects. Under 42 U.S.C. 300g– 1(b)(3)(B), the agency is directed ''to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable.'' The agency is further directed ''in a document made available to the public in support of a regulation [to] specify, to the extent practicable— (i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and

[26] National Research Council, *Science and Judgment in Risk Assessment*, at 185, ("EPA should make uncertainties explicit and present them as accurately and fully as feasible and needed for risk management decision-making. To the greatest extent feasible, EPA should present quantitative, as opposed to qualitative, representations of uncertainty."), Washington DC: National Academy Press, 1994.

[27] See Carnegie Commission on Science, Technology and Government, *Risk and the Environment: Improving Regulatory Decision Making*, New York, NY, June 1993, at 87 ("Regulatory agencies should report a range of risk estimates when assessing risk and communicating it to the public. How risk estimates, whether derived from an inventory or not, are conveyed to the public significantly affects the way citizens perceive those risks. Single-value risk estimates reported to the public do not provide an indication of the degree of uncertainty associated with the estimate. Such numbers do not convey the conservative nature of some risk estimates.").

the methodology used to reconcile inconsistencies in the scientific data.'' These SDWA quality standards should be met, where feasible, in all risk assessments which address adverse health effects.

4. Standards Related to Objectivity

Risk assessments must be scientifically objective, neither minimizing nor exaggerating the nature and magnitude of the risks. On a substantive level, objectivity ensures accurate, reliable and unbiased information. When determining whether a potential hazard exists, weight should be given to both positive and negative studies, in light of each study's technical quality. The original and supporting data for the risk assessment must be generated, and the analytical results developed, using sound statistical and research methods.

Beyond the basic objectivity standards, risk assessments subject to this Bulletin should use the best available data and should be based on the weight of the available scientific evidence.[28] The requirement for using the best available scientific evidence was applied by Congress to risk information used and disseminated pursuant to the SDWA Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A)&(B)). Under 42 U.S.C. 300g–1(b)(3)(A), an agency is directed ''to the degree that an agency action is based on science,'' to use ''(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).'' Agencies have adopted or adapted this SDWA standard in their Information Quality Guidelines for risk assessments which analyze risks to human health, safety, and the environment. We are similarly requiring this as a general standard for all risk assessments subject to this Bulletin.

In addition to meeting substantive objectivity standards, risk assessments must be accurate, clear, complete and unbiased in the presentation of information about risk. The information must be presented in proper context. The agency also must identify the sources of the underlying information (consistent with confidentiality protections) and the supporting data and models, so that the public can judge for itself whether there may be some reason to question objectivity. Data should be accurately documented, and error sources affecting data quality should be identified and disclosed to users.

A risk assessment report should also have a high degree of transparency with respect to data, assumptions, and methods that have been considered. Transparency will increase the credibility

[28] Risk Commission Report, Vol. 1, at 38 ("Because so many judgments must be based on limited information, it is critical that all reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.") The Risk Commission Report provides examples of the kinds of considerations entailed in making judgments on the basis of the weight of the scientific evidence in a toxicity study: quality of the toxicity study; appropriateness of the toxicity study methods; consistency of results across studies; biological plausibility of statistical associations; and similarity of results to responses and effects in humans. Vol. 2 at 20,1997.

of the risk assessment, and will allow interested individuals, internal and external to the agency, to understand better the technical basis of the assessment.

5. Standards Related to Critical Assumptions

Risk assessments should explain the basis of each critical assumption and those assumptions which affect the key findings of the risk assessment. If the assumption is supported by, or conflicts with, empirical data, that information should be discussed. This should include discussion of the range of scientific opinions regarding the likelihood of plausible alternate assumptions and the direction and magnitude of any resulting changes that might arise in the assessment due to changes in key assumptions. Whenever possible, a quantitative evaluation of reasonable alternative assumptions should be provided. If an assessment combines multiple assumptions, the basis and rationale for combining the assumptions should be clearly explained.

6. Standards Related to the Executive Summary

Every risk assessment should contain an executive summary which discloses the objectives and scope, the key findings of the assessment, and the key scientific limitations and uncertainties in the risk assessment. Presentation of this information in a helpful and concise introductory section of the report will not only foster improved communication of the findings, but will also help ensure that the risk assessment is appropriately utilized by diverse end users. Major limitations are those that are most likely to affect significantly the determinations and/or estimates of risk presented in the assessment.

The executive summary should also place the estimates of risk in context/perspective with other risks familiar to the target audience. Due care must be taken in making risk comparisons. Agencies might want to consult the risk communication literature when considering appropriate comparisons. Although the risk assessor has considerable latitude in making risk comparisons, the fundamental point is that risk should be placed in a context that is useful and relevant for the intended audience.[29]

7. Standards Related to Regulatory Analysis

When a risk assessment is being produced to support or aid decision making related to regulatory analysis, there are additional standards that should be met. Risk assessors should consult OMB Circular A-4, which addresses requirements designed to improve the quality of regulatory impact analyses. For major rules involving annual economic effects of $1 billion or more, a formal quantitative analysis of the relevant uncertainties about benefits and costs is required.[30] In this Bulletin, we highlight important aspects of risk assessments useful for regulatory analysis:

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[29] National Research Council, *Improving Risk Communication*, Washington DC: National Academy Press, 1989, at 165-79; see also Risk Commission Report, Volume 1, at 4, One of the key recommendations of the Risk Commission Report was that the problems a regulation is intended to address should be placed in their "public health and ecological context.", 1997.

[30] US Office of Management and Budget, *Circular A-4*, Sept, 2003, available at: http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.

1) The scope of the risk assessment should include evaluation of alternative options, clearly establishing the baseline risk analysis and the risk reduction alternatives that will be evaluated. When relevant, knowledge of the hazard and anticipated countermeasures should be understood in order to accurately capture the baseline risk.

2) The risk assessment should include a comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered, and describe, to the extent feasible, any significant countervailing risks caused by alternative mitigation measures.[31]

3) The risk assessment should include information on the timing of exposure and the onset of the adverse effect(s) as well as the timing of control measures and the reduction or cessation of adverse effects.

4) When estimates of individual risk are developed, estimates of population risk should also be developed. Estimates of population risk are necessary to compare the overall costs and benefits of regulatory alternatives.

5) When a quantitative characterization of risk is made available, this should include a range of plausible risk estimates, including central estimates. A "central estimate" of risk is the mean or average of the distribution; or a number which contains multiple estimates of risk based on different assumptions, weighted by their relative plausibility; or any estimate judged to be most representative of the distribution.[32] The central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk.[33]

Section V: Special Standards for Influential Risk Assessments

In addition to the standards presented in section IV, all influential risk assessments should meet certain additional standards. When it is not appropriate for an influential risk assessment to adhere to one or more of the standards in this section of the Bulletin, the risk assessment should contain a rationale explaining why the standard(s) was (were) not met.

1. Standard for Reproducibility

Influential risk assessments should be capable of being substantially reproduced. As described in the OMB Information Quality Guidelines, this means that independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of precision. Public access to original data is necessary to satisfy

[31] Graham, J.D., Jonathan B. Wiener (eds), *Risk Versus Risk: Tradeoffs in Protecting Health and the Environment*, Harvard University Press, Cambridge, MA, 1995.
[32] See, e.g., Holloway, CA, *Decision Making Under Uncertainty: Models and Choices* (1979), at 76, 214, 91-127 Theodore Colton, *Statistics in Medicine* (1974), at 28-31.
[33] National Research Council, *Science and Judgment in Risk Assessment*, at 170-75, Washington DC: National Academy Press, 1994.

this standard, though such access should respect confidentiality and other compelling considerations.[34] It is not necessary that the results of the risk assessment be reproduced. Rather, someone with the appropriate expertise should be able to substantially reproduce the results of the risk assessment, given the underlying data and a transparent description of the assumptions and methodology.

2. Standard for Comparison to Other Results

By definition, influential risk assessments have a significant impact. In such situations, it is appropriate for an agency to find and examine previously conducted risk assessments on the same topic, and compare these risk assessments to the agency risk assessment. A discussion of this comparison should be incorporated into the risk assessment.

3. Standard for Presentation of Numerical Estimates

When there is uncertainty in estimates of risk, presentation of single estimates of risk is misleading and provides a false sense of precision. Presenting the range of plausible risk estimates, along with a central estimate, conveys a more objective characterization of the magnitude of the risks. Influential risk assessments should characterize uncertainty by highlighting central estimates as well high-end and low-end estimates of risk. The practice of highlighting only high-end or only low-end estimates of risk is discouraged.

This Bulletin uses the terms "central" and "expected" estimate synonymously. When the model used by assessors is well established, the central or expected estimate may be computed using standard statistical tools. When model uncertainty is substantial, the central or expected estimate may be a weighted average of results from alternative models. Formal probability assessments supplied by qualified experts can help assessors obtain central or expected estimates of risk in the face of model uncertainty.[35]

4. Standard for Characterizing Uncertainty

Influential risk assessments should characterize uncertainty with a sensitivity analysis and, where feasible, through use of a numeric distribution (e.g., likelihood distribution of risk for a given individual, exposure/event scenario, population, or subpopulation). Where appropriate,

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[34] See US Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 FR 8456, ("However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections. '') Feb. 22, 2002.

[35] National Research Council, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, Washington, DC: National Academies Press, 2002; Cooke, RM, *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press, New York, NY, 1991; Evans, JS, JD Graham, GM Gray, RL Sielken, *A Distributional Approach to Characterizing Low-Dose Cancer Risk*, Risk Analysis, vol. 14(1), 1994, pp. 25-34; Hoffman, O, S Kaplan, *Beyond the Domain of Direct Observation: How to Specify a Probability Distribution that Represents the State-of-the-Knowledge About Uncertain Inputs*, Risk Analysis, vol. 19(1), 1999, pp. 131-134; Morgan, MG, M Henrion, M Small, Uncertainty: *A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, Cambridge, UK, 1990.

this should include sufficient description so that the lower and upper percentiles and the median, mean, mode, and shape of the uncertainty distribution are apparent.

When one or more assumptions are used in a risk assessment, the assessor may evaluate how plausible changes in the assumptions influence the results of the assessment. An assumption may be used for a variety of reasons (e.g., to address a data gap or to justify the selection of a specific model or statistical procedure). Professional judgment is required to determine what range of assumptions is plausible enough to justify inclusion in the sensitivity analysis. Sensitivity analysis is particularly useful in pinpointing which assumptions are appropriate candidates for additional data collection to narrow the degree of uncertainty in the results. Sensitivity analysis is generally considered a minimum, necessary component of a quality risk assessment report.

A model is a mathematical representation -- usually a simplified one -- of reality. Where a risk can be plausibly characterized by alternative models, the difference between the results of the alternative models is model uncertainty. For example, when cancer risks observed at high doses of chemical exposure are extrapolated to low doses (i.e., doses below the range of empirical detection of cancer risk), a dose-response model must be employed to compute low-dose risks. Biological knowledge may be inadequate to predict the shape of the dose-response curve for cancer in the low-dose region. While it is common for risk assessors to use a model where cancer risk is proportional to dose (even at low doses), there are cases where it has been demonstrated, through huge epidemiological studies or detailed biologic data from the laboratory, that a non-linear dose-response shape is appropriate. When risk assessors face model uncertainty, they need to document and disclose the nature and degree of model uncertainty. This can be done by performing multiple assessments with different models and reporting the extent of the differences in results.[36] A weighted average of results from alternative models based on expert weightings may also be informative.[37]

When the model used by assessors is well established, the central or expected estimate may be computed using classical statistics. When model uncertainty is substantial, the central or expected estimate may be a weighted average of the results from alternative models.[38] Judgmental probabilities supplied by scientific experts can help assessors obtain central or

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[36] Holland, CH, RL Sielken, *Quantitative Cancer Modeling and Risk Assessment*, Prentice-Hall, Englewood Cliffs, New Jersey, 1993; Olin, S, W Farland, C Park, L Rhomberg, R Scheuplein, T Starr, J Wilson (eds), *Low-Dose Extrapolation of Cancer Risks: Issues and Perspectives*, International Life Sciences Institute, Washington, DC, 1995.

[37] Morgan, MG, M Henrion, M Small, Uncertainty: *A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, Cambridge, UK, 1990; Cooke, RM, *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press, New York, NY, 1991; National Research Council, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, Washington, DC: National Academies Press, 2002.

[38] Clemen, RT, *Making Hard Decisions: An Introduction to Decision Analysis*, Second Edition, Duxbury Press, Pacific Grove, CA, 1996; Morgan, MG, M Henrion, M Small, Uncertainty: *A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, Cambridge, UK, 1990; Hoffman, O, S Kaplan, *Beyond the Domain of Direct Observation: How to Specify a Probability Distribution that Represents the State-of-the-Knowledge About Uncertain Inputs*, Risk Analysis, vol. 19(1), 1999, pp. 131-134.

expected estimates of risk in the face of model uncertainty.[39] Central or expected estimates of risk play an especially critical role in decision analysis and cost-benefit analysis.[40]

Statistical uncertainty sometimes referred to as data uncertainty or parameter uncertainty occurs when some data exist on the value of an input, but the value of the input is not known with certainty. If a sample of data exists on an input, the degree of statistical uncertainty in the input value is influenced by the size of the sample and other factors. Risk assessors should document and disclose the nature and degree of statistical uncertainty.

5. Standard for Characterizing Results

Results based on different effects observed and/or different studies should be presented to convey how the choice of effect and/or study influences the assessment. Authors of the assessment have a special obligation to evaluate and discuss alternative theories, data, studies and assessments that suggest different or contrary results than are contained in the risk assessment. When relying on data from one study over others, the agency should discuss the scientific justification for its choice.

6. Standard for Characterizing Variability

A risk is variable when there are known differences in risk for different individuals, subpopulations, or ecosystems. In some cases variability in risk is described with a distribution. Where feasible, characterization of variability should include sufficient description of the variability distribution so that the lower and upper percentiles and the median, mean, and mode are apparent.[41] This section should also disclose and evaluate the most influential contributors to variation in risk. This characterization should reflect the different affected populations (e.g., children or the elderly), time scales, geography, and other parameters relevant to the needs and objectives of the risk assessment. If highly exposed or sensitive subpopulations are highlighted, the assessment should also highlight the general population to portray the range of variability.[42]

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[39] Morgan, MG, M Henrion, M Small, Uncertainty: *A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, Cambridge, UK, 1990; Cooke, RM, *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press, New York, NY, 1991; Evans, JS , JD Graham, GM Gray, RL Sielken, *A Distributional Approach to Characterizing Low-Dose Cancer Risk*, Risk Analysis, vol. 14(1), 1994, pp. 25-34.

[40] Pate-Cornell, ME, *Uncertainties in Risk Analysis: Six Levels of Treatment*, Reliability Engineering and System Safety, vol. 54(2-3), 1996, pp. 95-111; Clemen, RT, *Making Hard Decisions: An Introduction to Decision Analysis*, Second Edition, Duxbury Press, Pacific Grove, CA, 1996; Viscusi, WK, *Rational Risk Policy*, Clarendon Press, Oxford, UK, 1998.

[41] Burmaster, DE, PD Anderson, *Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Analysis*, Risk Analysis, vol. 14(4), 1994, pp.477-481.

[42] Cullen, AC, HC Frey, Probabilistic Techniques in Exposure Assessment: A Handbook for Dealing with Variability and Uncertainty in Models and Inputs, Plenum Press, New York, NY, 1999; Hattis, D, DE Burmaster, *Assessment of Variability and Uncertainty Distributions for Practical Risk Analyses*, Risk Analysis, vol. 14(5), 1994, pp.713-730; National Research Council, *Human Exposure for Airborne Pollutants: Advances and Opportunities*, Washington, DC: National Academies Press 1991.

7. Standard for Characterizing Human Health Effects

Since the dictionary definition of "risk" refers to the possibility of an adverse consequence or adverse effect, it may be necessary for risk assessment reports to distinguish effects which are adverse from those which are non-adverse. Given that the capacity of science to detect effects is rapidly growing, sometimes faster than our ability to understand whether detected or predicted effects are adverse, the adversity determination is not always an obvious one.

Where human health effects are a concern, determination of which effects are adverse shall be specifically identified and justified based on the best available scientific information generally accepted in the relevant clinical and toxicological communities.

In chemical risk assessment, for example, measuring the concentration of a chemical metabolite in a target tissue of the body is not a demonstration of an adverse effect, though it may be a valid indicator of chemical exposure. Even the measurement of a biological event in the human body resulting from exposure to a specific chemical may not be a demonstration of an adverse effect. Adversity typically implies some functional impairment or pathologic lesion that affects the performance of the whole organism or reduces an organism's ability to withstand or respond to additional environmental challenges. In cases where qualified specialists disagree as to whether a measured effect is adverse or likely to be adverse, the extent of the differences in scientific opinion about adversity should be disclosed in the risk assessment report. In order to convey how the choice of the adverse effect influences a safety assessment, it is useful for the analyst to provide a graphical portrayal of different "safe levels" based on different effects observed in various experiments. If an unusual or mild effect is used in making the adverse-effect determination, the assessment should describe the ramifications of the effect and its degree of adversity compared to adverse effects that are better understood and commonly used in safety assessment.

Although the language in this section explicitly addresses human health endpoints, for other endpoints, such as ecological health, it is expected that the agency would rely upon information from a relevant group of experts, such as ecologists or habitat biologists, when making determinations regarding adversity of effects.

8. Standard for Discussing Scientific Limitations

Influential risk assessments should, to the extent possible, provide a discussion regarding the nature, difficulty, feasibility, cost and time associated with undertaking research to resolve a report's key scientific limitations and uncertainties.

9. Standard for Addressing Significant Comments

An agency is expected to consider all of the significant comments received on a draft influential risk assessment report. Scientific comments shall be presumed to be significant. In order to ensure that agency staff is rigorous in considering each significant comment, it is typically useful to prepare a "response-to-comment" document, to be issued with, or as part of,

the final assessment report, to summarize the significant comments and the agency's responses to those comments. Agency responses may range from revisions to the draft report or an acknowledgement that the agency has taken a different position than the one suggested by the commenter. Where agencies take different positions than commenters, the agency response to comments should provide an explicit rationale for why the agency has not adopted the position suggested by the commenter (e.g., why the agency position is preferable or defensible).

Section VI: Updates

Influential risk assessments should provide information or analysis, within the intended scope of the assessment, which assists policy makers in determining whether more data needs to be gathered or whether the assessment can be based on the data and assumptions currently available. Since risk assessment is typically an iterative process, with risk estimates subject to refinement as additional data are gathered, it is useful for assessments to disclose how fast the relevant database and assumptions are evolving and how likely it is that the database and assumptions will be significantly different within several months or years. While risk assessments should offer insight into what additional scientific understanding might be achieved through additional data collection and/or analysis, the decisions about whether to invest in additional inquiry, whether to take interim protective steps while additional inquiry is underway, or whether to act promptly without additional inquiry are policy decisions that are beyond the scope of the risk assessment report.

Each agency should, taking into account the resources available, priorities, and the importance of the document, consider revising its influential risk assessments as relevant and scientifically plausible information becomes available. Each agency should (1) have procedures in place that would ensure it is aware of new, relevant information that might alter a previously conducted influential risk assessment, and (2) have procedures in place to ensure that this new, relevant information is considered in the context of a decision to revise its previously conducted assessment. In addition, as relevant and scientifically plausible information becomes available, each agency shall consider updating or replacing its assumptions to reflect new data or scientific understandings.[43]

Section VII: Certification

For each risk assessment subject to this Bulletin, the agency shall include a certification, as part of the risk assessment document, explaining that the agency has complied with the

[43] See National Research Council, *Science and Judgment in Risk Assessment*, at 90, Washington DC: National Academy Press, 1994, ("Over time, the choice of defaults should have decreasing impact on regulatory decision-making. As scientific knowledge increases, uncertainty diminishes. Better data and increased understanding of biological mechanisms should enable risk assessments that are less dependent on default assumptions and more accurate as predictions of human risk."); Risk Commission Report, Volume 2, at iv ("Agencies should continue to move away from the hypothetical . . . toward more realistic assumptions based on available scientific data."), 1997.

requirements of this Bulletin and the applicable Information Quality Guidelines, except as provided in Section VIII.

Section VIII: Deferral and Waiver

The agency head may waive or defer some or all of the requirements of this Bulletin where warranted by compelling rationale. In each such instance, the agency shall include a statement in the risk assessment document that the agency is exercising a deferral or waiver as well as a brief explanation for the deferral or waiver. If the agency head defers the risk assessment requirements prior to dissemination, the risk assessment requirements shall be complied with as soon as practicable. A compelling rationale might cover health and safety risk assessments which are time-sensitive or need to be released due to an emergency situation. It is expected that a need for such a deferral would be an infrequent event. In the rare case of a time-sensitive necessary release, a complete risk assessment, which meets the standards set out in this Bulletin, should be provided to the public as soon as is practicable.

Section IX: OIRA and OSTP Responsibilities

OIRA, in consultation with OSTP, is responsible for overseeing agency implementation of this Bulletin. OIRA and OSTP shall foster learning about risk assessment practices across agencies.

Section X: Effective Date

The requirements of this Bulletin apply to: (1) final public risk assessments disseminated after 12 months following the publication of this Bulletin in final form, and (2) draft risk assessments disseminated after six months following the publication of this Bulletin in final form. These dates are necessary to ensure Federal agencies have sufficient time to both (1) become familiar with these standards and (2) incorporate these standards into ongoing risk assessments.

Section XI: Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

RISK ASSESSMENT BULLETIN

I. Definitions.

For purposes of this Bulletin, the term—

1. "agency" has the same meaning as the Paperwork Reduction Act, 44 U.S.C. § 3502(1);

2. "influential risk assessment" means a risk assessment the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions;

3. "risk assessment" means a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment.

II. Applicability.

1. To the extent appropriate, all agency risk assessments available to the public shall comply with the standards of this Bulletin.

2. This Bulletin does not apply to risk assessments performed with respect to:

a. inspections relating to health, safety, or environment;

b. individual agency adjudications or permit proceedings (including a registration, approval, or licensing) unless the agency determines that

i. compliance with this Bulletin is practical and appropriate and

ii. the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings; and

c. an individual product label, or a risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use.

III. Goals.

1. The objectives of the assessment shall be a product of an iterative dialogue between the assessor(s) and the agency decisionmaker(s).

2. The scope and content of the risk assessment shall be determined based on the objectives of the assessment and best professional judgment, considering the benefits and costs of acquiring additional information before undertaking the assessment.

3. The type of risk assessment prepared shall be responsive to the nature of the potential hazard, the available data, and the decision needs.

4. The level of effort put into the risk assessment shall be commensurate with the importance of the risk assessment.

5. The agency shall follow appropriate procedures for peer review and public participation in the process of preparing the risk assessment.

IV. General Risk Assessment and Reporting Standards.

Each agency risk assessment shall:

1. Provide a clear statement of the informational needs of decision makers, including the objectives of the risk assessment.

2. Clearly summarize the scope of the assessment, including a description of:

a. the agent, technology and/or activity that is the subject of the assessment;

b. the hazard of concern;

c. the affected entities (population(s), subpopulation(s), individuals, natural resources, ecosystems, or other) that are the subject of the assessment;

d. the exposure/event scenarios relevant to the objectives of the assessment; and

e. the type of event-consequence or dose-response relationship for the hazard of concern.

3. Provide a characterization of risk, qualitatively and, whenever possible, quantitatively. When a quantitative characterization of risk is provided, a range of plausible risk estimates shall be provided.

4. Be scientifically objective:

a. as a matter of substance, neither minimizing nor exaggerating the nature and magnitude of risks;

b. giving weight to both positive and negative studies in light of each study's technical quality; and

c. as a matter of presentation:

i. presenting the information about risk in an accurate, clear, complete and unbiased manner; and

ii. describing the data, methods, and assumptions used in the assessment with a high degree of transparency.

5. For critical assumptions in the assessment, whenever possible, include a quantitative evaluation of reasonable alternative assumptions and their implications for the key findings of the assessment.

6. Provide an executive summary including:

a. key elements of the assessment's objectives and scope;

b. key findings;

c. key scientific limitations and uncertainties and, whenever possible, their quantitative implications; and

d. information that places the risk in context/perspective with other risks familiar to the target audience.

7. For risk assessments that will be used for regulatory analysis, the risk assessment also shall include:

a. an evaluation of alternative options, clearly establishing the baseline risk as well as the risk reduction alternatives that will be evaluated;

b. a comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered, and assess, to the extent feasible, countervailing risks caused by alternative mitigation measures;

c. information on the timing of exposure and the onset of the adverse effect(s), as well as the timing of control measures and the reduction or cessation of adverse effects;

d. estimates of population risk when estimates of individual risk are developed; and

e. whenever possible, a range of plausible risk estimates, including central or expected estimates, when a quantitative characterization of risk is made available.

V. Special Standards for Influential Risk Assessments.

All influential agency risk assessments shall:

1. Be "capable of being substantially reproduced" as defined in the OMB Information Quality Guidelines.

2. Compare the results of the assessment to other results published on the same topic from qualified scientific organizations.

3. Highlight central estimates as well as high-end and low-end estimates of risk when such estimates are uncertain.

4. Characterize uncertainty with respect to the major findings of the assessment including:

a. document and disclose the nature and quantitative implications of model uncertainty, and the relative plausibility of different models based on scientific judgment; and where feasible:

b. include a sensitivity analysis; and

c. provide a quantitative distribution of the uncertainty.

5. Portray results based on different effects observed and/or different studies to convey how the choice of effect and/or study influences the assessment.

6. Characterize, to the extent feasible, variability through a quantitative distribution, reflecting different affected population(s), time scales, geography, or other parameters relevant to the needs and objectives of the assessment.

7. Where human health effects are a concern, determinations of which effects are adverse shall be specifically identified and justified based on the best available scientific information generally accepted in the relevant clinical and toxicological communities.

8. Provide discussion, to the extent possible, of the nature, difficulty, feasibility, cost and time associated with undertaking research to resolve a report's key scientific limitations and uncertainties.

9. Consider all significant comments received on a draft risk assessment report and:

a. issue a "response-to-comment" document that summarizes the significant comments received and the agency's responses to those comments; and

b. provide a rationale for why the agency has not adopted the position suggested by commenters and why the agency position is preferable.

VI. Updates.

As relevant and scientifically plausible information becomes available, each agency shall, considering the resources available, consider:

1. revising its risk assessment to incorporate such information; and

2. updating or replacing its assumptions to reflect new data or scientific understandings.

VII. Certification.

For each risk assessment subject to this Bulletin, the agency shall include a certification explaining that the agency has complied with the requirements of this Bulletin and the applicable Information Quality Guidelines, except as provided in Section VIII.

VIII. Deferral and Waiver.

The agency head may waive or defer some or all of the requirements of this Bulletin where warranted by compelling rationale. In each such instance, the agency shall include a statement in the risk assessment document that the agency is exercising a deferral or waiver as well as a brief explanation for the deferral or waiver. If the agency head defers the requirements prior to dissemination, the agency shall comply with them as soon as practicable.

IX. OIRA and OSTP Responsibilities.

OIRA, in consultation with OSTP, shall be responsible for overseeing agency implementation of this Bulletin. OIRA and OSTP shall foster better understanding about risk assessment practices and assess progress in implementing this Bulletin.

X. Effective Date.

The requirements of this Bulletin apply to: (1) final public risk assessments disseminated after twelve months following the publication of this Bulletin in final form, and (2) draft risk assessments disseminated after six months following the publication of this Bulletin in final form.

XI. Judicial Review.

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

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Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget

Committee to Review the OMB Risk Assessment Bulletin

Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

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[1]This study was planned, overseen, and supported by the Board on Environmental Studies and Toxicology.

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Preface

In an effort to improve the overall practice of risk assessment in the federal government, the Office of Management and Budget (OMB) released its Proposed Risk Assessment Bulletin on January 9, 2006, with a stated objective to "enhance the technical quality and objectivity of risk assessments prepared by federal agencies." The bulletin presents specific standards for risk assessments disseminated by federal agencies. OMB and the sponsoring agencies (Environmental Protection Agency, U.S. Department of Agriculture, Department of Defense, Department of Energy, Department of Health and Human Services, Department of Labor, and National Aeronautics and Space Administration) requested that the National Research Council (NRC) conduct a scientific review of the bulletin.

In this report, the NRC's Committee to Review the OMB Risk Assessment Bulletin provides its assessment of the OMB bulletin. The committee evaluates the standards presented in the bulletin, comments on the impact of the bulletin on the practice of risk assessment in the federal government, identifies critical elements missing from the bulletin, evaluates the consistency of the bulletin with previous reports of NRC and other organizations, and determines whether the draft bulletin has met OMB's stated objective.

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following for their review of this report: Lawrence Barnthouse, LWB Environmental Services, Inc.; Robert J. Budnitz, Lawrence Livermore National Laboratory; David Gaylor, Gaylor and Associates; J. Paul Gilman, Oak Ridge Center for Advanced Studies; Daniel Krewski, University of Ottawa; Jonathan Levy, Harvard School of Public Health; Roger O. McClellan, Albuquerque, New Mexico; Ali Mosleh, University of Maryland; Gilbert Omenn, University of Michigan Medical School; and Paul Slovic, Decision Research.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by B. John Garrick, Laguna Beach, California, and John C. Bailar, III, University of Chicago. Appointed by NRC, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the committee and the institution.

The committee gratefully acknowledges the following for making presentations to the committee: Linda Abbott, U.S. Department of Agriculture; Nancy Beck, Office of Management and Budget; Al Cobb, Department of Energy; Shannon Cunniff, Department of Defense; Homayoon Dezfuli, National Aeronautics and Space Administration; Steve Galson, Christopher Portier, and Christine Sofge, Department of Health and Human Services; John Graham, RAND Graduate School; Judith Graham, American Chemistry Council; George Gray, Environmental Protection Agency; Stephen Heinig,

Association of American Medical Colleges; Alan Krupnick, Resources for the Future; Gilbert Omenn, University of Michigan Medical School; William Perry, Department of Labor; Lorenz Rhomberg, Gradient Corporation; Jennifer Sass, Natural Resources Defense Council; and Robert Shull, OMB Watch.

The committee is also grateful for the assistance of the NRC staff in preparing this report. Staff members who contributed to this effort are Jennifer Saunders, associate program officer; Norman Grossblatt, senior editor; John Brown, program associate; and James J. Reisa, director of the Board on Environmental Studies and Toxicology. Primary among the staff was Ellen K. Mantus, project director, whose knowledge, careful working with the committee, and extreme diligence brought this report to completion.

I would especially like to thank the members of the committee for their efforts throughout the development of this report.

John F. Ahearne, Chair
Committee to Review the OMB Risk
Assessment Bulletin

Contents

Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget

Summary

In January 2006, the Office of Management and Budget (OMB) released a draft bulletin that proposes technical guidance for risk assessments produced by the federal government. The bulletin defines *risk assessment* broadly, states several goals for risk assessment, and proposes general risk assessment and reporting standards and special standards for influential risk assessments. The stated intent of the bulletin is "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards," and it follows several other influential documents issued by OMB, including the Information Quality Guidelines, the Information Quality Bulletin on Peer Review, and Circular A-4, which pertains primarily to benefit-cost analysis and cost-effectiveness analysis. Recognizing the potential impact on federal agencies, OMB—with the Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA), the Department of Defense (DOD), the Department of Energy (DOE), the Department of Health and Human Services (DHHS), the Department of Labor (DOL), and the National Aeronautics and Space Administration (NASA)—asked the National Research Council (NRC) to conduct an independent review of the bulletin. In response to that request, NRC convened the Committee to Review the OMB Risk Assessment Bulletin, which prepared this report.

COMMITTEE'S CHARGE AND APPROACH TO ITS CHARGE

The committee was asked to conduct a scientific and technical review of the proposed bulletin and to determine whether it meets OMB's objective to "enhance the technical quality and objectivity of risk assessments prepared by federal agencies." In performing its task, the committee was asked to comment, in general terms, on how the guidance will affect the practice of risk assessment in the federal government, to identify critical elements that might be missing from the guidance, and to assess whether there are scientific or technical circumstances that might limit applicability of the guidance. In addition, the committee was asked whether OMB appropriately incorporated recommendations from previous reports of the NRC and other organizations into the proposed risk assessment guidance.

To accomplish its task, the committee held a large public meeting during which it heard presentations from the study sponsors and other invited speakers from private industry, universities, trade associations, and environmental groups. The committee reviewed numerous documents cited in the bulletin and reviewed public comments submitted to OMB on the bulletin. The committee also requested information from the federal agencies on their risk assessment practices and their view of the potential impact of the bulletin on current practices. The committee reviewed both the bulletin and the accompanying supplementary information, and reference to "the bulletin" in this summary includes both the bulletin and the supplementary information.

Although this report touches on some statutory, policy, and budgetary issues, it is not a comprehensive review of all potential impacts of the bulletin. Rather, it is primarily a review of the science involved and the technical applications of the bulletin. Furthermore, much of the language used (and the examples provided) in the bulletin is related to human health risk assessment and not

engineering, ecologic, or behavioral risk assessment. The committee recognizes that each of these fields has generated risk assessment methods that address specific interests. However, the committee was tasked with reviewing the bulletin and not providing a comprehensive treatment of risk assessment, so its comments focus mainly on human health risk assessment, as did the OMB bulletin.

COMMITTEE'S REVIEW

Consistency with NRC and Other Reports

The general thrust of the bulletin appears to be consistent with many of the themes and recommendations in reports by previous NRC committees and other expert organizations. The bulletin emphasizes the need to define objectives clearly and to ensure that assessments yield results that are both faithful to underlying scientific knowledge and useful for decision-making. The committee, however, is concerned that the bulletin is inconsistent with previous recommendations in a number of ways, including its presentation of a new definition of risk assessment, its omission of discussion of the important role of default assumptions and clear criteria to modify or depart from defaults, its proposal of risk *assessment* standards related to activities traditionally regarded as risk *management* activities, and its requirement for formal analyses of uncertainty and presentation of "central" or "expected" risk estimates. In several respects, the bulletin attempts to move standards for risk assessment into territory that is beyond what previous reports have recommended and beyond the current state of the science. Such departures from expert studies are of serious concern, because any attempt to advance the practice of risk assessment that does not reflect the state of the science is likely to produce the opposite effect.

Definition of Risk Assessment and the Bulletin's Goals

The bulletin defines risk assessment as "a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment." That definition conflicts with long-established concepts and practices that have defined risk assessment as a *process* that involves hazard identification, hazard characterization or dose-response assessment, exposure assessment, and risk characterization. The definition in the bulletin is too broad and encompasses not only traditional risk assessments but the *components* of risk assessment. Such a definition, which captures a variety of analyses under the same name, could cause great confusion. Moreover, several standards proposed in the bulletin are not applicable to individual components of risk assessment or other types of documents that might be classified as risk assessment under the proposed definition.

The bulletin defines five goals of risk assessment that are related to problem formulation, completeness, character of risk assessment, resources expended, and peer review and public participation. Taken as a whole, the five goals indicate that a risk assessment should be tailored to the specific need for which it is undertaken; balanced in scope, time, and cost with the importance of the issue; and peer-reviewed and released for public comment. The goals mostly emphasize efficiency, rather than quality, in the conduct of risk assessment. Thus, the goals do not all support the primary purpose of the bulletin—"to enhance the technical quality and objectivity of risk assessments."

Proposed Standards for Risk Assessment

The bulletin proposes seven standards for general risk assessment—one of which refers to risk assessments for regulatory analysis—and nine special standards for influential risk assessments. The committee found this structure problematic, because one may not know at the outset whether an analysis

will constitute an "influential" risk assessment. Furthermore, arbitrarily separating risk assessment into two broad categories (general and influential) ignores the continuum of risk assessment efforts. The committee reviewed each standard and provides comments on them in this report. In general, the committee found many of the standards to be unclear or flawed. Standards on presentation of specific information, uncertainty, and adversity of health effects exemplify the problems.

Several standards require the presentation of "a range of plausible risk estimates" that includes "central or expected estimates." The discussion regarding this requirement is incomplete and confusing. Those numerical quantities are meaningful only in the context of some distribution that arises when variability and uncertainty are taken into consideration. A central estimate and a risk range might be misleading in situations when sensitive populations are of primary concern. Thus, the choice of summary statistics cannot be a blanket prescription but must reflect the specific context.

Standards for influential risk assessments require a formal characterization of uncertainty. However, the description of uncertainty and variability in the bulletin is oversimplified and does not recognize the complexities of different types of risk assessments or the need to tailor uncertainty analysis to a given agency's particular needs. Furthermore, there is no scientific consensus to support the bulletin's universal prescriptions for how uncertainty should be evaluated. In the absence of clear guidance regarding the conduct of uncertainty analysis, there is a serious danger that agencies will produce ranges of meaningless and confusing risk estimates, which could result in risk assessments of reduced rather than enhanced quality and objectivity.

Finally, for influential risk assessments, the bulletin states that "where human health effects are a concern, determinations of which effects are adverse shall be specifically identified and justified." The bulletin's definition of *adverse effect* implies a *clinically* apparent effect, which ignores a fundamental public-health goal to control exposures well before the occurrence of any possible functional impairment of an organism. Dividing effects into "adverse" and "nonadverse" ignores the scientific reality that adverse effects may be manifest along a continuum. The committee concludes that the bulletin's treatment of adverse effects is too simplistic and restrictive and ignores important factors in determining appropriate effects to evaluate, the scientific information available, and an understanding of the underlying biochemical mechanisms for an effect of interest.

Omissions from the Bulletin

Omission of several relevant topics limits the utility of the bulletin as balanced and comprehensive risk assessment guidance. Specifically, OMB has proposed a bulletin addressing risk assessment in the federal government; however, the bulletin focuses mainly on biologic systems, with an emphasis on human health risk assessment. The vast majority of examples it presents (and the authorities cited) apply to toxicologic and other human health end points. By reducing risks to human health risks, as important as they may be, OMB commits a serious error in neglecting risk assessment of technology and engineered structures. Those are of vital importance to such agencies as DOE, DOD, and NASA and therefore to the general public and the economic vitality of the United States. The bulletin's incomplete and unbalanced approach to engineering risk assessment (as well as ecologic and other types of risk assessment) contradicts its stated objective of improving the quality of risk assessment throughout the federal government. Unless all risk assessment disciplines are considered, any government-wide guidance on risk assessment would be unacceptable.

Furthermore, the bulletin gives little attention to sensitive populations, the often pivotal role of risk assessment policy in choices regarding default options, the integral role of risk communication, and standards for risk assessments submitted by outside parties for use in the rule-making process. With reference to risk communication, the committee agrees with previous NRC reports that view risk communication as a dialogue with users of risk assessment throughout the process that helps to ensure its relevance and credibility and does not see it as a one-way, end-of-the process activity. The bulletin also fails to explain the basis for exempting risk assessments associated with licensing and approval processes.

Perhaps the most glaring omission is the absence of criteria and information for gauging the benefits to be achieved by implementing the bulletin (that is, a benefit-cost analysis). Although OMB has implied that the agencies currently do not meet the standards that it seeks to establish, it has not established a baseline of each agency's risk assessment proficiency, including the extent to which generally satisfactory and high-quality risk assessments are produced or how some agencies fall short of the specified standards. Specifically, OMB has not established which agencies do not appear to know what good practices are and which agencies do not have the ability, resources, or incentives to meet the standards. Similarly, OMB has not identified the costs that could be encountered in implementing the bulletin. Thus, OMB has not determined the impact of the bulletin on federal agencies.

Impact on Risk Assessment Practices in the Federal Government

Although OMB did not construct a baseline reflecting current agency risk assessment practices, the committee concludes on the basis of agency comments and its own knowledge of risk assessment practices that some aspects of the bulletin could be beneficial but that the costs—in terms of staff resources, timeliness of completing risk assessments, and other factors—are likely to be substantial. Overall, the committee concludes that the potential for negative impacts on the practice of risk assessment in the federal government, although varied and uncertain to some extent, would be very high if the currently proposed bulletin were implemented.

COMMITTEE'S CONCLUSIONS AND RECOMMENDATIONS

On the basis of its review, the committee concludes that the OMB bulletin is fundamentally flawed and recommends that it be withdrawn. Although the committee fully supports the goal of increasing the quality and objectivity of risk assessment in the federal government, it agrees unanimously that the OMB bulletin would not facilitate reaching this goal. The committee also agrees that OMB should encourage the federal agencies to describe, develop, and coordinate their own technical risk assessment guidance. Therefore, the committee recommends that, after additional study of current agency practices and needs, a different type of risk assessment bulletin be issued by OMB. That bulletin should outline goals and general principles of risk assessment designed to enhance the quality, efficiency, and consistency of risk assessment in the federal government. It should direct the agencies to develop technical guidance that would implement the general principles, be consistent with the individual agencies' legislative mandates and missions, and draw on the expertise that exists in federal agencies and other organizations. The technical guidance developed or identified by the agencies should be peer-reviewed and contain procedures for ensuring compliance with the guidance within the agencies. Although OMB should determine whether the technical guidance developed by the agencies fully addresses the general principles, the committee recommends that development and peer review of agency technical guidance be left to the agencies. The committee strongly recommends that federal agencies addressing similar hazards or risks work together to develop common technical guidance for risk assessment; that would help to achieve the appropriate consistency among agencies in risk assessment practices.

The committee arrived at its position after deliberate consideration of many factors. The committee began with the working assumption that its role would be to recommend modifications, if necessary. After digging deeply into the bulletin and after extensive discussion, the committee reluctantly came to its conclusion that the bulletin could not be rescued.

Risk assessment is not a monolithic process or a single method. Different technical issues arise in assessing the probability of exposure to a given dose of a chemical, of a malfunction of a nuclear power plant or air-traffic control system, or of the collapse of an ecosystem or a dam. Thus, one size does not fit all, nor can one set of technical guidance make sense for the heterogeneous risk assessments undertaken

by federal agencies. Although the bulletin generally acknowledges that diversity and attempts to meet it with frequent references to "where appropriate" or "where feasible," the bulletin does not reflect an adequate understanding of the many risk assessment disciplines, particularly those devoted to analyzing the risks of engineered structures and natural systems. Its narrow focus on human health risk assessment makes it inappropriate as across-the-board guidance for all risk assessments conducted throughout the federal government. Furthermore, as stated above, the committee strongly recommends that technical guidance be produced by the individual agencies and that agencies dealing with the same or similar hazards work together to produce common guidance to ensure an appropriately consistent approach.

The committee agrees that there is room for improvement in risk assessment practices in the federal government and that additional guidance would help "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies." However, the committee concludes that OMB should limit its efforts to stating goals and general principles of risk assessment. The details should be left to the agencies or expert committees appointed by the agencies, wherein lies the depth of expertise to address the issues relevant to their specific types of risk assessments.

7

Conclusions and Recommendations

For the reasons presented in this report, the committee concludes that the bulletin proposed by the Office of Management and Budget (OMB 2006) is fundamentally flawed and recommends that it be withdrawn. Although the committee fully supports the goal of increasing the quality and objectivity of risk assessment in the federal government, it agrees unanimously that the OMB bulletin would not facilitate federal agencies in reaching this goal. The committee also agrees that OMB should encourage the federal agencies to describe, develop, and coordinate their own technical risk assessment guidance. Therefore, the committee recommends that after additional study of current agency practices and needs, a different type of risk assessment bulletin be issued by OMB. It should outline goals and general principles of risk assessment designed to enhance the quality, efficiency, and consistency of risk assessment in the federal government. It should direct the agencies to develop technical guidance that would implement the general principles, be consistent with each agency's legislative mandates and missions, and draw on the expertise that exists in federal agencies and other organizations. The technical guidance developed or identified by the agencies should be peer-reviewed and contain procedures for ensuring agency compliance with the guidance. Although OMB should determine whether the technical guidance fully addresses the general principles, it should not be involved in the development or peer review of agency technical guidance. The committee strongly recommends that agencies addressing similar hazards or risks work together to develop common technical guidance for risk assessment. In that way, the appropriate consistency would be achieved in the federal government in risk assessment practices.

The committee arrived at its position after extensive discussion and deliberate consideration of many factors, including primarily the great variations in risk assessments among and within federal agencies and the fact that the expertise in risk assessment in the federal government resides, for the most part, in the agencies or with those with whom the agencies work.

Risk assessment is not a monolithic process or a single method. All risk assessments share some common principles, but their application varies widely among domains. Different technical issues arise in assessing the probability of exposure to a given dose of a chemical, of a malfunction of a nuclear power plant or air-traffic control system, or of the collapse of an ecosystem or a dam. And different technical issues arise in assessing the consequences of an accidental release from a nuclear power facility and an accidental release of a pesticide.

Risk assessment is not a field peopled with all-purpose experts. There are some with expertise in toxicology, decision analysis, dose-response assessment, ecologic risk assessment, engineering, and exposure assessment. In industry, some firms that specialize in one domain would not take on work in another. Federal agencies have staff familiar with the issues that are relevant to their missions; agencies without resident expertise have contractors with whom they have been working or associations to which they can turn.

One size does not fit all, nor can one set of technical guidance make sense for the heterogeneous risk assessments undertaken by federal agencies. Although the bulletin reflects that diversity and attempts to meet it with frequent references to "where appropriate" or "where feasible," the committee concludes that this approach is not workable for the agencies. As stated above, the committee strongly recommends that technical guidance be produced by the agencies and that agencies dealing with the same or similar hazards work together to produce common guidance to ensure an appropriately consistent approach.

As noted above, the committee agrees that there is room for improvement in risk assessment practices in the federal government and that additional guidance would help "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies." However, the bulletin conveys the impression that risk assessments can and should achieve total objectivity. Although any scientific work should be free of bias, scientifically accurate, and based on reliable evidence, risk assessments cannot be wholly objective, because some important assumptions and judgments are based on policy or statutes. The committee strongly concludes that OMB should limit its efforts to stating goals and general principles of risk assessment and to directing the agencies to develop technical guidance consistent with the goals and principles. The committee has not provided suggestions for specific goals and principles in this report, because that was beyond the scope of its task.

CONCLUSIONS

Other conclusions that led to the committee's position that the OMB bulletin should be withdrawn are provided below. Three overarching conclusions are especially important.

- In view of the diversity of risk assessment responsibilities and proficiencies in the federal government, it would be difficult, if not impossible, to produce a single detailed technical guidance document that would be applicable to all federal agencies.
- New guidance that departs from established risk assessment principles and practices and is not supported by the current state of the science is unlikely to achieve the goals stated in the bulletin.
- Without baseline assessments of current risk assessment practices, needs, and capacities for improvement in the federal agencies, neither OMB nor the committee can make informed judgments on the kinds of guidance needed to reach the goals set forth in the bulletin and the related resources required to achieve that end.

Conclusions that are related to specific aspects of the proposed bulletin are provided below.

- In some general respects, the bulletin's requirements for risk assessments (for example, the call for balanced presentations of data and for explicit justification of scientific conclusions) are consistent with previous reports, including those cited in the bulletin. However, other aspects of the bulletin are inconsistent with previous reports in important ways. For example, it adopts a new definition of risk assessment and ignores, without explaining, the important impact that risk assessment policies have on the process, such as the need for consistent defaults and for clear criteria for moving away from the defaults. Without explicit and clear direction on such matters, agency risk assessments are more susceptible to being manipulated to achieve a predetermined result. The bulletin's call for formal analyses of uncertainties and for undefined "central or expected estimates" may, in the absence of adequate peer-reviewed technical guidance on the evaluation and expression of uncertainties, result in risk characterizations of reduced, rather than enhanced, quality. Those are serious concerns because any attempt to advance the practice of risk assessment that does not reflect the state of the art on these topics is likely to produce the opposite effect.

- The proposed definition of risk assessment in the OMB bulletin departs without justification from long-established concepts and practices, including those developed by National Research Council (NRC) and other expert committees and endorsed in existing peer-reviewed guidelines. In particular, the proposed definition broadens the definition of risk assessment to include components of risk assessment, such as hazard assessment and exposure assessment. Such a broadening, which treats different procedures under the same name, is needlessly confusing. More important, several of the standards proposed in the bulletin are not applicable to individual components of risk assessment. The committee also disagrees with defining risk assessment as a document; risk assessment is a process from which documents can result.
- The dominating theme of the bulletin and its supplementary information is improving the quality of risk assessments undertaken by federal agencies, but the stated goals do not all support this theme. The goals stated in the bulletin and the supplementary information emphasize *efficiency* in the conduct of risk assessment activities more than *quality*.
- The discussion of the range of risk estimates and central estimates in the proposed bulletin is incomplete and confusing. A central estimate and risk range might be misleading when sensitive populations are of primary concern. Those numerical quantities are meaningful only in the context of some distribution characterizing variable traits or uncertainties. The choice of summary statistics cannot be a blanket prescription but must reflect the specific context.
- The description of uncertainty and variability in the bulletin is simplistic. It does not recognize the complexities of different types of risk assessments or the need to tailor uncertainty analysis to an agency's particular needs. There is no scientific consensus to support the bulletin's universal prescriptions for how uncertainty should be evaluated.
- The bulletin's treatment of adverse effects is simplistic and too restrictive. Effects chosen for risk assessment may be adverse effects, precursor effects, or nonadverse effects. The point of departure to be chosen in a risk assessment depends on a number of factors, such as the questions being addressed, the scientific information available, and an understanding of the underlying mechanisms for the effect of interest.
- The bulletin is silent on several important aspects of the risk assessment process. Specifically, it gives little attention to risk assessments for which the end point is major failure of engineered systems, to sensitive populations, to the often decisive role of risk assessment policy in choices regarding default options, to the integral role of risk communication, and to risk assessment standards for stakeholder assessments submitted for use in the rule-making process. The bulletin also fails to explain the basis for exempting risk assessments associated with licensing and approval processes.
- Although risk assessment and risk management are closely related and it is desirable to build links between them, the committee agrees with accepted practice that they are distinct. The bulletin blurs the important distinction between them by setting risk assessment standards related to risk mitigation and comparative-risk activities usually regarded as risk management. Risk assessors should not be required to undertake what have been traditional risk management functions, such as identifying alternative mitigation strategies.
- The bulletin claims that it avoids addressing risk communication in any detail, but it includes quite specific guidance on this topic. The guidance provided is not well informed or consistent with previous expert panel reports. In general, the bulletin takes the outmoded view that risk communication is mainly a matter of disseminating key findings after a risk assessment has been completed and not the contemporary view that it is a continuing discussion among risk assessors, risk managers, and stakeholders from start to finish. The more objectionable risk communication guidance in the bulletin includes instructions to the agencies always to communicate ranges of plausible estimates and always to compare assessed risks with other familiar risks—guidance that is not consistent with relevant research literature.
- Although OMB has not constructed a baseline reflecting current agency risk assessment practices, the committee concludes on the basis of agency comments and its own knowledge of risk assessment

practices that there are aspects of the bulletin that could be beneficial but that the cost—in staff resources, timeliness of completing risk assessments, and other factors—are likely to be substantial. Overall, the committee concludes that, while varied and uncertain to some extent, the potential for negative impacts on the practice of risk assessment in the federal government is very high if the currently proposed bulletin were to be implemented.

RECOMMENDATIONS

The committee offers OMB the following recommendations to consider in developing a new risk assessment bulletin.

- After withdrawing the current bulletin and before proceeding further, OMB should produce a description of current agency risk assessment practices and resources and the likely effects (both benefits and costs) of changing those practices.
- Before mandating substantial changes in agency risk assessment practices, OMB should ensure that sufficient funds and staffing are available on a continuing basis to support the agencies in their risk assessment responsibilities. Adequate staffing and funding are prerequisites to the kind of risk assessment envisioned in the bulletin.
- OMB should ensure that any government-wide risk assessment bulletin takes full account of and makes allowance for variations among agencies with respect to the types of risk assessments they engage in, the resources they have to devote to risk assessments, and their proficiency in risk assessment generally.
- Any guidance on risk assessment should provide a definition of risk assessment that is compatible with previous NRC documents and guidelines of other expert organizations; does not include information documents or individual components of risk assessment, such as hazard or exposure assessment; preserves the clear conventional distinctions between risk assessment and risk management; and refers to a process, not a document.
- OMB should develop goals for risk assessment that emphasize the central objective of enhanced scientific quality and the complementary objectives of efficiency and consistency among agencies evaluating the same or similar risks. The goals should support the production of risk assessments that provide clear, relevant, and scientifically sound information for policy-makers.
- OMB should develop general principles for risk assessment that are fully consistent with the recommendations provided by previous committees of NRC and those of other expert organizations. The committee recommends that the affected federal agencies develop their own technical risk assessment guidelines that are consistent with the OMB general principles.
- The committee strongly recommends that discussion of uncertainty and variability, presentation of risk results, definition of adversity, and other similar topics be reserved for the technical guidance to be developed by the agencies.

REFERENCES

NRC (National Research Council). 1983. Risk Assessment in the Federal Government: Managing the Process. Washington, DC: National Academy Press.

OMB (U.S. Office of Management and Budget). 2006. Proposed Risk Assessment Bulletin. Released January 9, 2006. Washington, DC: Office of Management and Budget, Executive Office of the President [online]. Available: http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf [accessed Oct. 11, 2006].

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW.
New Executive Office Building
Room 10201
Washington, DC 20503

June 15, 2006

Re: Comments on Proposed Risk Assessment Bulletin

Dear Dr. Beck:

The American Chemistry Council (ACC or the Council) is pleased to submit comments on the Office of Management and Budget's Proposed Risk Assessment Bulletin[1]. The Council represents the leading companies engaged in the business of chemistry[2].

ACC and its members make substantial, ongoing investments in research to support product development, health, safety and environmental protection, and to abide by product stewardship and regulatory policies. Chemistry is a science-based industry, and ACC has long sought to improve the quality of government science generally and risk assessment in particular. For example, in response to OMB's Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, ACC filed an extensive set of comments (63 pages plus five appendices) that primarily focused on EPA's risk assessment practices.[3] Appendix 5 to those comments provided 62 additional pages of examples of EPA risk assessments that overstated risks. ACC's comments were the principal drivers behind EPA's 2004 staff paper on the Agency's risk assessment principles and practices – a document which defended the appropriateness of many of the practices to which ACC objected.[4] These controversies are still largely unresolved, and thus ACC has a substantial interest in the Bulletin.

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[1] Notice of availability at 71 Fed. Reg. 2600 (Jan. 17, 2006).

[2] Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $460 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

[3] ACC, "Comments to the Office of Management & Budget; Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations," filed May 5, 2003. These comments and Appendix 5 are attached.

[4] EPA Office of the Science Advisor Staff Paper, *An Examination of EPA Risk Assessment Principles and Practices* (EPA/100/B-04/001) (Feb. 2004).

ACC has strongly supported OMB's efforts – through its Information Quality Act (IQA) Guidelines, [5] the Peer Review Bulletin, [6] Circular A-4,[7] and otherwise – to assure that the highest quality scientific work products are consistently and assiduously applied in support of regulatory policy. The proposed Risk Assessment Bulletin continues those efforts, and ACC applauds OMB for issuing it. We believe the Bulletin, once finalized, will improve the uneven performance of risk assessments at EPA and other federal agencies by setting a unified, upgraded standard.

The attached comments highlight the strengths that we have identified in the document, and recommend a number of improvements that we believe are vital to its success. We understand that many important issues associated with the Bulletin will only become clear as it is implemented, and we look forward to a continuing dialogue with OMB before and after its final publication. Should you or other OMB staff have any questions on, or need clarification of, ACC comments, please don't hesitate to contact either of us at 703-741-5000.

Sincerely,

James W. Conrad, Jr.
Assistant General Counsel

Richard A. Becker, Ph.D. DABT
Senior Toxicologist/Senior Director

Attachment: Comments of the American Chemistry Council on the Proposed Risk Assessment Bulletin (released for public review and comment in January, 2006)

[5] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8452 (Feb. 22, 2002).
[6] OMB, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664 (Jan. 14, 2005).
[7] OMB, *Circular A-4* (Sept. 2003).

NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

June 15, 2006

FILED ELECTRONICALLY
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Re: NRDC Comments on the OMB Proposed Risk Assessment Bulletin

Dear Dr. Beck:

The Natural Resources Defense Council (NRDC), a national non-profit public interest organization, offers these comments in response to the Office of Management and Budget's (OMB) Proposed Risk Assessment Bulletin, release on January 9, 2006,[1] which will be peer-reviewed by the National Academies of Science.[2]

The views expressed herein are presented on behalf of NRDC's over 1 million members and activists, who help us protect our nation's public health, safety, and environmental safeguards. Such safeguards were born from a deliberative public process, and although these protections may come at some cost, they deliver tremendous benefits from decreased risks of cancer, to safer automobiles, and increased energy savings. Thus, we believe those who wish to change these safeguards should engage in the same deliberative process used to create them.

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[1] Office of Info. & Reg Affs., OMB, Proposed Risk Assessment Bulletin (Jan. 2006), available at www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf

[2] National Academies. Review of the OMB Risk Assessment Bulletin. BEST-K-06-02-A (E. Mantus) www8.nationalacademies.org/cp/projectview.aspx?key=34282

OMB intends its Proposed Risk Assessment Bulletin to provide, "clear, minimum standards for the scientific quality of federal agency risk assessments."[3] Foreshadowing the broad misgivings about this Bulletin from diverse interests, Members of Congress have already identified issues of general concern in a May, 2006 letter issued by the Ranking Members of the House Science, Energy & Commerce, Government Reform, and Transportation and Infrastructure Committees.[4] Although NRDC supports OMB's stated goal of improving agency risk assessment practices, we too have grave misgivings about this troubling proposal. We, therefore, urge OMB to withdraw it from any further public consideration.

STANDARD DEFINITIONS

Within comments written In March, 1995, the following risk-related terminology was issued by the Office of Science and Technology Policy, Executive Office of the President which may be helpful in discussing the current Bulletin:

- ***Risk Assessment***: A process used to evaluate and describe how dangerous a substance or hazard is (i.e. how big is the problem?)
- ***Risk characterization***: An evaluation of available data on a hazard (including exposure and effects), and their associated strengths, limitations, and uncertainties, resulting in a description of the expected risks associated with the hazard.
- ***Risk Management***: The decision-making process by which the results of a risk assessment are integrated with other information, including social, economic, and legal considerations, as well as the actions taken as a result (i.e. what are we going to do about it?)

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[3] Graham, J as quoted in a press release of the Office of Management and Budget. January 9, 2006

[4] Letter to R. Cicerone, President, National Academies of Science from Congressmen B. Gordon, JD Dingell, HA Waxman, JL Oberstar. May 5, 2006 http://sciencedems.house.gov/press/PRArticle.aspx?NewsID=1103

- ***Risk Communication***: The process by which the risk assessor, policymakers, and other individuals discuss risk with one another, including communication between risk assessors and risk managers, and communication between risk assessors and managers and the public.
- ***Comparative risk analysis***: The comparison of risks to one another, which can include the comparison of individual risks or the comparison of groups of risks (i.e. how big is this problem compared to others?)
- ***Risk Analysis***: A comprehensive term encompassing various risk-related activities such as risk assessment, risk management, risk communication, and comparative risk analysis.

RISK ASSESSMENT NEEDS TO SUPPORT REGULATORY ACTION

Risk assessments are conducted under a wide variety of conditions, for a wide variety of purposes, under numerous federal and state statutes, and in widely varying contexts. Risk assessments involve calculating the increase in risk (e.g. illness, injury, or death) associated with exposure (e.g. acute or chronic) to a hazardous agent (where hazard is a quantitative estimate of potency). An agency's ability to collect robust data on exposure and hazard is often very limited. It cannot, for instance, go out and intentionally expose people to precise, measurable levels of carcinogens and then document the increase in cancer rates. Most often, an agency must collect data through other means, often using experimental data from well-designed animal and non-animal studies conducted under controlled laboratory conditions. Still, uncertainties and data gaps abound when extrapolating experimental data to risk for the general population that includes people of diverse ages, lifestyles, nutritional status, genetic make-up, and health status. This makes quantitative risk assessment something between a science and a guessing game, depending on the reliability of the input data.

As a practical matter, however, a regulatory agency must protect the public from preventable risks. To do this in a systematic and scientifically supported manner, an agency collects the available data, and then fills in identified data gaps with adjustment factors, estimates, extrapolations from the

observed range of data to the unobserved range, and with the use of mathematical models. All of these approaches rely heavily on expert judgment, assumptions, and extrapolations. The final risk assessment, including model results, can vary widely depending on the built-in judgments, assumptions, and data. For example, a model may assume an average resting breathing rate, or a heavier breathing rate to capture a working or exercising scenario; the choice may produce widely divergent predictions for the amount of an air pollutant that enters the lungs in a given time.

Regulatory agencies know that the realities of constantly emerging new science and the frailties inherent in available evidence dictate that it will never eliminate all major assumptions and judgments from its decision-making. Our public health and environmental programs, however, would not be effective if incontrovertible evidence of harm were a prerequisite of regulatory action. To quote Bradford Hill, the father of knowledge criteria for epidemiology:

> "*All scientific work is incomplete-whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action it appears to demand at a given time*." (Bradford Hill, 1965)

However, without *any* scientific support for regulatory decisions, courts will strike down any proposed protections for lack of sufficient evidence. The terrible paradox is that waiting for "evidence" is usually a matter of waiting for an increase in disease and death among the exposed population. Thus, a significant issue for agencies is how much analysis is necessary before promulgating a rule. Courts have consistently acknowledged the need to proceed without full evidence, citing the precautionary goals of most environmental statutes, see Reserve Mining, Ethyl, recent DC Cir Clean Air opinion. In the legal decision of American Trucking on remand, the DC Cir affirmed the propriety of "err[ing] on the side of caution". American Trucking Assns. v. EPA, 283 F.3d 355, 369 (D.C. Cir. 2002).

NRDC CONCERNS WITH THE OMB PROPOSED RA BULLETIN

The Bulletin is mandatory, rather than guidance, thus forcing increased burdens on the issuance of regulations and on information supporting regulatory actions

Because the OMB Risk Assessment proposal is a "Bulletin" rather than guidance it has a prescriptive force behind it; it's mandatory. It dictates rather than suggests. Protestations about flexibility notwithstanding, in fact the bulletin says, "Shall" rather than "may". It dictates to the Agencies what they must do without fail. In fact, each section of the Bulletin begins with the word "shall". For example:

- "…all agency risk assessments available to the public shall comply with the standards of this Bulletin" (II.2)
- The scope and content of each risk assessment "shall" consider the "benefits and costs of acquiring additional information before undertaking the assessment" (III.2).
- All influential agency risk assessments "shall compare the results of the assessment to other results published on the same topic…" (V.1).

It is unreasonable to expect a one-size-fits-all risk assessment approach to be appropriate for all risk assessments across all agencies and under all conditions, as we detail in the following comments. The prescriptive nature of this Bulletin suggests that its goal is not to improve risk assessment across all federal agencies, but instead to force an increasingly burdensome workload on agencies as a means of shackling agencies from taking regulatory action.

The Bulletin re-defines risk assessment to force itself upon all activities that assemble and synthesize scientific information

The Bulletin does not adopt the standard definitions long used by risk assessors, but instead broadens the definition of risk assessment "for purposes of this Bulletin" to include, "a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment" (I.3., p. 23). Within the discussion of the Bulletin, this is further defined as applying to, "*documents that <u>could</u> be used for risk assessment*

purposes, such as an exposure or hazard assessment that might not constitute a complete risk assessment as defined by the National Research Council" (p. 8) (underline added for emphasis).

To demonstrate the unusually broad scope of this Bulletin, the discussion specifically identifies examples of assessment that are not normally considered to be risk assessment but that are intended to fall within the purview of this Bulletin:

- margin of exposure estimates,
- hazard determinations,
- EPA Integrated Risk Information System used by regulators to set clean up and emission limits
- assessment that support EPA National Ambient Air Quality Standards to set limits on air emissions
- FDA tolerance value that set an upper limit on the tolerable levels of toxics allowed in food products
- ATSDR toxicological profiles that provide scientific hazard information to the general public and state and federal regulators
- HHS/NTP substance profiles that provide toxicological information to regulators and the public
- NIOSH current intelligence bulletins and criteria documents that provide updated scientific information to regulators and the public
- risk assessments performed as part of economically significant rulemakings

It is of significant concern that this Bulletin forces itself upon any piece of information that could conceivably be used for an assessment even though it is not in fact a risk assessment (see standard definitions above). This is so extensive and inclusive that it is difficult to imagine how such a broad definition that is forced across all federal agencies would not result in forcing many federal information assembling activities to a screeching halt. Many risk assessment scholars believe that this may be the intent of the Bulletin, and not just collateral damage. Either result is unacceptable and profoundly inconsistent with the protective nature of environmental and safety legislation.

The Bulletin protects industry assessments from scrutiny

Maybe because of the astoundingly broad reach of the Bulletin, the sectors that are exempted from coverage are worth some scrutiny. The Bulletin specifically does not apply to registration, approval, or licensing, and does not apply to product labels (II.2., p. 23). These are specific agency responsibilities that heavily rely on data and risk assessments provided by the product registrant, i.e. the product manufacturer, producer, or supplier. For example, the registration of pesticides and agricultural pesticides relies almost exclusively on toxicity and exposure data sponsored by the registrant, usually unpublished, and not accessible to the public. This Bulletin protects from scrutiny the risk information that is most likely to be biased, weak, incomplete, and unreliable.

Numerous examples of biased industry science have been reported in the scientific literature: 1) U.S. Environmental Protection Agency (EPA) scientists compared the results from registrant-submitted mutagenicity studies to the EPA Office of Pesticide Programs with those from the published literature, and found a selection bias where registrant-submitted studies on atrazine mutagenicity all reported no mutagenic activity, whereas over a dozen studies in the published literature reported mutagenic activity.[5] 2) An analysis of studies submitted to EPA on the effects of atrazine on frog reproductive development reported that financial sponsorship was a strong predictor of study outcome (p=0.009); funding sources varied for studies reporting adverse effects (including government and industry funding) whereas all of the studies that failed to detect adverse effects were funded by the manufacturer of atrazine.[6] 3) An analysis of 115 published studies on low-dose effects of the plastics-component Bisphenol A found that over 90% of government-funded studies reported significant low-dose effects, whereas none of the industry-funded studies did, and that, "Some industry-funded studies have ignored the results of positive controls, and many studies

[5] Dearfield KL, Stack HF, Quest JA, Whiting RJ, Waters MD. 1993. A survey of EPA/OPP and open literature data on selected pesticide chemicals tested for mutagenicity. I. Introduction and first ten chemicals. Mutat Res 297(3):197-233.

[6] Hayes T. 2004. There is no denying this: defusing the confusion about atrazine. BioSci 54(12):1138-1149.

reporting no significant effects used a strain of rat that is inappropriate for the study of estrogenic responses".[7] 4) Studies of documents from the tobacco industry archives have revealed evidence of concerted industry efforts to obscure the contribution of secondhand smoke and other environmental toxics to disease through the development of their own version of "good epidemiological practices" and "sound science".[8] As Professor Wendy Wagner reported in her recent article, a close examination of instances of scientific misdeeds showed little evidence that the ostensible target of the guidance – federal agency studies – have shown a pattern of bias.[9] In other words, as others have already asked, what problem does this bulletin fix?

The broad sweep taken by this Bulletin in its definition of risk assessment and specific inclusion of exposure and other assessments makes it unlikely that it was by accident that the Bulletin forces itself on data that supports regulatory action, but carves out a specific exception for industry data.

The Bulletin forces itself upon scientific and policy issues

The Bulletin forces economic analyses to precede risk assessments. The Bulletin states that the scope and content of each risk assessment "shall" consider the "benefits and costs of acquiring additional information before undertaking the assessment" (III.2). At one level, it is a good idea to ensure that there is real value to the additional information. But the requirement of a full assessment is unfair and unreasonable. It forces each risk assessment to undertake a full evaluation of the costs and benefits of conducting the assessment prior to initiating any and all assessments across all federal agencies

[7] vom Saal FS, Hughes C. 2005. An extensive new literature concerning low-dose effects of bisphenol A shows the need for a new risk assessment. Environ Health Perspect 113(8):926-933.

[8] Ong EK, Glantz SA. 2001. Constructing "sound science" and "good epidemiology": tobacco, lawyers, and public relations firms. Am J Public Health 91(11):1749-1757.

[9] Wendy E. Wagner, The "Bad Science" Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation, 66(fall) Law & Contemp. Problems 63 (2003)

and under all conditions. The need to gather information and data should not be *a priori* contingent on an economic calculation. Moreover, it is unclear if the cost benefit analysis needs to comply with this Bulletin? If it does, this obvious tautology appears to lead to an unending pre-assessment analysis. If not, it seems rather ironic and disingenuous that an economic analysis that does not have to meet any standards of quality can be used to prevent a quality assessment from being initiated.

The Bulletin forces an unconventional scientific definition that dismisses early molecular events as non-adverse. The Bulletin states that, "where human health effects are a concern, determinations of which effects are adverse shall be specifically identified and justified…" (V.7., p. 25). This is an inappropriate attempt to force a scientific issue and a subsequent policy decision into a direction that suits OMB. The Bulletin goes so far as to define an adverse effect as typically implying "some functional impairment or pathological lesion that affects the performance of the whole organism or reduces an organism's ability to withstand or respond to additional environmental challenges" (p. 20). From the earliest periods of environmental law to the present, courts (e.g., Lead Industries) have recognized that effects that are precursors of frank illness are legitimate and indeed important markers to effectuate the protective goals of environmental legislation. NRDC agrees with OMB that delineating an adverse effect from a pre-adverse or non-adverse effect is becoming increasingly relevant as the scientific frontier of knowledge advances into molecular epidemiology, genotoxicology, and other sophisticated scientific arenas. It is clear now that each interaction between our bodies and the outside environment will induce thousands of cellular and molecular responses, and that a multi-disciplinary scientific discourse will be required to identify transient or homeostatic responses from those that are likely to induce permanent alterations such as cancer or neurological impairments. However, this cuts in the opposite direction from the directive, suggesting that earlier precursors rather than later ones will be increasingly important. Moreover – and especially in this period of rapid scientific advance – it is not the role of the White House, OMB, or even of

risk assessment to force the scientific discourse in a direction that *a priori* dismisses early molecular events as non-adverse.

Perchlorate is an example of OMB favoring the answer it wants over a rigorous risk assessment. Although OMB has been touting perchlorate as an example of a poorly-conducted EPA assessment that benefited from the more rigorous risk assessment performed by the National Academies,[10] nothing could be farther from the truth. In fact, whereas the National Academies does not perform risk assessment (only hazard assessment) and did not include any risk assessors on its scientific committee, the EPA assessment was a true risk assessment; it was quantitative, it included both exposure and hazard components, it considered each and every toxicological study ever done on perchlorate, it reviewed both published and unpublished studies, and it was a rigorous multi-agency intensive effort that spanned over a decade. However, the effort was delayed significantly by interference from the main polluters, the Department of Defense and its military contractors.[11] In 1998 the DOD and PSG contracted for more scientific studies on perchlorate toxicology,[12] but when EPA reported that the data supported a limit of no more than 1 ppb in water based on abnormal brain development in the offspring of perchlorate-exposed mother rodents,[13] PSG submitted a Data Quality Act petition against its own studies

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[10] Graham, J. Public presentation to the National Academies, May 22, 2006, and presentation to the Society for Risk Analysis, May 23, 2006. Washington, DC

[11] for a detailed review of the perchlorate assessment, see: Sass, J. (2004) US Department of Defense and White House working together to avoid cleanup and liability for perchlorate pollution. Int J Occup Env Health, 10: 330-334.

[12] Developmental Neurotoxicity Study, Argus Research Laboratories, 1998. Repeat morphometry with Argus 2001 Effects Study. Repeat DNT performed by US Navy, Bekkedal et al, 2000.

[13] Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (2002 External Review Draft). U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC, NCEA-1-0503, 2002.

claiming the data was of too poor quality to be useful.[14] With DOD and the polluters digging in their heels, the EPA risk assessment was sent to the National Academies, where a hazard assessment was performed of the available toxicity data. EPA relied on the National Academies hazard assessment to set a preliminary remediation goal of 24.5 ppb for cleanup. From this example, the most obvious lesson learned is that OMB is not the appropriate arbiter of risk assessment.

The Bulletin forces agencies to devote equal time to flat-earthers and other scientists-for-hire. In numerous places the Bulletin forces agencies to respond to any and all submissions, comments, hypotheses, analyses, and alternate analyses, as if each were of equal scientific value. The Bulletin specifically states that an agency risk assessment must be "scientifically objective" by "giving weight to both positive and negative studies in light of each study's technical quality", and in an "unbiased manner" (IV.4., p. 24). In fact, all studies are not equal and should not be given equal weight.

The regulated industries are known to seed the scientific literature with "anti-data" that reports on the absence of harm from its products or processes. This is the negative data that the Bulletin specifically forces the agencies to contend with. In one of the most egregious examples of White House data manipulation, this past June (June 08, 2005) a top White House environmental official and former oil industry lobbyist, Phillip A. Cooney, was shown to have repeatedly manipulated government reports to downplay the threat of global warming. Documents obtained by the Government Accountability Project revealed that between 2002 and 2003, Cooney, the chief of staff for the White House Council on Environmental Quality, edited drafts of climate change reports to weaken their conclusions that human activity contributes to global warming.

Forcing regulators to give equal weight to negative data is not likely an accidental or unintended effect of this Bulletin. Manufacturing uncertainty to

[14] Girard, M. Letter from the Chairman, Perchlorate Study Group submitted to U.S. EPA Information Quality Guidelines staff. Aerojet, Sacramento, CA. December 3, 2003

force agency inaction is often exactly what industry and OMB may seek to accomplish with such proposals. The tobacco industry introduced the technique of manufactured doubt as a means to deny health impacts and delay regulation of its products: "*Doubt is our product since it is the best means of competing with the 'body of fact' that exists in the mind of the general public. It is also a means of establishing controversy*." (1969 internal tobacco industry memo, stamped "confidential") Studies of documents from the tobacco industry archives have revealed evidence of concerted industry efforts to obscure the contribution of secondhand smoke and other environmental toxics to disease through the development of their own version of "good epidemiological practices" and "sound science", thereby infusing the scientific literature with "anti-data" intended to obfuscate scientific consensus (Ong and Glantz 2001). The OMB Bulletin stands in a long tradition of infusing uncertainty, subjecting evidence of harm to repeated challenges *ad infinitum*, and derailing or delaying regulatory actions.

OMB has not presented a compelling empirical justification for forcing a one-size-must-fit-all approach for all agencies. OMB insists on empirical evidence in the rulemaking process. But the Bulletin lacks any empirical evidence about the nature and extent of the problems with risk assessment practices in each of the agencies. The Bulletin only contains general pronouncements that the risk assessment process can be improved to be better understood, transparent, and more objective. Without knowing the specificity of the problems that the agencies and interested stakeholders are confronting, it becomes difficult to craft an appropriate solution or solutions.

Instead of presenting empirical evidence of the problems, OMB leaped to a solution, but again it failed to provide any evidence demonstrating the efficacy of its proposed one-size-fits-all solution for all agencies.

By rushing to judgment, OMB's Bulletin would effectively force the government to engage in a vast, unwieldy experiment. What is appropriate and necessary for the Food and Drug Administration in calculating and conducting risk assessments may not be appropriate for the Environmental Protection

Agency, for example, because different agencies have important differences in their statutory and regulatory mandates and procedural strictures. Likewise, the level of scientific rigor that a full risk assessment may undergo is likely to be far to stringent for a screening level assessment, a simple exposure assessment, a limited site-specific assessment, or a non-quantitative risk assessment such as the EPA IRIS program, the CDC NHANES biomonitoring data, or the NIEHS Report on Carcinogens. The Bulletin strips federal experts of the ability to exercise expert judgment in developing assessments that are site-specific, timely, and responsive.

OMB has not presented any legal basis giving it the authority to effectively amend eviscerate existing statutory mandates. Although NRDC agrees that improvements should be made in agency risk assessment practices, we are troubled that OMB did not present any legal basis for engaging in this reform endeavor, which will effectively eviscerate existing statutory mandates by requiring the calculation of "central" risk estimates and the quantification of remedial costs as part of a risk assessment for health-based statutes. Whatever authorities OMB may have, it is only through a tortured interpretation of existing law that OMB could derive implicit authority to effectively amend virtually all of the nation's public health, safety, and environmental laws that are premised on the precautionary principle.

The Clean Air Act is such a statute. Section 109 of the Clean Air Act instructs EPA to use a health-based standard for setting ambient air quality standards. In setting the levels, the U.S. Supreme Court has consistently held that the statute and its legislative history make clear that economic considerations should play no part. Consequently, it would be unlawful for OMB to require the agency to quantify costs of proposed standards as part of its risk assessment. Because Congress never implicitly or expressly empowered OMB to amend these statutes by executive fiat, we therefore urge OMB to withdraw its Proposed Bulletin.

Judicial review

A special section, XI, on judicial review states that the Bulletin, "is not intended to, and does not create any right or benefit, substantive or procedural, enforceable at law or in equity, against the Unites States, its agencies or other entities, its officers or employees, or any other person" (XI. p. 26). A press release issued by the U.S. Chamber of Commerce last week (May 18, 2006) stated, "*If the Bulletin is not judicially reviewable, then agencies can ignore it," said William Kovacs, vice president of the Chamber's environment, technology & regulatory affairs division. "What measures will OMB undertake to ensure that the agencies follow the instructions set out in the Bulletin? Unfortunately, the Bulletin lacks clarity on this important matter*."[15] The Chamber of Commerce is correct that OMB has been disconcertingly vague on this critical issue. Is it any wonder that Corporate America wants to increase the force of this Bulletin? It is very likely to bring regulatory actions to a stand-still, especially if outside parties like the Chamber of Commerce can bring a legal challenge against the agencies every time they step out of the straightjacket that this Bulletin places around them.

CONCLUSION

As it is now proposed, this Bulletin contains several significant weaknesses that are likely to be used by industry and the regulated community to challenge regulatory actions *ad infinitum*. The Bulletin imposes costly and time-consuming burdens on federal agencies to respond to challenges by outside parties. It is unnecessarily broad in its application and gives little or no deference to the judgments of the agencies which have the actual scientific expertise to conduct and evaluate risk analyses. It is unfairly burdensome to regulators while giving industry assessments a free pass. And, it pre-ordains a built-in bias against issuance of health protection on key scientific and policy issues. Most concerning

[15] U.S. Chamber of Commerce Press Statement. U.S. Chamber: OMB Risk Assessment Bulletin Must Be Judicially Reviewable. May 18, 2006. http://www.uschamber.info/ct/u12v2W91xzO9/

is that despite these biases towards industry interests, the Bulletin is mandatory as opposed to providing guidance or recommendations. If it is truly the goal of OMB to "provide clear, minimum standards for the scientific quality of federal agency risk assessments"[16], then it should clearly state that it is guidance only and not prescriptive, that it is not judicially reviewable, and that it is not applicable to all assessments in all situations.

REQUEST FOR RESPONSE FROM OMB

1. OMB's Risk Assessment Bulletin appears to require agencies to conduct cost-benefit analysis and comparative risk assessment to be done in conjunction with risk assessments. What legal authority, if any, authorizes OMB to require agencies to conduct cost-benefit and comparative risk assessment when doing so may contravene the underlying statute?

2. Given that OMB often demands evidence in the rulemaking process, what are the problems with the current implementation of agency risk assessments that lead OMB to conclude its Risk Assessment Bulletin was necessary? What problem is OMB trying to fix, and how will this broad and forceful Bulletin fix that problem without creating new ones?

3. The proposed risk assessment guidance directs agencies to perform substantial analysis to estimate benefits, which can be used as part of cost-benefit analysis. However, there is no corresponding guidance that requires equivalent detailed analytical rigor when estimating costs. Does OMB intend that cost estimation must requires at least as much attention to uncertainty and variability for costs as it does for benefits? If so, why is this not stated in the Bulletin?

[16] Office of Management and Budget. Press release. OMB requests peer review of proposed risk assessment bulletin. January 9, 2006.

4. Please provide the public with an estimate of the additional costs each agency will incur annually to produce risk assessments under the Risk Assessment Bulletin and an estimate of the corresponding benefits in terms of improved risk analysis.

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Meeting Record Regarding: Lead; Renovation, Repair, and Painting Progrm

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Date: 1/15/2008

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Materials provided to OMB (2 pages, 227 kb)

Economic Analysis for the Renovation, Repair, and Painting Program Proposed Rule

Economic and Policy Analysis Branch
Economics, Exposure and Technology Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

February 2006

Executive Summary

This report presents an economic analysis of alternative regulatory options to establish work practice standards, plus training and certification requirements, for persons engaged in renovation activities for compensation in housing units containing lead-based paint. These requirements apply to contractors who renovate, remodel and/or paint housing units where there is lead-based paint, as well as to residential building owners and managers who may perform these activities themselves or have their staff do so. The regulation is being proposed under authority of §402(c) of the Toxic Substances Control Act (TSCA). Title IV of TSCA was established by the Residential Lead-Based Paint Hazard Reduction Act of 1992, also known as Title X of the Housing and Community Development Act of 1992 (Public Law 102-550).

Past use of lead-based paint has resulted in contamination that continues to pose human health hazards. Disturbing the lead-based paint, such as happens during renovation activities, is likely to create lead hazards. Since many residences built before 1978 have lead-based paint, it is likely that renovation activities occurring in these units will contribute to lead hazards unless appropriate containment and clean-up practices are employed. The Renovation, Repair and Painting (RRP) Rule is designed to prevent lead hazards from renovation activities.

The training and work practice standards required and fostered by the proposed RRP rule will yield health benefits to individuals living in renovated units and to their neighbors. The proposed rule will reduce lead exposure by containing the lead contamination generated by renovation activities and reducing the amount of such contamination remaining after completion of the activities. EPA anticipates that the rule will further develop a market for lead-safe renovation services that has been established by past lead awareness rules, such as the §406(b) rule which requires compensated renovators to distribute lead awareness pamphlets to owners and occupants of most pre-1978 residential housing before beginning renovations.

The proposed rule requires certification of firms (including self-employed contractors and property manager/lessors) that perform renovation, remodeling and/or painting in housing units subject to the regulations. A certified firm must assign to each renovation performed by the firm at least one renovator who has received formal training in EPA-approved work practices from an EPA-accredited course. In addition, certified firms must provide on-the-job training in these approved work practices for the rest of their staff who will be performing RRP activities in regulated housing. The proposed rule also requires containment of the work area to prevent the spread of dust and debris, specialized cleaning practices, and cleaning verification procedures to ensure that proper cleanup has occurred.

EPA considered two regulatory approaches: prescriptive and flexible regulations for the proposed work practice standards. Under the prescriptive approach, EPA would require the use of specific work practices for all RRP jobs covered under the rule and that are at risk of causing lead contamination. The flexible approach relies on the required training, and the renovator's own experience, to determine the extent of containment needed in any particular situation. The flexible approach increases the cost effectiveness of the regulation by reducing work practice costs.

This economic analysis considers four regulatory options with two phases. In Phase 1, Option A addresses pre-1978 housing, Option B and D both address pre-1960 housing, and Option C addresses pre-1950 housing. In Phase 2, all the options address pre-1978 housing. In both phases coverage of the rule is limited to rental housing and owner-occupied housing where a child under the age of six resides. Table ES-1 describes the housing stock subject to the regulations under each of the four options. Options A, B

and C are flexible in terms of the application of specific work practices while Option D is prescriptive. EPA is proposing Option B.

Table ES-1: Definitions of the Regulatory Options

	First Year – Phase 1	Second Year – Phase 2
Option A	All renter-occupied target housing units built before 1978, and owner-occupied target housing units built before 1978 where a child under the age of six resides. Flexible application of work practices	All renter-occupied target housing built before 1978, and owner-occupied target housing units built before 1978 where a child under the age of six resides. Flexible application of work practices
Option B	All renter-occupied target housing units built before 1960, and owner-occupied target housing units built before 1960 where a child under the age of six resides, plus all target housing units built before 1978 where a child with an increased blood-lead level resides.[a] Flexible application of work practices	Same as Option A.
Option C	All renter-occupied target housing units built before 1950, and owner-occupied target housing units built before 1950 where a child under the age of six resides, plus all target housing units built before 1978 where a child with an increased blood-lead level resides.[a] Flexible application of work practices	Same as Option A.
Option D	The prescriptive option. Covers the same housing units as Option B – but requires specific work practices.	The prescriptive option. Covers the same housing units as Option B – but requires specific work practices.

[a] Where increased is defined as greater than or equal to 10 µg/dL or a State or local government level of concern, if lower.
The proposed rule is Option B.

Cost of the Various Options

For purposes of this analysis, the costs associated with the regulatory impact of the Renovation, Repair, and Painting (RRP) Rule are divided into three categories: (1) training costs, (2) work practice costs, and (3) certification costs (which include the firm's paperwork burden and government administrative and enforcement costs). The general approach of the analysis is to first estimate the number of affected activities or entities, then estimate the incremental regulatory cost per-activity or entity affected. Finally, the incremental costs and the number of affected activities and entities are combined to estimate the total costs.

The number of RRP events covered by the rule varies across regulatory options in Phase 1 because the coverage of the regulation in Phase 1 varies across options, but under any of the options the number of events covered is substantial, as are the number of events that are performed in compliance with the rule. As shown in Table ES-2, approximately 10.7 million events per year would be conducted in compliance with the rule under Option A. Slightly more than one-half this amount, about 5.8 million events, would be conducted in compliance with the rule in the first year under Options B and D. In the first year, about 4.3 million events would be conducted in compliance with the rule under Option C. (Based on existing

literature about regulatory compliance rates in the construction industry, the analysis assumes that 75 percent of events in regulated housing are conducted in compliance with the rule.) In Phase 2 of the rule, the number of RRP events conducted in compliance with the rule is the same for all four options, about 4.4 million events per year.

Because not all housing units built before 1978 have lead-based paint, the number of RRP events that need to use lead safe work practices (LSWP) is a subset of the total number of units covered by the rule. In Phase 1, between 8.1 million (Option A) and 3.7 million (Option C) events will use LSWP. In Phase 2, an estimated 4.4 million RRP events will be using LSWP. Despite the increased coverage of the rule in Phase 2, the number of events with LSWP in Phase 2 is smaller than in Phase 1 because the accuracy of lead paint test kits in terms of detecting the presence or absence of lead is expected to have improved by then. The current tests have a high false positive rate (estimated to average 63 percent), resulting in the frequent use of LSWP when they are not necessary, i.e., when lead is not present. The improved tests are expected to have a false positive rate of 10 percent.

Table ES-2: Number of RRP Events

Description of Options				Number of Events per Year (millions)			
	Phase 1 Scope	Phase 2 Scope	Work Practices Flexible?	Phase 1 Events	Phase 1 Events with LSWP	Phase 2 Events	Phase 2 Events with LSWP
Option A[a]	Pre-78 R/C	Pre-78 R/C	Yes	10.7	8.1	10.7	4.4
Option B[a]	Pre-60 R/C	Pre-78 R/C	Yes	5.8	4.8	10.7	4.4
Option C[a]	Pre-50 R/C	Pre-78 R/C	Yes	4.3	3.7	10.7	4.4
Option D[a]	Pre-60 R/C	Pre-78 R/C	No	5.8	4.8	10.7	4.4

Notes:
R/C = All rental units plus owner-occupied units with children under the age of 6 years
LSWP = Lead Safe Work Practices
Number of events assumes 75% post-rule compliance
In Phase I, paint spot tests assumed to have a false positive rate of 63%, in Phase 2 they are assumed to have a 10% false positive rate.

[a] About 65 percent of U.S. households reside in buildings constructed before 1980, 34 percent reside in buildings constructed before 1960 and 22 percent reside in building constructed before 1950. Approximately 58 percent of all RRP events in pre-1978 and pre-1960 housing take place in renter-occupied or child-occupied housing. This percentage is slightly higher (about 63 percent) for RRP events in pre-1950 housing.

Work practice costs are estimated for each of several types of RRP events and for different sizes of housing units. These unit costs are multiplied by the number of events of each RRP type and housing type to estimate the total work practice-related costs for each regulatory option. The RRP events and the range of unit costs associated with each type are shown in Table ES-3.

Table ES-3: Summary of Housing Unit Containment, Cleaning, and Verification Compliance Costs (2005$)		
Event Type	**Range of Costs per Event**	
	Low	**High**
Kitchen Remodel	$28	$132
Bathroom Remodel	$23	$63
Additions	$26	$117
Non-Room-Specific Interior Wall[a]	$57	$528
Non-Room-Specific Window/Door[b]	$58	$528
Interior Paint	$42	$285
Whole Exterior Remodel	$161	$281
Exterior Remodel in Contained Area[c]	$77	$77
Exterior Paint	$161	$281

[a] Events that involve changes to a wall or walls, where the location is not specified. For example: re-wiring or repair/replace heating or cooling systems.
[b] Repair/replacement of windows and/or doors, where the room is not specified.
[c] Outside repair/remodeling work that involves a specified part of the home, e.g. installation of a deck.
Source: See Section 4.5.8.

In addition to the number of covered RRP events in compliance with the rule and their unit costs, the other major factors in determining the costs of the rule are the number of firms certified, the number of personnel trained, and the costs of training and certification. All of the regulatory options require that each certified firm (including property managers and lessors who perform their own RRP work in regulated housing, as well as construction firms conducting RRP in regulated housing) employ at least one renovator who has taken an EPA-accredited training course and provide on-the-job training for all other staff who will be performing RRP activities in regulated housing. As shown in Table ES-4, the number of firms certified and the number of persons trained expands as the coverage of the rule expands. Thus Options B/D and C have larger numbers in the first year of Phase 2 than does Option A. By the second year of Phase 2, the number of firms certified and persons trained each year has leveled out to approximately 54 thousand firms certified or recertified, approximately 62 thousand renovators taking training or refresher courses, and nearly 277 thousand other workers getting on-the-job training each year.

Table ES-4: Estimated Number of Establishments Seeking Certification and Workers and Renovators Seeking Training			
	Option A[a]	**Options B & D[a]**	**Option C[a]**
Year 1			
Total Number of Establishments (with Employees and without) Seeking Certification [c]	163,979	86,539	59,571
Total Number of Renovators Trained [b,c]	186,811	98,588	67,866
Total Number of Workers Trained [b,c]	279,221	147,357	101,437
Year 2			
Total Number of Establishments (with Employees and without) Seeking Certification [c]	54,436	105,851	123,756
Total Number of Renovators Trained [b,c]	62,015	120,589	140,987
Total Number of Workers Trained [b,c]	278,076	278,076	278,076
Year 3			
Total Number of Establishments (with Employees and without) Seeking Certification [c]	54,212	54,212	54,212
Total Number of Renovators Trained [b,c]	61,761	61,761	61,761
Total Number of Workers Trained [b,c]	276,935	276,935	276,935

[a] About 65 percent of U.S. households reside in buildings constructed before 1980, 34 percent reside in buildings constructed before 1960 and 22 percent reside in building constructed before 1950. Approximately 58 percent of all RRP events in pre-1978 and pre-1960 housing take place in renter-occupied target housing units and owner-occupied target housing units where a child under the age of six resides. This percentage is slightly higher (about 63 percent) for RRP events in pre-1950 housing. Of the regulated housing, 75 percent are assumed to comply with the regulations.

[b] Components may not add up to totals due to rounding.

[c] The number of firms and individuals certified and trained, respectively, is reduced by 0.04 percent per year to account for housing that is removed from the regulated housing stock due to demolition or conversion to non-housing uses. Thus the demand for lead-safe renovation services is reduced over time.

See Table ES-1 for option descriptions.

Source: EPA calculations – see Section 4.3.

The costs of the various regulatory options follow the number of events, with Option A having the largest costs under Phase 1 (see Table ES-5). Option D costs exceed the costs of Option B, even though they cover the same units, because Option D provides less flexibility in defining the extent of the area to be contained and cleaned. Option A costs decline substantially in Phase 2 for two reasons. First, most of the initial training and certification costs for Option A have been borne in Phase 1, while under Options B, C and D, a substantial amount of initial training and certification is occurring in Phase 2. Second, with the improved lead paint test kits available in Phase 2, the number of RRP events that use LSWP declines for all the options. The 50-year annualized costs provide a measure of the steady-state costs for each option. As shown, once the initial start-up costs have been absorbed, Options A through C have relatively similar annual costs of between $488 million and $505 million, using a 3 percent discount rate, or between $518 million and $551 million using a 7 percent discount rate. Option D continues to have substantially higher costs due to its prescriptive nature.

The cost estimates account for the RRP events in the baseline that already use some of the work practices to be required under this rule. In situations where contractors are already using these practices they will experience a smaller increase in operating costs, which is accounted for in the cost estimates. All

contractors that perform RRP in regulated housing, however, will incur the training and certification costs due to the rule.

Table ES-5: Estimated Total Costs

Description of Options				Costs (millions 2005$)			
	Phase 1 Scope	Phase 2 Scope	Work Practices Flexible?	Phase 1	Phase 2	50-Year Annualized	
						3% Discount Rate	7% Discount Rate
Option A	Pre-78 R/C	Pre-78 R/C	Yes	$ 924	$ 495	$ 505	$ 551
Option B	Pre-60 R/C	Pre-78 R/C	Yes	$ 531	$ 552	$ 492	$ 526
Option C	Pre-50 R/C	Pre-78 R/C	Yes	$ 393	$ 572	$ 488	$ 518
Option D	Pre-60 R/C	Pre-78 R/C	No	$ 645	$ 649	$ 588	$ 629

Notes:
R/C = All rental units plus owner-occupied units with children under the age of 6 years
Assumes 75% post-rule compliance
In Phase I, lead paint test kits are assumed to have a false positive rate of 63%, in Phase 2 they are assumed to have a 10% false positive rate

Benefits of the Rule

The number of people protected by this rule varies with the variation in the universe of housing units covered by the rule. In Phase 1, Option A covers the largest number of individuals, including the largest number of children under the age of six years (see Table ES-6). By Phase 2, all options cover nearly 5.3 million individuals per year, including over 780 thousand children under the age of six years old. Similar to the cost estimates, the number of individuals and children protected assumes that 75 percent of RRP work will be in compliance after the rule takes effect, and that there is some baseline use of LSWP. Based on the limited amount of information currently available about the baseline use of LSWP, the analysis assumes that approximately 20 percent of individuals and children living in regulated units with RRP already receive the benefits that the rule would provide.

As discussed earlier, based on other compliance studies, this analysis assumes a compliance rate of 75 percent. However, the Agency's goal continues to be 100 percent compliance. If that goal were achieved, then over 1 million children under the age of six years old would be protected by the rule. At that rate, however, both the costs and the benefits would be higher than shown in the other tables.

Table ES-6: Number of Individuals Protected by the Regulatory Options

Description of Options				Number of Individuals Occupying Units with LBP, where LSWP are Used Due to the Rule[a] (thousands per year)				
				Children under 6 Years of Age			All Individuals	
	Phase 1 Scope	Phase 2 Scope	Work Practices Flexible?	75% Compliance Rate		100% Compliance Rate[b]	75% Compliance Rate	
				Phase 1	Phase 2	Phase 2	Phase 1	Phase 2
Option A	Pre-78 R/C	Pre-78 R/C	Yes	787	783	1,138	5,309	5,287
Option B	Pre-60 R/C	Pre-78 R/C	Yes	668	783	1,138	4,529	5,287
Option C	Pre-50 R/C	Pre-78 R/C	Yes	520	783	1,138	3,659	5,287
Option D	Pre-60 R/C	Pre-78 R/C	No	668	783	1,138	4,529	5,287

Notes:
R/C = All rental units plus owner-occupied units with children under the age of 6 years
LSWP = Lead Safe Work Practices
In Phase 1, lead paint test kits are assumed to have false positive rate of 63%, in Phase 2 they are assumed to have a 10% false positive rate
[a]Number of individuals is incremental above those occupying units where LSWP are currently practiced in the baseline.
[b] If 100 percent compliance were achieved, both the costs and the benefits would be higher than shown in the tables based on 75 percent compliance.

Lead causes a number of adverse health effects in people of all ages. Of particular concern are children under the age of six years, but older children and adults also suffer effects from lead exposure In this analysis, only a few of these health effects have been quantified. One of the factors restricting the scope of the benefits estimation is the limited amount of available data, including well-specified dose response relationships, on which to quantify and monetize many of the health and developmental effects. Therefore this benefits assessment focuses on two major categories of health effects: effects on cognitive function in young children (under the age of six) and cardiovascular disease (hypertension, coronary heart disease and stroke) and premature mortality in adults. There are additional uncertainties in the quantification of adult effects, which are addressed in Section 5.5.5.

Even where the dose-response relationships are known, many cases are not included in the estimates because exposure levels cannot be estimated for all potentially affected individuals. For example, the benefit estimates presented in this report are based on reductions in lead ingestion; they do not include reductions in lead inhalation, although that is also likely to occur. Likewise, benefits are estimated only for people living in the housing units; they do not include potential benefits to visitors or neighbors. In addition, ecological benefits, as well as benefits to family pets, are not included in the estimates.

It is important to note that the monetary values assigned to the avoided adverse health effects are based on medical costs avoided, not willingness-to-pay to avoid these ailments and/or premature death. Likewise, the value of the IQ points that will be gained due to this rule are valued in terms of increased earnings, not willingness-to-pay.[1]

[1] Note that dose-response functions only allow for estimating IQ impacts among children less than six years of age, and the health effects only for adults over the age of 40. Other groups who are among the total individuals occupying units with lead-based paint in Table ES-6 are not included in the benefit estimates.

This analysis estimates the benefits of the proposed regulation in terms of IQ deficits in children and increased blood pressure and related health effects in adults. Quantitative estimates of benefits are provided in two scenarios. Scenario 1 quantifies benefits for both children and adults. Scenario 2 assumes additional cleaning in the baseline compared to Scenario 1, and only quantifies benefits for children. This approach is in recognition of the relatively larger uncertainties associated with adult health effects (pending completion of other EPA documents), as well as the particular concern about children expressed in Title X of the Residential Lead-Based Paint Hazard Reduction Act of 1992. The Agency is more confident in the estimates for children's IQ effects then it is for the estimates of adult benefits. While recognizing that adults may also benefit from the training and practices required under the rule, Scenario 2 does not try to quantify these benefits due to the uncertainties that currently exist.

Net Benefits

Based on the subset of benefits that have been monetized in this analysis, Table ES-7 and Table ES-8 display the annualized net benefits estimated for the four regulatory options under Scenarios 1 and 2, respectively. Each table presents annualized net benefits calculated at both a 3 percent and a 7 percent discount rate. Net benefits under Scenario 1 are substantially greater than those under Scenario 2. Scenario 1 assumes less baseline cleaning than Scenario 2 and it quantifies adult health benefits as well as children's IQ benefits. Under either Scenario, annualized net benefits calculated using a 7 percent discount rate are slightly larger than those calculated using a 3 percent discount rate. Under both scenarios and all options net benefits are positive, i.e., the benefits are larger than the costs.

When comparing options on the basis of annualized net benefits, there is relatively little difference among the three flexible options (Options A, B and C). This is not surprising, since the primary differences in these options occur in the first year the rule takes effect. After that year, all options address the same universe of pre-1978 housing. And after the second year, the population of firms and renovators being trained and re-trained levels off to approximately the same number each year. The only substantial difference is between the flexible options and the prescriptive Option D. The lack of flexibility appears as a roughly $100 - $150 million reduction in annualized net benefits as compared to the other options.

Table ES-7: Comparison of Options – Scenario 1 -- Annualized Costs and Net Benefits					
	Annualized Cost (millions 2005$)[a]	**Children's IQ Benefits – Annualized (millions 2005$)[b]**	**Adult Health Benefits – Annualized (millions 2005$) [b]**	**Sum of Children's IQ and Adult Benefits -- Annualized (millions 2005$)**	**Net Benefits – Children's IQ and Adult Health -- Annualized [c] (millions 2005$)**
	Annualized using 3 Percent Discount Rate				
Option A	$ 505	$947 - $5,336	$2,262	$3,209 - $7,599	$2,704 - $7,093
Option B	$ 492	$941 - $5,311	$2,250	$3,191 - $7,562	$2,699 - $7,069
Option C	$ 488	$934 - $5,267	$2,235	$3,170 - $7,503	$2,682 - $7,015
Option D	$ 588	$941 - $5,311	$2,250	$3,191 - $7,562	$2,603 - $6,973
	Annualized using 7 Percent Discount Rate				
Option A	$551	$1,008 - $5,680	$2,408	$3,415 - $8,087	$2,865 - $7,537
Option B	$526	$997 - $5,633	$2,385	$3,383 - $8,019	$2,857 - $7,493
Option C	$518	$984 - $5,551	$2,358	$3,342 - $7,909	$2,824 - $7,391
Option D	$629	$997 - $5,633	$2,385	$3,383 - $8,019	$2,754 - $7,390

[a] Developed in Chapter 4

[b] Developed in Chapter 5 – range for children's IQ benefits reflects alternative models for blood lead, exposure estimates and population of children

[c] Difference between sum of benefits and costs

Table ES-8: Comparison of Options – Scenario 2[a] – Annualized Costs and Net Benefits			
	Annualized Cost[b] (millions 2005$)	**Children's IQ Benefits – Annualized[c] (millions 2005$)**	**Net Benefits[d] – Children's IQ Only (millions 2005$)**
Annualized using 3 Percent Discount Rate			
Option A	$ 505	$774 - $4,354	$269 - $3,849
Option B	$ 492	$770 - $4,329	$277 - $3,837
Option C	$ 488	$764 - $4,298	$276 - $3,810
Option D	$ 588	$770 - $4,329	$181 - $3,741
Annualized using 7 Percent Discount Rate			
Option A	$551	$824 - $4,635	$273 - $4,084
Option B	$526	$816 - $4,587	$290 - $4,061
Option C	$518	$805 - $4,530	$287 - $4,012
Option D	$629	$816 - $4,587	$187 - $3,958

[a] While recognizing that adults will benefit from the rule, Scenario 2 does not try to quantify adult benefits. There are additional uncertainties in the quantification of adult effects, which are addressed in Section 5.5.5.

[b] Developed in Chapter 4

[c] Developed in Chapter 5 – range reflects alternative models for blood lead, exposure estimates and population of children

[d] Difference between sum of benefits and costs

NIPPING IRIS IN THE BUD: SUPPRESSION OF ENVIRONMENTAL SCIENCE BY THE BUSH ADMINISTRATION'S OFFICE OF MANAGEMENT AND BUDGET

A staff report by the Majority Staff of the Subcommittee on Investigations and Oversight
for Subcommittee Chairman Brad Miller
Committee on Science and Technology
U.S. House of Representatives

June 11, 2009

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NIPPING IRIS IN THE BUD: SUPPRESSION OF ENVIRONMENTAL SCIENCE BY THE BUSH ADMINISTRATION'S OFFICE OF MANAGEMENT AND BUDGET

By the end of the Bush Administration, the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) process was broken. What began two decades ago as an initiative at EPA to establish a reliable database on what science said about the risks of particular chemicals devolved by the end of the Bush Administration into a tortured round of interagency bickering, mediated and even stimulated by the Office of Information and Regulatory Affairs (OIRA). As a result of the IRIS process breaking down, public health offices across the country and around the world, as well as concerned citizens, were left without the reliable, expanding, up-to-date database of chemical risks that they had come to rely upon.

The Bush Administration's OIRA used its position at the top of the Executive branch to force EPA to undergo a multi-year, interagency review ostensibly designed to establish a new process for creating new or updated IRIS database entries. At the same time, OIRA both supplied detailed scientific challenges to proposed IRIS entries and coordinated scientific comment from agencies across the government. OIRA's own scientific comments on proposed listings included detailed editorial comments that would have changed the import and meaning of the scientific findings in EPA's documents. All of this was done in secret, without any acknowledgement to the public or the Congress that OIRA was calling the shots.[1] IRIS was broken, not by accident, but through conscious, sustained effort from officials in OIRA.

1. The Subcommittee has carried out extensive work on OIRA's role in relationship to IRIS. In 2008, the Subcommittee held two hearings on this subject. The first of these hearings was on May 21, 2008, when the Subcommittee took testimony from Dr. George Gray, the then-Assistant Administrator for Research and Development at EPA, and Ms. Susan Dudley, the then-Administrator of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget. Additionally, Mr. John Stephenson of GAO testified on findings regarding the lack of productivity in the IRIS process. In the second hearing, on June 12, 2008, the Subcommittee received testimony from Mr. Jerry Ensminger (U.S.M.C., retired) , Mr. Lenny Seigel (Executive Director, Center for Public Environmental Oversight), and Dr. Linda Greer (Directer of the Health Program at the Natural Resources Defense Council). On June 11, 2008 Chairman Miller sent a document request to OMB asking for all materials relating to OIRA's involvement in the proposed IRIS entry for trichloroethylene (TCE). In response, the Committee received a few boxes of materials. The great majority of those materials were either peer reviewed articles, articles done by EPA staff, or research reports done under contract to industry or polluting agencies. Subcommittee staff were obliged to visit OMB's office to review thousands of pages of documents and take notes because the office refused to provide copies. A clear picture of OIRA's almost daily involvement on TCE emerged from that review. However, OIRA refused to provide access to most documents regarding interagency communications or internal communications surrounding TCE. Because the 110th Congress was drawing to a close, it was not practical to push for a subpoena for these records. We were never shown any document that could have been construed as having Executive Privilege attached to it. OIRA's entire approach appeared to amount to little more than obstruction of the work of the Subcommittee; in a sense, OIRA did to the Subcommittee's investigation what they have perfected in terms of slow-rolling IRIS proposals.

BACKGROUND

OIRA is a small office of some 50 career staff housed inside the Office of Management and Budget (OMB). With origins in the Paperwork Reduction Act of 1980, OIRA's role has expanded well beyond simply trying to reduce the paperwork burden on citizens and businesses to being the central White House voice, some would say choke-point, on regulations of all varieties. It has been OIRA that has most passionately and persistently insisted on using cost-benefit analysis in assessing proposed regulations, even in the face of criticism that such calculations tend to understate benefits because many of them are so hard to monetize, like the value of a human life.[2] Historically, it has been staffed by statisticians, economists and lawyers. There are real differences between the way OIRA operated under President Bill Clinton and under President George W. Bush, but there is a consistent theme of OIRA being a watchdog on what regulatory agencies were attempting to do to comply with statutes and, on occasion, court orders.

In the 110th Congress, at the direction of Subcommittee Chairman Brad Miller (D-NC), the Subcommittee on Investigations and Oversight looked very carefully at how OIRA was interfering with the science-based work of regulatory agencies. In addition to two hearings on Executive Order 13422, which the Bush Administration put in place to empower OIRA to control regulatory agendas at agencies across the government—an order the Obama Administration has now withdrawn--the Subcommittee held two hearings on the IRIS at EPA. IRIS provided a perfect example of how OIRA was branching out into challenging the science being done at regulatory agencies.

A chemical's entry in the IRIS database is nothing more than a science-based assessment of risks associated with a particular chemical. IRIS entries are produced in the Office of Research and Development (ORD) of EPA, and those entries are not an expression of regulatory intent or advice. The entries are not even all that is required of a complete risk assessment as defined in the seminal National Academies of Science report, *Risk Assessment in the Federal Government: Managing the Process* (1983).[3] And risk assessment is a long step away from a regulatory effort, which is described in the terminology of the panel as "risk management." However, the absence of IRIS entries for widely used, toxic chemicals leaves state and local regulators, first responders, and citizens without crucial information that can guide their response to an emergency or an emerging health or environmental threat.

OIRA has been involved in the IRIS process since the closing years of the Clinton

2 . "Life's Value Shrinks at EPA," Matthew Madia, OMB Watch, July 22, 2008.

3. In that 1983 report, "Risk Assessment in the Federal Government: Managing the Process," the National Research Council panel identified four components of a complete risk assessment: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. IRIS reflects science that addresses the first two conditions. In discussing the difference between risk assessment and risk management, the Academy panel wrote: "Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision." See the discussion on page 3 of the 1983 report.

Administration. Initially OIRA was pulled into the process to facilitate interagency discussions about particular chemicals proposed for IRIS listings. Agencies that had a record of pollution with certain chemicals were concerned that new IRIS standards would trigger the long march to new regulations and the end result would be that the polluting agencies would have to change their practices and clean up legacy wastes. Those who polluted saw that disputing what scientific research had found about the risks of a particular chemical could become the first line of defense against the distant possibility of regulation.[4] By the late 1990s, OIRA was playing a role as facilitator for interagency discussions regarding particularly contentious proposed IRIS listings.[5]

Suppressing IRIS entries essentially shuts down the flow of coherent, reliable information about what chemicals pose what kinds of risks. Testimony received by the Subcommittee at the second day of hearings on this subject emphasized the important role of IRIS as a public health and safety resource. That hearing, entitled, "Toxic Communities: How EPA's IRIS Program Fails the Public," took testimony from U.S.M.C. (retired) Master Sergeant Jerry Ensminger, the Executive Director of the Center for Public Environmental Oversight, Mr. Lenny Siegel, and Dr. Linda E. Greer, Director for Health Programs at the Natural Resources Defense Council. Mr. Ensminger was particularly compelling in making a case for why polluting agencies such as DOD should not be allowed privileged access to discussions about the science of potential pollutants.

> It is a known fact that the United States Department of Defense is our nation's largest polluter. It is beyond my comprehension why an entity with that type of reputation and who has a vested interest in seeing little to no environmental oversight would be included in the scientific process. Not only are they obstructing science, they are also jeopardizing the public health for millions of people all around the world... and yet this Administration and past Congresses have allowed DOD's tentacles to infiltrate the realm of science.[6]

Mr. Ensminger was stationed at Camp LeJeune. His daughter, Janey, died of acute

4 . This effort by polluters, or those who fear regulation of whatever stripe, of pushing the struggle back to what the science says about a particular risk rather than arguing over how to structure a regulation has been described as "paralysis by analysis." Science lends itself to endless study because there is never an absolute, final answer to any question, but always another layer of research that could add to the body of accumulated knowledge. If those who want to avoid regulation can shift the terms of discussion from the risk management end of the spectrum to the science and what uncertainties remain, a regulatory struggle need never begin. For analysis of how this process has unfolded among regulated industries, see, David Michaels, Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health, Oxford University Press, New York, 2008.

5 . A new report from the Center for Progressive Reform has some of this history. The Subcommittee was also able to review records from 1998 when OIRA first began to push into the interagency struggles over characterizing risks to former marines and their families from TCE and other chemicals at Camp LeJeune. At that time, OIRA's interest was more in the costs of the studies and making sure the then-proposed survey study met OIRA quality standards. OIRA reviews all survey instruments as part of its authority under the Paperwork Reduction Act of 1980.

6. "Toxic Communities: How EPA's IRIS Program Fails the Public," Hearing before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, June 12, 2008, p. 132.

lymposytic leukemia. Water at the Camp was contaminated with trichloroethylene (TCE) and perchlorate (perc) and these chemicals, as well as other volatile organic compounds in the water system at the Camp, may have caused Janey's condition. DOD has been working for many years to block new IRIS standards on TCE and perc.

In the Bush Administration, OIRA's involvement changed in scope and kind. John Graham, the first director of OIRA, brought in technical specialists—including toxicologists—to tend to science-based discussions of proposed environmental regulations, guidance and IRIS entries. Graham also oversaw a complete overhaul—some might describe it as an endless evolution—of the review and approval process for IRIS proposals. This report will describe that tumultuous review process, how it impacted EPA's productivity and independence, and the true nature of OIRA's role in the interagency review process.[7]

OIRA DOES SCIENCE

Before turning to how the IRIS process was subjected to ongoing interagency negotiations, it is worth examining the day-to-day reality of working on IRIS entries. OIRA has always claimed to Congress and the public that its sole function was as a facilitator of interagency science discussions. John Graham's successor at OIRA, Susan Dudley, described OIRA's role in language that might have applied during the late-Clinton years. An exchange Ms. Dudley had with Subcommittee Chairman Miller in testimony before the Subcommittee on May 21, 2008 is worth quoting at length:

> Chairman Miller. Ms. Dudley, do you think it is part of the role of OMB... to review scientific assessments prepared by other agencies of government?
>
> Ms. Dudley. OMB serves a coordinating function. We coordinate interagency review of various things, so OMB's role I think is a legitimate role. We have scientists that engage other scientists throughout the Federal Government in reviewing IRIS assessments.
>
> Chairman Miller. Well, I understand that there is one toxicologist that works for OIRA, is that correct?
>
> Ms. Dudley. You know, I am not sure exactly their credentials. We have toxicologists, risk assessors, statisticians.
>
> Chairman Miller. Well, they are remarkably productive, because they respond point by point in great detail at great length to the assessments that come up from the scientific agencies of government. Is that all done in-house or are there others who are invited to participate in OIRA's work or OMB's work?

7 . Rebecca Clarren, "The EPA's Stalin Era," Salon.com, November 11, 2008. This article has a succinct discussion of how IRIS entries, or the lack of them, impacts communities facing pollution problems.

> Ms. Dudley. No, it is certainly an interagency effort. So OMB doesn't provide the—we don't do the analysis, we coordinate it with other agencies. So we take advantage of the expertise throughout the Federal Government.[8]

Later in that same hearing:

> Ms. Dudley. We talk to other federal scientists. Our role is coordinating the scientific dialogue between scientists within the Federal Government.[9]

George Gray, then the EPA Assistant Administrator for ORD, helpfully confirmed this version of OIRA's actions in answer to a question from Chairman Miller about what happened at the OMB interagency review step in the then-new IRIS process announced on April 10, 2008:

> Dr. Gray. This is when the Office of Management and Budget would coordinate a review of the document by other federal agencies... *[in answer to a follow-on question, he continued]* It is my understanding, and I don't know how OMB does the formal process for reviewing these, but this would go out to all of the federal agencies to have an opportunity to comment.[10]

Dudley represented to the Subcommittee that OIRA had scientists on staff so that they could facilitate interagency science discussions of IRIS entries. Gray confirmed this image of OIRA as a simple coordinator of discussion and materials. However, the Subcommittee has ample documentation showing that OIRA's staff scientists did far more than merely coordinate and facilitate science discussions across agencies. OIRA's staff scientists directly challenged the science put forward by EPA IRIS staff in very detailed peer review-type comments.

For example, on December 22, 2005, John Vandenberg, Associate Director for Health at the National Center for Environmental Assessment, ORD, EPA sent an e-mail to Nancy Beck, an OIRA toxicologist brought on staff by John Graham. It read, in relevant part:

> Attached are Toxicological Reviews for four polybrominated diphenyl ethers. This has gone through the EPA IRIS development and review process and is now ready for submittal to an external peer review panel.... We're providing this to see if you'd like to discuss, and would like to know as soon as possible since we'd like to move this toward external

8 . "EPA's Restructured IRIS System: Have Polluters and Politics Overwhelmed Science?," Hearings before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, May 21, 2008, p. 64. The Subcommittee was in possession of some records showing detailed peer review-style OIRA comments at the time of this hearing. Other records came to the Subcommittee in response to the June 11, 2008 document request from Mr. Miller to Ms. Dudley.

9. "EPA's Restructured IRIS System," p. 71.

10 . "EPA's Restructured IRIS System," pp. 68-69.

peer review and completion in a timely manner.

Two months later, on February 15, 2006, Nancy Beck sent back an e-mail:

> Hi John-
> Attached are agency comments on the draft. Comments came in only from HHS.... let me know how EPA plans to respond to comments. If a conversation is easiest, we can set that up.

The characterization of comments as being only from HHS is misleading. The CDC/ATSDR provided just a paragraph of text expressing their pleasure in the approach EPA is using. NIEHS provided somewhat more commentary—several brief paragraphs, but also additional science references that EPA could consult.

But these "agency comments" were not the sum of comments to come back from Beck. Beck provided more than 11 pages of OIRA's own, very specific editorial and substantive review comments. For example, in discussing the EPA IRIS draft on polybrominated diphenyl (BDE-209), Beck writes:

- page 4- in the Swedish studies how is EPA sure that internal dose is due to inhalation and not dermal absorption?

- page 7- in the distribution section it would be useful to discuss the age-dependent differences in distribution that are mentioned.

- page 14- says the half live is "short"(sic). What is this relative to? For some chemicals a half life of a week would be considered long.

- page 14- what species are the studies referred to in the last paragraph in the half life section? Are these data from rodents?

- page 31- "Together, these studies suggest that decaBDE has a very limited potential to activate the AhR signal transduction pathway, which **is considered to be a key** ~~is the critical~~ toxicological mechanism for many persistent aromatic hydrocarbons." Please also add a citation for this?" *[emphasis in original]*

These comments were chosen at random from approximately 130 bulleted comments provided by Nancy Beck in the response document (see attachment A).

Of the items quoted above, the last observation in the list is very disturbing because it

represents a substantive editorial change regarding how to characterize the science. White House staff re-writing the "science" was a recurring problem during the Bush Administration's term in office. The most famous case was probably that of Philip Cooney, chief of staff at the Council of Environmental Quality, editing out climate change science language in an annual report on climate programs to play up uncertainty regarding climate change.[11] In the Beck review of the EPA submission of polybrominated diphenyl there are numerous editorial comments altering language, and some appear to enhance uncertainty or reduce the profile of the effect being discussed. Beck repeatedly strikes "neurobehavioral developmental toxicity" or "neurobehavioral toxicity" to replace it with "changes in spontaneous motor behavior" or similar constructions. At one point, Beck edits a statement on accumulation differing by age in the following way (Beck's edits in bold):

> this may imply that different activities may expose different age groups more than others, or that some PBDE congeners may accumulate differently with age, **however the sample size here is very small and firm conclusions cannot be made.**[12]

You don't have to be a scientist to recognize that many of the comments made by Beck are exactly what one would expect from a scientific peer reviewer. But the role of providing the kind of expert feedback Beck was offering is properly for external peer reviewers; that is why an agency assembles a group of experts to provide their best advice and ask smart questions.

However, Beck took upon herself the role that should be reserved for external peer reviewers. Further, she adopted that role from one of the most powerful perches in the Executive branch: OMB. From that post, her words implicitly had the endorsement of the President and the President's top staff. This gives a weight to her observations that no external peer reviewer—no matter how much more expert than Beck—carries. At a minimum, OIRA's intervention added another layer of review and response that delayed moving an IRIS entry through the process. EPA was not in a position to ignore OIRA's comments, and would end up engaging them before they could move forward to external reviews. Looking over the record of endless process reforms and direct review comments and challenges, one could conclude that the whole point of the exercise was to delay IRIS products.

The Subcommittee has records of exchanges similar to that on polybrominated diphenyl on other chemicals. The Subcommittee received an e-mail record from 2005 between

11. For the original story on this, see Andrew Revkin, "Bush Aide Softened Greenhouse Gas Links to Global Warming," New York Times, June 8, 2005; "Editor of Climate Report Resigns," NYT, June 10, 2005; "Ex-Bush Aide Who Edited Climate Reports to Join ExxonMobil," NYT, June 15, 2005.
12 . This quote and proceeding are from a chain of e-mails and interagency documents that are attachment "A". They begin with an e-mail from John Vandenberg to Amy Mills of EPA and others, dated 02/27/2006, and titled "Re: Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE.

OMB and EPA of dibutyl phthalate review prior to submitting it for external review.[13] As with the polybrominated diphenyl review, that OIRA/interagency review also took approximately two months between the time EPA sent language to OIRA and the time OIRA provided comments back. The Subcommittee also has two sets of comments on toluene: an OIRA response to a February 2005 EPA draft and an EPA compilation of responses to December 2003 OMB comments regarding an external review draft of a toluene toxicological review. This documentary chain suggests that toluene went through one external review in 2003, the draft revised and then reviewed by OIRA; then the toluene draft entry went through further internal EPA developments followed by another round of OIRA review and response more than a year later.[14]

The extent and detail of OIRA's comments vary from chemical to chemical, and they appear to become more elaborate over time. But each example is a powerful illustration that neither Susan Dudley nor George Gray was candid with the Subcommittee about the role of OIRA or the impact of its interventions on EPA's work. Subcommittee staff has been told by one person on the inside of these reviews that the documents in the possession of the Subcommittee are relatively mild compared to, for example, OIRA's efforts on perchlorate. Of course none of these communications were available to the public. There was no way to know that Dudley and Gray were not telling Congress the unvarnished truth because the entire process was veiled behind "deliberative process" claims of privilege. Transparency was anything but the watchword for what OIRA was doing to IRIS both in substance and process between 2003 and 2008.

THE PROCESS IMPROVEMENT MERRY-GO-ROUND

OIRA intervention in the work of IRIS grew throughout the Bush years. It appears to have been a constantly expanding effort that endlessly tweaked the process for reviewing and discussing IRIS entries, and expanded the scope of OIRA's direct involvement in science discussions. While we do not have OIRA documents on this evolution, the Subcommittee does have some EPA documents that shed light on how EPA IRIS staff viewed the situation.

The earliest process e-mail the Subcommittee has is from John Vandenberg, Associate Director for Health at EPA's National Center for Environmental Assessment (NCEA) to Peter Preuss, Director of the NCEA, and others dated September 13, 2004. Comments by the authors of this report appear in italicized text and brackets.

Vandenberg writes,

> Nancy Beck *[OIRA toxicologist]* called me this morning and conveyed

13. This appears as attachment "B". Documents start with an e-mail from John Vandenberg to Bob Benson of EPA and others, dated 02/07/2006, titled "Interagency/OMB comments on Draft IRIS assessment of Dibutyl Phthalate."

14 . Records appear as attachments "C" and "D". The first has hand-written notation, "Comments from OMB (Margo Schwab) 4-19-05." The second is dated "December 30, 2003" and is titled, "Summary of OMB comments and EPA responses".

several things: 1) John Graham wants a briefing *[from IRIS staff]* on the naphthalene assessment, focused on **process** from here (e.g. interagency review, consideration of peer review comments). We should arrange in the next couple of weeks if possible. 2) She (Nancy) considers some of the external peer review comments to be significant." *[emphasis in original]*...

I told her we're evaluating the draft in light of peer review comments, that we've heard DOD plans to comment but we have not received any comments from them and I urged her to get them to share their comments. I sketched out the IRIS process insofar as it would normally proceed, noting that a formal interagency review would change the process (and that we'd share a document that reflects our revisions following external peer review). I mentioned IRIS Track (Paul Gilman had also mentioned it, they're interested in seeing it). I didn't give any specific dates to her (perhaps fortunately IRIS track was offline this morning!)

We should talk through how we want interagency review to occur, including any groundrules we want to get set up front to avoid paralysis (e.g., fixed time for other agencies to provide review comments; final disposition/decisionmaking by EPA/ORD on assessment document completion; criteria or conditions calling for additional external peer review). Especially for "biggies" that have interagency review we need to stake out a process that will lead us to be successful in terms of timeliness, clarity, consistency, etc. [15]

By May of 2005, EPA staff were engaged in a formal IRIS process brought on by OIRA's intervention. Vandenberg writes to Preuss and others, an e-mail entitled "IRIS process comments from OMB, next steps." Vandenberg writes:

In brief, Nancy Beck (and, she says, Dr. Graham) were expecting more detail than provided in the flow chart and 2-pager to address the 'details'. I pushed back, not wanting to have us wait several months to develop new SOPs [standard operating procedures], as this is premature. Nancy seemed to concur, though she is checking with Dr. Graham.

We ended up agreeing to slightly revise the 2-pager to add a bullet on next steps (i.e., public workshop to discuss process and details/issues) and to emphasize or elaborate on the improvements the process will bring.... Further I agreed that in our Federal Register notice announcing the workshop, we'll identify some of the topics and issues for discussion... OMB wants to review this FR notice....[16]

15 . E-mail from Vandenberg to Preuss and others, 09/13/2004, titled, "naphthalene – OMB request for briefing." Appears as attachment "E".

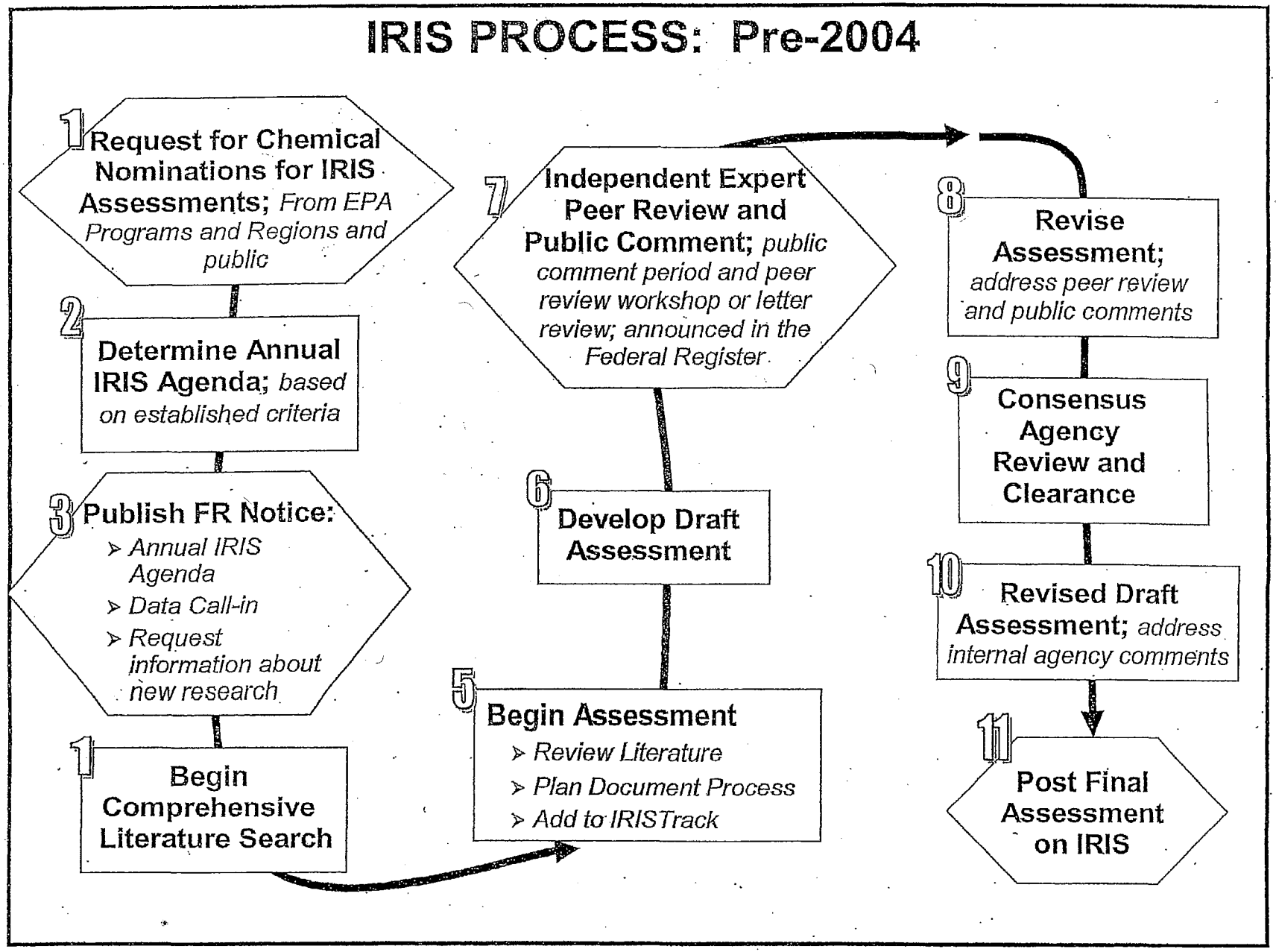
16 . E-mail from Vandenberg to Amy Mills and others, 05/24/2005, titled, "IRIS process comments from OMB, next steps." Appears as attachment "F".

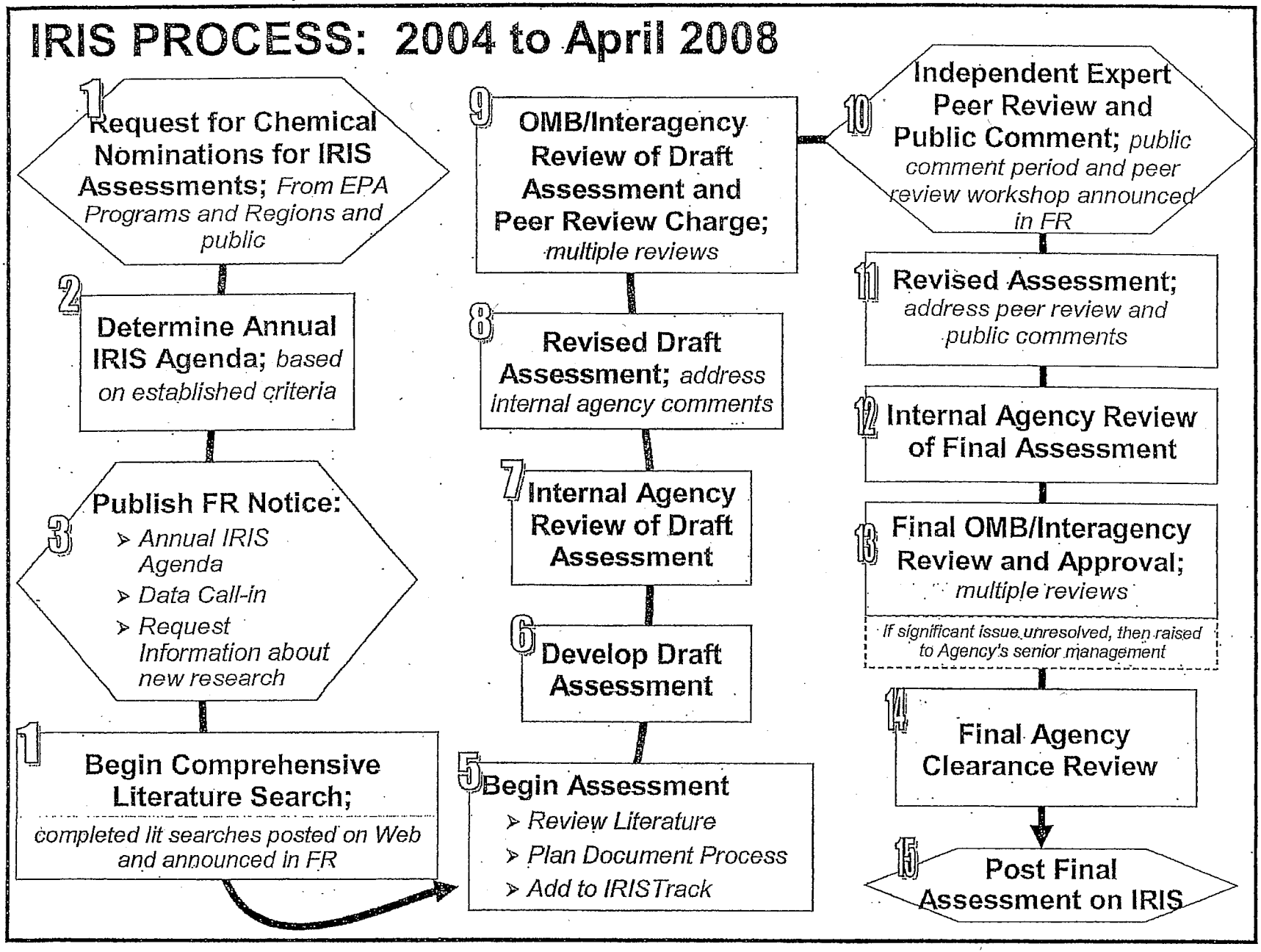
By February of 2006, the process was still under discussion. Preuss receives an e-mail from Shannon Cunniff of the Department of Defense's Material of Evolving Regulatory Interest Team (MERIT) that went to Nancy Beck at OIRA as well as many others in agencies across the government.

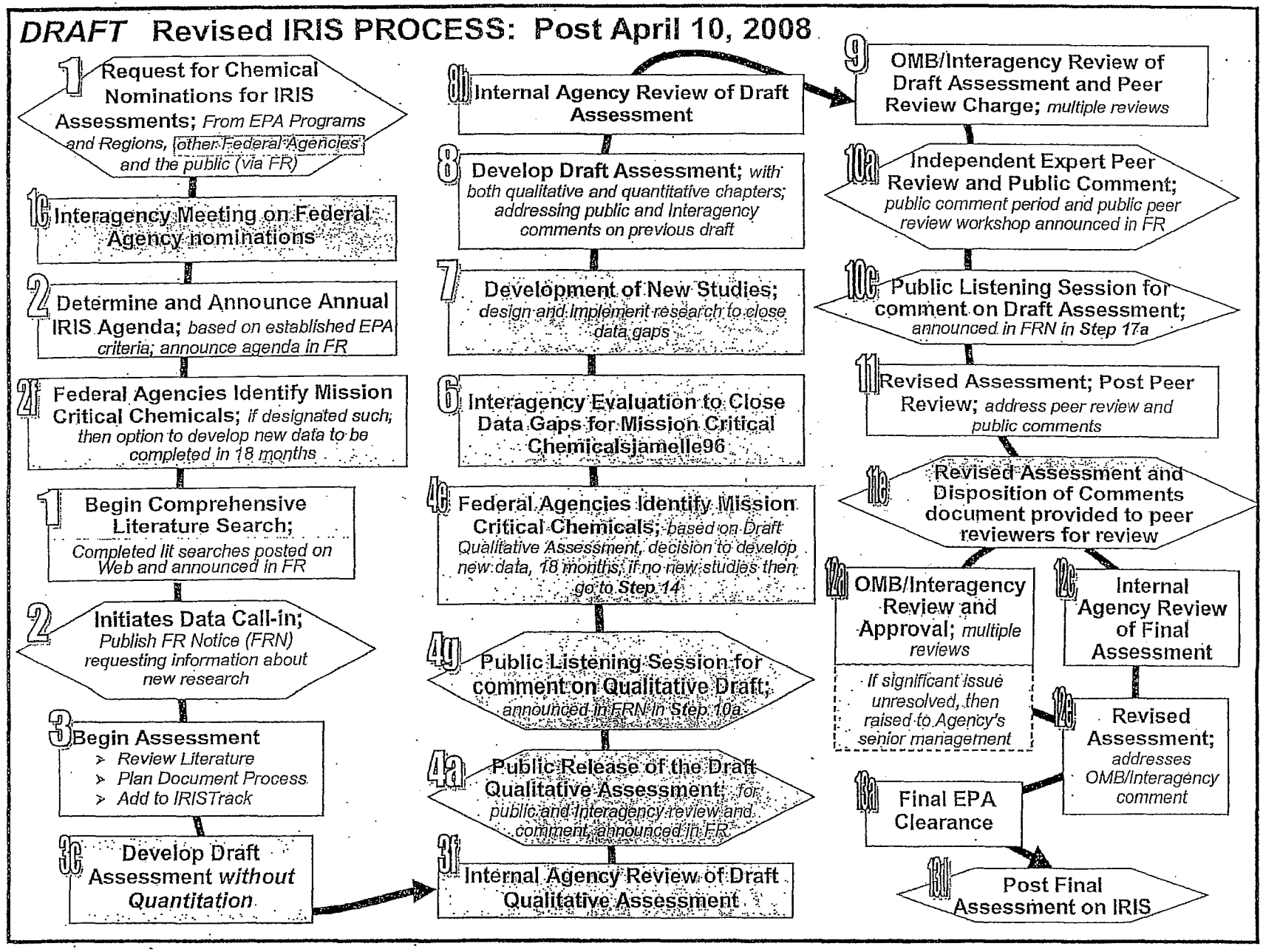
> OSD, NASA and DOE Sr. staff have reviewed ORD's proposed IRIS revisions chart and detailed explanation of some of the boxes and attached are our comments and suggestions. DHS and DOT were not on our last calls due to scheduling conflicts, so I can not assert to what degree they support these comments...
>
> What you have attached is a) the flow chart – we added numbers to all boxes but also retained your numbering of the latter 10 boxes that correspond to your detailed explanation – and b) an expanded detailed explanation of the boxes that includes, as we discussed, an [sic] proposed explanation for every step to help us all achieve clarity and eventually agreement.
>
> These inserts and changes were drafted by a committee of federal staff and recorded by Mitretek (so you might see Mitretek identified as a "commentor"(sic). All of our insertions or changes are in color and underlined.
>
> We suggest that after you look this over that we set up another multi-agency meeting to bring all the interested federal agencies together to discuss the process steps and see if together can reach consensus on the process, understand how or if this effort fits with Dr. Gray's visions for IRIS, and develop a plan for next steps.[17]

The Subcommittee does not have the attachments referenced in this e-mail. Nor do we have further records relating to the next steps and the final outcome.[18] We do have EPA IRIS staff's own process charts designed to record this evolving process as it moved from 2004 through 2008. The next three graphics are reproductions of IRIS staff efforts at developing a flow chart that would reflect the process, as they understood it, at each moment in time.

17 . E-mail from Shannon Cunniff, Department of Defense, to Preuss, Beck and others, 02/02/2006, titled, "DoD, NASA, DoE comments on IRIS revisions." Appears as attachment "g" in the report.
18. Note that GAO's report of March 2008, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System," shows a draft process which was under discussion in early 2008. See pages 46 and 47 of GAO-08-440.


IRIS PROCESS: Pre-2004
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions and public
2 Determine Annual IRIS Agenda; based on established criteria
3 Publish FR Notice:
Annual IRIS Agenda
Data Call-in
Request information about new research
1 Begin Comprehensive Literature Search
5 Begin Assessment
Review Literature
Plan Document Process
Add to IRISTrack
6 Develop Draft Assessment
7 Independent Expert Peer Review and Public Comment; public comment period and peer review workshop or letter review; announced in the Federal Register
8 Revise Assessment; address peer review and public comments
9 Consensus Agency Review and Clearance
10 Revised Draft Assessment; address internal agency comments
11 Post Final Assessment on IRIS


IRIS PROCESS: 2004 to April 2008
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions and public
2 Determine Annual IRIS Agenda; based on established criteria
3 Publish FR Notice:
Annual IRIS Agenda
Data Call-in
Request Information about new research
1 Begin Comprehensive Literature Search;
completed lit searches posted on Web and announced in FR
5 Begin Assessment
Review Literature
Plan Document Process
Add to IRISTrack
6 Develop Draft Assessment
7 Internal Agency Review of Draft Assessment
8 Revised Draft Assessment; address internal agency comments
9 OMB/Interagency Review of Draft Assessment and Peer Review Charge; multiple reviews
10 Independent Expert Peer Review and Public Comment; public comment period and peer review workshop announced in FR
11 Revised Assessment; address peer review and public comments
12 Internal Agency Review of Final Assessment
13 Final OMB/Interagency Review and Approval; multiple reviews
If significant issue unresolved, then raised to Agency's senior management
14 Final Agency Clearance Review
15 Post Final Assessment on IRIS


DRAFT Revised IRIS PROCESS: Post April 10, 2008
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions, other Federal Agencies and the public (via FR)
1c Interagency Meeting on Federal Agency nominations
2 Determine and Announce Annual IRIS Agenda; based on established EPA criteria; announce agenda in FR
2f Federal Agencies Identify Mission Critical Chemicals; if designated such, then option to develop new data to be completed in 18 months
1 Begin Comprehensive Literature Search; Completed lit searches posted on Web and announced in FR
2 Initiates Data Call-in; Publish FR Notice (FRN) requesting information about new research
3 Begin Assessment
Review Literature
Plan Document Process
Add to IRISTrack
3c Develop Draft Assessment without Quantitation
3f Internal Agency Review of Draft Qualitative Assessment
4a Public Release of the Draft Qualitative Assessment; for public and Interagency review and comment, announced in FR
4g Public Listening Session for comment on Qualitative Draft; announced in FRN in Step 10a
4g Federal Agencies Identify Mission Critical Chemicals; based on Draft Qualitative Assessment, decision to develop new data, 18 months, if no new studies then go to Step 14
6 Interagency Evaluation to Close Data Gaps for Mission Critical Chemicalsjamelle96
7 Development of New Studies; design and implement research to close data gaps
8 Develop Draft Assessment; with both qualitative and quantitative chapters; addressing public and Interagency comments on previous draft
8h Internal Agency Review of Draft Assessment
9 OMB/Interagency Review of Draft Assessment and Peer Review Charge; multiple reviews
10a Independent Expert Peer Review and Public Comment; public comment period and public peer review workshop announced in FR
10c Public Listening Session for comment on Draft Assessment; announced in FRN in Step 17a
11 Revised Assessment; Post Peer Review; address peer review and public comments
11e Revised Assessment and Disposition of Comments document provided to peer reviewers for review
12a OMB/Interagency Review and Approval; multiple reviews
If significant issue unresolved, then raised to Agency's senior management
12c Internal Agency Review of Final Assessment
12e Revised Assessment; addresses OMB/Interagency comment
13h Final EPA Clearance
13i Post Final Assessment on IRIS

The timeline reflected in these charts, and in the e-mails reviewed by the Subcommittee, suggests that it took three full years from the time OIRA's Graham triggered a formal effort to restructure the IRIS process until a new process had cleared all the internal hurdles. Remember that it was in February of 2006 that DOD's lead representative to interagency discussions was suggesting they should have another "multi-agency" meeting to hammer out an agreement. That agreement was not finalized until April of 2008.

Because the process continued to evolve, both before the process review began and during the formal review, IRIS staff was constantly trying to figure out what steps they needed to take to keep on track with IRIS proposals. These charts clearly reflect a process that became ever more complex and burdensome. But while the process was evolving, there was another level of chaos thrown into the IRIS mix. Uncertainties among EPA staff about how to proceed, absent a final approved process, show up in some documents in the Subcommittee's possession.

For example, in an e-mail from February 2, 2006, Vandenberg shares with IRIS staff comments that came from OIRA's Beck on dibutyl phthalates and writes,

> Our approach to these interagency comments (for perc and dichlorobenzenes) has been to carefully evaluate the comments and to develop a response to comments document. I recommend you create a document that addresses each comment (include their "comment" and our "responses" as one file) and provide a point-by-point evaluation. I encourage that the tone of our "responses" be thoughtful and that we make such changes as we deem warranted. If there are some larger science-policy issues or points made where it is unclear how to respond, then flag these for discussion.
>
> Please give me a sense of the time it may take you to respond to these comments (I'd expect a few weeks).

Vandenberg closes his note to staff with,

> Thank you for all your hard work on this document, it seems we'll soon be able to move ahead![19]

However, the IRIS Track currently shows the status of the dibutyl phthalate assessment start date as January 9, 2002 (four years prior to the Vandenberg e-mail quoted above) and now projects that just the draft development will be completed by the 4th quarter of 2010. Perhaps in the world of IRIS, taking eight years to move to complete the first milestone—of five—is considered as being "soon."[20]

Later in February 2006, Amy Mills, IRIS program director, writes to Vandenberg:

19 . "Interagency/OMB comments on Draft IRIS assessment of Dibutyl Phthalate." Attachment "B."
20 . The Track IRIS database was reviewed by Subcommittee staff on Friday, June 5.

> John – Are we expected to send a *revised assessment* along with the response to interagency comments to OMB? [Assuming that at least some of the comments result in some level of change to the assessment] As I recall we've done so before, but is there a pattern established? *[emphasis in original]*

Vandenberg replies,

> For perc the comments didn't result in a revised assessment (changes to charge questions)... for phosgene we did send a revised assessment over. *[see attachment X]* I recommend going ahead and making revisions so we can have it ready for external peer review, and probably will send over. My view is that the disposition of comments/changes are up to us, but of course all this is evolving still.[21]

At the Subcommittee's IRIS hearing on May 21, 2008, Gray and Dudley both addressed the April 10, 2008 process. While Gray's testimony described the new process as being "announced by EPA," Dudley used language suggesting that EPA had done the revision:[22]

> In response to concerns both with delays in implementing IRIS assessments and lack of transparency in the IRIS process, EPA has recently revised the process to clarify the role of the public and interagency reviewers and promote greater communication and sharing of information between all interested parties and EPA.

Based on this testimony, a reasonable person would assume that the new EPA IRIS process was solely the product of EPA's work, but as a result of the documents cited above (and attached to this report), Subcommittee staff can confirm that the then-new process, and its evolution, were driven by changing demands from OIRA. Further, it is apparent that other agencies—notably agencies that have environmental pollution issues—played a substantial role in shaping that process. Again, neither Dudley nor Gray was candid with the public or the Congress in the way they portrayed this process.

CONCLUSION

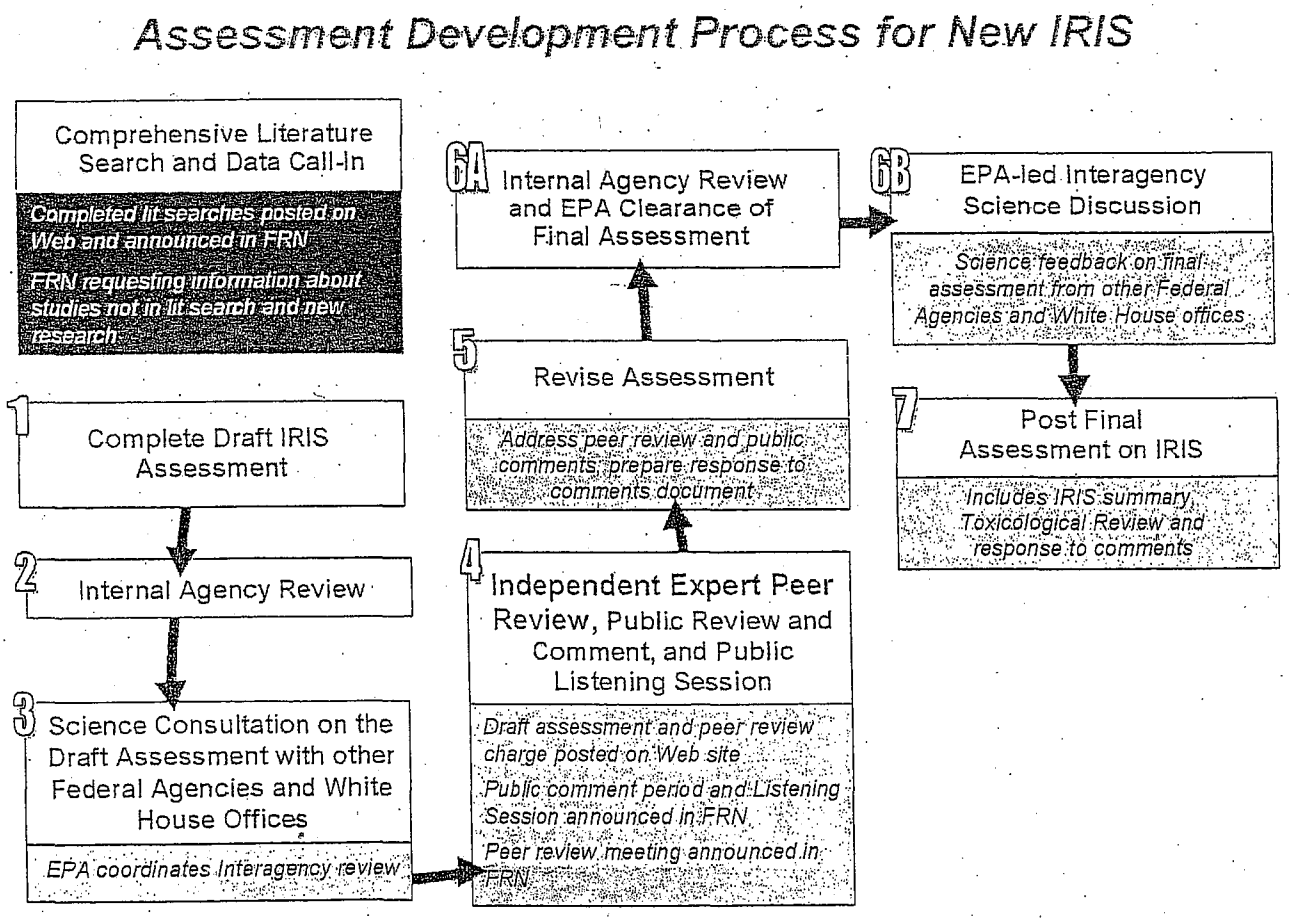
The Subcommittee held two days of hearings on the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) in the last Congress. Chairman Miller was critical of the failure of IRIS to produce timely new listings of risk assessments for chemicals. The Chairman also noted that the process had devolved to the point that only two new entries were being finalized a year while approximately 700 new chemicals were entering the marketplace each year.

A key concern regarding the new IRIS process (see chart below) announced on May 20,

21. "Re: Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE," attachment "A".
22 . "EPA's Restructured IRIS System," p. 53 for Gray and p. 58 for Dudley.

2009 is whether it will substantively empower EPA to push their entries forward. Because all interagency comments are to be solely about science, this new process could be interpreted as formally endorsing OIRA's past practice of having professional scientists on staff to discuss toxicology issues, scientist-to-scientist. Then the entire fiction of OIRA's role as merely a coordinator of an interagency process can fall away. So long as OIRA and OMB stand astride the top of the Administration as representatives for the White House in discussions with EPA or others, it is hard to see how transparency alone will limit OIRA's influence over EPA. The timelines that EPA announced with the new process may be helpful, but since there is no penalty for missing a goal, it may still come down to who has the most influence and EPA has rarely won that struggle in recent memory[23].

Given that so many of the same players who broke IRIS during the Bush years still stand in the agencies and in the White House complex, and that institutional powers and interests have not changed despite the November 2008 election results, it will take some time to determine whether EPA scientists really are calling the shots.



23 . The timelines associated with the new process can be found at attachment "H" in the report.

John Vandenberg/DC/USEPA/US
02/27/2006 10:02 AM

To: Amy Mills/DC/USEPA/US@EPA
cc: hammerstrom.karen@epa.gov, Mary Manibusan/DC/USEPA/US@EPA
bcc:
Subject: Re: Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE

For perc the comments didn't result in a revised assessment (changes to charge questions). EtO pending; for phosgene we did send a revised assessment over. I recommend going ahead and making revisions so we can have it ready for external peer review, and probably will send over. My view is that the disposition of comments/changes are up to us, but of course all this is evolving still.

John Vandenberg
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DC Research Triangle Park, NC
Tel: 202 564 3407 919 541 4527
Fax: 202 565 0090 919 541 5078
Amy Mills/DC/USEPA/US

Amy Mills/DC/USEPA/US
02/22/2006 10:17 AM

To: John Vandenberg/DC/USEPA/US@EPA
cc: Mary Manibusan/DC/USEPA/US@EPA, hammerstrom.karen@epa.gov
Subject: Re: Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE

John - Are we expected to send a *revised assessment* along with the response to interagency comments to OMB? [Assuming that at least some of the comments result in some level of change to the assessment.] As I recall we've done so before, but is there a pattern established?

Amy Mills
IRIS Program Dir.
(202) 564-3204
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Mailing address:
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Room 620E
Washington, DC 20007

PBDEs

John Vandenberg/DC/USEPA/US
02/22/2006 08:22 AM

To Mary Manibusan/DC/USEPA/US@EPA
cc Amy Mills/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, preuss.peter@epa.gov, Amanda
bcc
Subject Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE

History: This message has been replied to

Mary,
Attached below are the interagency comments for PBDE, please share these with the document co-authors.

The comments include general and detailed comments from OMB, a review by NIEHS that essentially used the charge questions as their charge with many references cited, and a short comment by CDC.

Our approach for dealing with comments has been to create a "Comment/Response" document which addresses each comment in turn. For many of the comments simple concurrence with the editorial suggestions may be noted. For others, a more detailed response is likely to be necessary, particularly if there is disagreement with the comment or if additional explanation is requested. Some comments also raise general issues regarding EPA risk assessment approaches, these can be flagged and discussed.

Please work with the PBDE authors to evaluate the comments and gauge the effort and time necessary to address the comments.

Thank you.
John

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----- Forwarded by John Vandenberg/DC/USEPA/US on 02/22/2006 08:07 AM -----

"Beck, Nancy" <Nancy_Beck@omb.eop.gov>
02/15/2006 06:05 PM

To John Vandenberg/DC/USEPA/US@EPA
cc Peter Preuss/DC/USEPA/US@EPA
Subject RE: Draft IRIS assessments for 4 PBDE

- CDC, NIEHS, ATSDR — OK with substance.

OMB Comments on PBDE's

General Comments applicable to all 4 draft documents:

- Has WHO or the EU completed any reviews? How are their findings similar or different to EPAs?

- In all 4 drafts, a section on mechanism of action is missing. Its not clear why. Additionally, studies that look at receptor binding are in the effects section—these studies belong in a section on mechanism of action. Binding to a receptor is not an adverse effect or a typical toxicological endpoint. Its not clear why EPA has treated it as such in these drafts.

- In distribution sections:
  - Its not clear why the summary is put first? This makes reading a bit confusing, suggest moving to the end of the distribution section to be consistent with format of other sections.
  - Please clarify: "Accordingly, the data are representative of exposure to a greater extent than distribution toxicokinetics and must be regarded in that fashion."
  - Throughout these sections for each study the sample size should be presented. Its very hard to know how representative the data are when these values are not transparently presented. In cases where EPA does not know the sample number, this should be stated. When samples are pooled, the number of samples that went into each pooled sample should be stated.
  - The tables in these sections should also provide sample number for each study and should also state the year the samples were collected as this seems very relevant and date of publication is not indicative of sample age.
  - For human data it would be useful to have a few sentences discussing how representative these data are/ are not.

- In metabolism sections:
  - These sections seem to include information on induction of metabolic enzymes (p450's, UDPGT) by BDE's, but induction of metabolic enzymes doesn't tell anything specific about how the compounds themselves are metabolized. Suggest moving this text to a section on mechanism of action in each document. It is not informative information when trying to determine how the BDE's are metabolized.

- In hazard ID sections:
  - Its not clear why studies looking at enzyme activity (PROD, EROD, etc) are discussed here. These studies should be discussed in a section on mechanism of action.
  - Its not clear why receptor interactions and receptor binding is discussed under "other studies" in this section. These studies should be discussed under mechanism of action sections in the document. Each document should have a section on mechanism/mode of action.
  - For the Viberg studies and Eriksson 2001 study it is never explained anywhere in the document what it means that there is hypoactivity and then later hyperactivity? Also

developmentally how does the time change between a 2 month old and 4 month old mouse relate to age changes in humans? What is the relevance of these spontaneous motor behavior changes in humans? How important is habituation in humans?

- Section on synthesis and evaluation of effects:
  - Discussion of enzyme induction should not be included here.
  - Discussion of human exposures does not seem to belong here

- Section on possible childhood susceptibility:
  - Its not clear why discussion of levels of BDEs in humans is included here. This information relates to exposure, not susceptibility. Exposure does not mean that there is differential susceptibility.
- Section on methods of analysis:
  - Documents should explain why BMD with 1 SD is being chosen, rather than another endpoint. Why didn't EPA also present BMD10 values? Text should mention that this gives an excess risk of 10% for the proportion of individuals above the 98th percentile for normally distributed effects.
  - In some documents a BMD of 0.5SD is presented in the appendix. How did EPA choose 1SD over 0.5SD?

- Justification for creating RfDs when uncertainty is so great is not clear.

General Comments on the charge:

- Has EPA given thought to the number and type of expertise on the review panel?
- The questions should not only ask if rationale and justification is transparent and objective, but should also ask experts if they agree with the EPA determinations.

Tetra (BDE-47):

- Page 11- for the Darnerud and Risberg study it would be useful to give the levels of radioactivity (or %'s) to help understand uptake. Its not clear what is meant by 'high' and 'intermediate'. What was the % labeling in the brain?

- Page 16- 3rd full paragraph- suggest deleting 1st sentence. Edit 2nd sentence to say "to assess whether PBDE's may be detrimental to neurodevelopment, Mazdai….."

- Page 18- suggest deleting (or provide citation for) the following: "Induction of these enzymes would suggest metabolic transformation of BDE-47, and this could affect the levels of T4, as the produced metabolites may have effects on T4 homeostasis by replacing T4 at TTR binding sites."

- Page 18- what is the citation for the following sentence: "It is hypothesized that the lack of response on serum TSH levels to the reduction in T4 levels is due to BDE-47 and/or its metabolites mimicking thyroid hormones and possibly binding to thyroid hormone receptors in the pituitary, thereby blocking TSH release."

- Page 18- Was the Eriksson study male mice only? If so this should be clearly stated. Were the "more pronounced aberrations" in behavior statistically significant (ie 2 month vs 4 month)?

- Page 20- suggest deleting: "Based on the data from the well-studied PCBs, CDDs and CDFs, the activation of these receptor sites is associated with immunotoxicity, reproductive effects and carcinogenesis, all endpoints of interest for PBDEs (Klaassen, 2001)." This sentence is unclear. Is there a page citation for Klaassen where this is stated?

- Page 22- please provide page citation for Klaassen, 2001 under section 4.4.1.2

- Page 24: edits in bold: "In summary, the mechanistic studies of the ER and Ah receptor indicate that the activity of the tetraBDEs are **much** lower than the activities of dioxin and PCBs. TetraBDE-77 appears to be the most active with the Ah receptor and most PBDEs appear to be **weak** antagonists for the Ah receptor rather than agonists**[what is citation for this?]**. Receptor-site mediated activity via the ER site appears to be minimal for the tetraBDEs."

- Page 25- Add that although the impact on CAR receptor is similar to non-coplanar PCBs, the implications of CAR activation is not well known.

- Page 26- since when is cell culture an endpoint in hazard ID? Suggest moving this text to sections on distribution and absorption as appropriate.

- Page 27: "Additional research is necessary to determine the ~~full~~ mutagenic potential of BDE-47."

- Page 27: Alterations of behavioral parameters, namely impaired motor functions and decreased habituation capability worsening with age, have been shown to occur in adult male mice neonatally exposed to BDE-47 (Eriksson et al., 2001). ~~These behavioral disturbances raise concerns about possible developmental neurotoxicity in children.~~

~~BDE-47 has been found in human milk, maternal and cord blood, and adipose tissues. Concentrations found are high in all human biological samples in the USA, relative to other countries. Fetuses and infants are exposed to BDE-47. Whether such exposure constitute a health risk for adverse neurodevelopmental effects in these population groups is not known at this time. An association between prenatal or neonatal exposures to BDE-47 and neurobehavioral dysfunction in humans has not been established.~~ This sentence is not about effects.

- Page 27: "Exposure of mice ~~and rats~~ to BDE-47 resulted in reduction of serum total and free thyroid hormone levels**, however no changes in TSH were seen** (Hallgren et al., 2001; Hallgren and Darnerud, 2002)."—the hallgren study was mice only and its not clear that any of the Hallgren and Darnerud effects were statistically significant, text does not say, thus I assume changes were not.

- Page 28- Additional *in vitro* or *in vivo* studies are not available to determine the ~~full~~ genotoxic potential of BDE-47."

- Page 29-under choice of study, its not clear why effects on MFO's are discussed here.

- Page 30-
  - 1st full paragraph: please provide a citation for the discussion of critical windows.
  - Its not clear that MeHg is a great example as there is very little data on specific windows during development that may lead to effects in humans- the large epi studies included exposures that occurred throughout development and into childhood. Suggest deleting this as an example. For lead, do we know of specific developmental windows where there is an effect?
  - Please clarify the discussion of hormone change effects. How do the changes seen relate to the findings in the Eriksson study? Can EPA say anything more specific? How do we know the results are "relevant to exposure in people"? what is this based on? Hormone stores and half lifes in rodents are quite different than levels in humans. How do we know that these exposure levels are relevant? What is meant by: "Taken together, the results elevate concern for environmental exposure to BDE-47 and support the use of this study as a principal study for deriving the RfD for BDE-47." How does the data elevate concern and why do they support using Eriksson as the principal study?

- Page 30/31- The description of the concerns with the Eriksson study is very good. It seems that other than the fact that the neurotox guidelines list functional neurotoxicity as an effect, and that there are PDBEs in human tissues, there is there is no support for relying on this study. The database is incredibly limited. There is one study—in one sex in one species with essentially no supporting similar studies and no information on mechanism of action. Only 2 doses were tested and the dose levels were an order of magnitude apart. This seems to be more of a range finding study than anything else. The UF EPA wants to apply is 3000 (with uncertainty in 4 different areas) and the certainty would be low. When uncertainty is so high, what is the value added of this RfD value? Is the science strong enough to support the use of this value for clean-ups conducted by program offices?

- Page 32-Choice of the database UF should not depend on whether or not cancer studies exist. Suggest deleting this reference.

- Page 32- "~~Neurobehavioral developmental toxicity~~ **Changes in spontaneous motor behavior** has been identified as the critical endpoint of concern in adult **male** mice following neonatal oral exposure to BDE-47 (Eriksson et al., 2001). ~~Since fetuses and infants are exposed to BDE-47 via maternal/cord blood and human milk, such exposure may constitute a health risk for adverse neurodevelopmental effects in these population groups.~~" Not clear why exposure is discussed here, specifically when doses are not put in a context of human body burden and actual exposure levels. Also the certainty in the RfD is so low its not clear that a risk to humans is real based on the data EPA has presented.

Penta (BDE-99):

- Page 4- in the Eriksson 2002 study were there any controls? Is it known if levels in the brain were DBE99 vs some metabolite that ended up with the radiolabel?

- Page 5:
  - This may imply that different activities may expose different age groups more than others, or that some PBDE congeners may accumulate differently with age, **however the sample size here is very small and firm conclusions cannot be made.**
  - is Johnson-restrepo published yet?

- Page 7-
  - Please state if the strong positive relationship seen in Ohta is statistically significant.
  - Please add a citation for: "In another study in Japan, PBDEs were not detected in 8 pooled human milk samples collected in 1973."

- Page 8- "This may be explained by the fact that PBDEs are relatively new contaminants in the environment, the time period for human exposure is therefore relatively short, and different age groups (except the 0-4 years group), may thus have experienced a similar lifetime exposure (Thomsen et al., 2002)." Do you mean to say **dissimilar** lifetime exposure? also change "flame retarded" to "flame retardant".

- Page 10- Please state the dose in the Hakk 2002a study.

- Page 11- in the 2nd full paragraph, please provide the percent of uptake into each tissue. Also has Darnerud and Risberg been published yet?

- Page 13-
  - 1st full and 4th paragraph- please clarify that the Hakk conclusions are relevant to rats.
  - in the Darnerude et al 2005 study, was this with and without BDE-99? Its not clear how this relates to BDE-99.

- Page 14-1st full paragraph, is this an EPA conclusion or should there be a citation?

- Page 15-
  - 1st full paragraph under half-life: 6 days is relatively high compared to what?
  - 2nd full paragraph under half-life: why is this discussing hexa and tetra BDE? Can we say anything about sex differences with increasing degree of bromination? What were the penta half lives anyways?

- Page 16-2nd full paragraph- suggest deleting 1st sentence. Edit 2nd sentence to say "To assess whether PBDE's may be detrimental to neurodevelopment, Mazdai….."

- Page 17- please explain why comparisons to Bromkal and Aroclor are reported. In the 4th paragraph was there any BDE-99 exposure?

- Page 18-Please state whether the elevations seen in Hakk 2002a were statistically significant.

- Page 18- its not clear how studies are ordered in section 4.3.1. Chronological might make reading easier- or by author so readers can see how things develop (eg in 2002 Viberg tested 1 dose but in 2004 did essentially the same study with multiple doses).

- Page 19-The no-observed-adverse-effect level (NOAEL) for ~~developmental neurotoxic~~ **spontaneous motor behavior** effects in this study was 0.4 mg/kg.

- Page 21-In conclusion, the behavioral disturbances observed in adult mice following neonatal exposure to BDE-99 are induced during a defined critical period of neonatal brain development, and mice at PND 10 are **more** susceptible to the neurotoxic effects of BDE-99 **than at PND 3, 10 or 19 where minimal or no effects were seen**.

- Page 21- The purpose of the PDBE exposure in the Ankarberg study is not clear.

- Page 23- A two-day delayed appearance of screen climbing response was seen in the high-dose group (30 mg/kg/day); Please state if this was statistically significant.

- Page 26-The NOAEL/LOAEL values in this study indicate that rats are equally or perhaps less sensitive than mice to the **spontaneous motor behavior** ~~developmental neurotoxic~~ effects of BDE-99.

- Page 28-
  - "In summary, treatment of rats with BDE-99 on GD 6 resulted in a dose-dependent decrease in daily sperm production, spermatid count, and relative epididymis weight in rat offsprings at 0.06 and 0.3 mg/kg." Do you mean PND 140?
  - "The LOAEL in this study was 0.06 mg/kg based on increases in certain locomotor activity parameters on PND 36 and PND 71". Its not clear from the text that there were effects at this dose at PND 36.

- Page 40- the discussion of gender differences should note that many studies were conducted in males only.

- Page 40- this study mentions many supporting studies to support use of Viberg 2004a- however don't most of these studies have the same study design problems? Shouldn't this be stated? Are there other better designed studies that support using Viberg and neurobehavioral effects, particularly since so little is known about mode of action? How do we know that these exposure levels are relevant? What is meant by: "Taken together, the results elevate concern for environmental exposure to BDE-99 and support the use of this study as a principal study for deriving the RfD for BDE-99." How does the data elevate concern and why do they support using Eriksson as the principal study?

- Page 43-
  - 1st full paragraph: please provide a citation for the discussion of critical windows.
  - Its not clear that MeHg is a great example as there is very little data on specific windows during development that may lead to effects in humans- the large epi studies

included exposures that occured throughout development and into childhood. Suggest deleting this as an example. For lead, do we know of specific developmental windows where there is an effect?

- Page 44- it would be useful to present a table with all the BMD values from the different studies

- Page 45-Does it make sense to set an RfD with an UF of 3000 with low confidence? Is there anything EPA is confident of? Are there any data on mechanism of action that may help? This is an order of magnitude lower than the previous RfD, yet the certainty in the data does not appear to have increased.

- Page 47- Not clear why exposure is discussed here, specifically when doses are not put in a context of human body burden and actual exposure levels.

Hexa (BDE-153):

- Page 4: "Of the hexaBDE congeners, BDE-153 is ~~therefore~~ present at higher levels than BDE-154 in both the penta- and octaPBDE commercial products."

- Page 5-" This property of hexaBDE is ~~quite~~ evident from the data on distribution in humans. The human data come from monitoring of PBDEs in human populations rather than from measured dosing studies."

- Page 5- what were the levels of hexaBDE in adipose?

- Page 6- unclear why the following is included in this section: "Concentrations of PBDEs were, on average, similar to those for PCBs. PBDE concentrations did not increase with increasing age of the subjects, whereas concentrations of PCBs increased with increasing age in males but not in females. These results suggest differences between PBDEs and PCBs in their sources or time course of exposure and disposition."

- Page 7-
  - in liver section, suggest deleting text regarding BDE 47 and 99, is not relevant.
  - the human milk section talks of PDBE levels being higher than those in Japan or Europe. How do the Hexa BDE levels compare?
  - Focus throughout the distribution and elimination sections should be on hexa and not total or other BDEs

- Page 11-1st paragraph under 4.1: suggest deleting 1st sentence. Edit 2nd sentence to say "To assess whether PBDE's may be detrimental to neurodevelopment, Mazdai….."

- Page 14- "The NOAEL for BDE-153 (92.5% pure) in this study (Viberg et al., 2003) was 0.45 mg/kg, and the LOAEL 0.9 mg/kg for changes in spontaneous motor behavior, worsening with increasing age, and for effects on learning and memory ability." What is meant by learning and memory ability? Is this relearning?

- Page 14- suggest deleting: "Based on the data from the well-studied PCBs, CDDs and CDFs, the activation of these receptor sites is associated with immunotoxicity, reproductive effects and carcinogenesis, all endpoints of interest for PBDEs (Klaassen, 2001)." This sentence is unclear. Is there a page citation for Klaassen where this is stated? Please also provide a citation for: "Xenobiotic compounds with the strongest Ah receptor binding affinity tend to be those with the greatest toxic potency."

- Page 16- please provide a page citation for: "Receptor induced mitogenic activity has been linked to tumor formation in the affected organs (Klaassen, 2001)."

- Page 17: "In summary, the mechanistic studies of ~~the Ah receptor and~~ the estrogen receptor indicate that the activity of BDE-153 and BDE-154 are significantly lower than the activities of dioxin and PCBs." Isnt there essentially no ER activity? Why not just say this?

- Page 18- Please state what binding to the CAR receptor mean as far as effect goes.

- Page 18: "The **meaning** ~~importance~~ of this observation for humans has yet to be resolved."

- Page 18: "Alterations of behavioral parameters, namely impaired spontaneous motor behavior worsening with age, and effects on learning and memory capability have been shown to occur in adult male mice neonatally exposed to BDE-153 (Viberg et al., 2003). These behavioral disturbances raise concerns about possible developmental toxicity in children." Considering the problems with study design, is this truly a concern? How do these disturbances relate to what we may see in humans? Are the disturbances actually adverse?

- Page 20- The description of the concerns with the Viberg study is very good. It seems that other than the fact that the neurotox guidelines list functional neurotoxicity as an effect, and that there are PDBEs in human tissues, there is there is no support for relying on this study. The database is incredibly limited. There is one study—in one species (its not clear if it is males only-text seems to go back and forth with this) with essentially no supporting similar studies and no information on mechanism of action. The UF EPA wants to apply is 3000 (with uncertainty in 4 different areas) and the certainty would be low. When uncertainty is so high, what is the value added of this RfD value? Is the science strong enough to support the use of this value for clean-ups conducted by program offices?

- Page 20-
  - 1st full paragraph: please provide a citation for the discussion of critical windows.
  - Its not clear that MeHg is a great example as there is very little data on specific windows during development that may lead to effects in humans- the large epi studies included exposures that occured throughout development and into childhood. Suggest deleting this as an example. For lead, do we know of specific developmental windows where there is an effect?

- Page 21-Does it make sense to set an RfD with an UF of 3000 with low confidence? Is there anything EPA is confident of? Are there any data on mechanism of action that may help?

Deca (BDE-209):

- Page 4- in the Swedish studies how is EPA sure that internal dose is due to inhalation and not dermal absorption?

- Page 7- in the distribution section it would be useful to discuss the age-dependent differences in distribution that are mentioned.

- Page 14- says the half live is "short". What is this relative to? For some chemicals a half life of a week would be considered long.

- Page 14- what species are the studies referred to in the last paragraph in the half life section? Are these data from rodents?

- Page 31-"Together, these studies suggest that decaBDE has very limited potential to activate the AhR signal transduction pathway, which **is considered to be a key** ~~is the critical~~ toxicological mechanisms for many persistent aromatic hydrocarbons." Please also add a citation for this?

- Page 32-
  - "Results from these studies provide ~~no~~ evidence that parent decaBDE in the presence or absence of exogenous liver metabolic system **does not** react directly or indirectly with DNA to cause either gene mutations, DNA damage, or chromosomal effects."
  - suggest deleting the 1st paragraph in 4.5. this section should not present hypotheses, particularly when the previous text does not support them. It makes things confusing.
  - much of the discussion in this section is on mechanism and does not belong here.
  - -~~"Given that the critical toxicological mechanism for many persistent aromatic hydrocarbons involves binding to the aryl hydrocarbon receptor (AhR), DNA binding, and gene expression,~~ Several *in vivo* and *in vitro* studies....."

- Page 33
  - "DecaBDE also caused thyroid gland follicular cell hyperplasia in male mice and thyroid tumors in male and female mice**[previous text says thyroid tumors were in male mice only]**, effects that are indicative of thyroid toxicity (NTP, 1986). ~~Based on these effects, decaBDE may share the general property of organohalogenated compounds in which *in vivo* exposure in rodents results in reduction of serum total and free thyroid hormone (T_4) levels (Legler and Brouwer, 2003).~~ Its not clear why this is relevant here.
  - the doses in Zhou were up to 100mg/kg. Seems odd to say that lack of effects is due to insufficient target dose—isnt it really just a lack of effect, considering the high dose?
  - seems odd that the Norris, 1973 study is mentioned for the first time here and is not discussed earlier.

- Page 34- suggest deleting sentence beginning with "a number of studies.." as its not clear what studies these are and all the IRIS drafts find no effect. Also the text says no studies

were found that looked at deca, however the last sentence in this paragraph discusses findings of such a study. This is confusing.

- Page 41-
  - in discussing the choice descriptor it would be useful to provide more information- e.g. the effects are seen at extremely high doses only. Is this a situation where the classification should be dependent on exceeding a certain dose?
  - What does the information on mechanisms and dosing tell us about likelihood of effects at environmental doses? Should this factor into EPAs decision to quantitate?
  - Why does EPA believe the evidence is on the strong end of the spectrum? This is not explained at all. The cancer guidelines call for a narrative discussion. This assessment could do a better job providing this information, in conjunction with the descriptor label.
  - Why is a dose response assessment deemed appropriate here? Considering the high doses tested and the lack of genotoxicity, what is EPAs rationale for doing dose response assessment? This needs to be further bolstered. It seems as though effects in each study were quite limited, particularly considering the doses.

- Page 42- "The increase in the radioactivity in the brain coupled with the behavioral disturbances on exposure to decaBDE on postnatal day 3 appear to suggest that differences may exist in the absorption and metabolism of decaBDE between neonates and slightly older ones and that the effect persisted and also worsened with age." When did the increase in radioactivity occur? Its not clear that significant differences in absorption and metabolism exist.

- Page 44
  - Does it make sense to use the Viberg study for the RfD? There is one study—in one species, in one sex, with essentially no supporting similar studies and no information on mechanism of action. Only 2 doses were tested. The UF EPA wants to apply is 300 and the certainty would be likely low. Is the science strong enough to support the use of this value for clean-ups conducted by program offices?
  - what does the following sentence mean: "In some respects the observation that effects occurred with such limited dosing argues for the importance of this study."?
  - The description of the concerns with the Viberg study is very good. It seems that other than the fact that the neurotox guidelines list functional neurotoxicity as an effect, and that there are PDBEs in human tissues, there is there is no support for relying on this study.

- Page 45-
  - 1st full paragraph: please provide a citation for the discussion of critical windows.
  - Its not clear that MeHg is a great example as there is very little data on specific windows during development that may lead to effects in humans- the large epi studies included exposures that occurred throughout development and into childhood. Suggest deleting this as an example. For lead, do we know of specific developmental windows where there is an effect?

- Is 20mg/kg a reasonable dose to expect humans to receive? Is this dose level relevant to todays exposure levels?
- Does it make sense to set an RfD in this situation?? Is there anything EPA is confident of? Are there any data on mechanism of action that may help?

- Page 48
  - suggest deleting: 'Furthermore, a developmental neurotoxicity study in mice has been conducted (Viberg et al., 2003)." Considering all the problems with the study design, its hard to believe that EPA believes this study fulfills all the criteria for DNT testing.
  - Its not clear to me why an UF for database is not needed here. What is it that makes the Deca database so much stronger than the other BDEs?
  - Is this sentence true: "When an RfD is based on systemic NOAEL of 1120 mg/kg/day from the NTP study, a database UF should be applied." Doesn't it depend on the database not the actual study that was used?

- Page 49-discussion of EPAs confidence in the proposed RfD is missing.

- Page 52-
  - Just because the data can be modeled, doesn't explain why quantitation is conducted, when the weight of evidence is only suggestive and for each endpoint the strength of evidence is relatively weak. Did EPA choose to model only because it could be done? What is EPAs confidence in the values that come out of the model considering the WOE?
  - why did EPA choose to use the linear multistage model? Were any other options discussed or tried? Does the fact that not mutagenicity is seen decrease EPAs confidence in doing this quantitatively?

- Page 53
  - what has changed since 1987, when EPA decided not to do a quantitative cancer value?
  - how does the NRC cancer slope factor derivation differ from the EPA derivation? Did they use similar methodologies and similar studies? If not, why were EPAs choices different?

- Page 54
  - "DecaBDE also has been shown to induce **spontaneous motor behavior changes in one study of male mice** ~~neurobehavioral toxicity~~."
  - "These data suggested that there is a critical window for the induction of behavioral disturbances, and the neurotoxic effect of neonatal decaBDE exposure was persistent and also worsened with age **in male mice.**

- Page 55
  - more narrative discussion of the cancer classification is needed.

- "In addition, only **one study** ~~limited tests~~ on motor activity **was** ~~were~~ conducted. This paragraph certainly undermines EPAs rationale for why a database UF is not needed.

- Page 56- considering that the evidence is suggestive, EPA should discuss how reliable the slope factor value is believed to be. What is the confidence in this number? Does EPA suggest that it be broadly used? Is there a dose level above or below which is should be used?

NIEHS comments:

December 2005
CHARGE TO EXTERNAL REVIEWERS FOR THE IRIS TOXICOLOGICAL REVIEWS OF
2,2',4,4'-Tetrabromodiphenyl Ether (BDE-47) CASRN 5436-43-1
2,2',4,4',5-Pentabromodiphenyl Ether (BDE-99) CASRN 60348-60-9
2,2',4,4',5,5'-Hexabromodiphenyl Ether (BDE-153) CASRN 68631-49-2
2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl Ether (BDE-209) CASRN 1163-19-5
The U.S. EPA is conducting a peer review of the scientific basis supporting the human health assessment of BDE-47, BDE-99, BDE-153 and BDE-209 that will appear on the Agency's online database, the Integrated Risk Information System (IRIS). The draft documents for the external peer review contain a description of the oral database, reference dose, qualitative cancer assessment for BDE-47, BDE-99 and BDE-153, and a quantitative cancer assessment for BDE-209. Please provide detailed responses to the charge questions below.

GENERAL QUESTION
Are you aware of other published peer-reviewed toxicological studies not included in these Toxicological Reviews that could be of relevance to the health assessment of BDE-47, BDE-99, BDE-153 or BDE-209?

1. QUESTIONS RELATED TO THE DERIVATION OF THE REFERENCE DOSE FOR BDE-47, BDE-99, BDE-153 and BDE-209
1.1 Have the rationale and justification for deriving RfDs on the basis of the neurobehavioral toxicity studies been transparently and objectively described in the Toxicological Reviews of BDE-47, BDE-99, BDE-153 and BDE-209? Are there additional studies that should be considered for deriving the RfDs for any of the four PBDE congeners?

The Eriksson, Viberg et al group at the Uppsala Univeristy, Sweden have reported on various neurotoxic effects of the PBDE isomers. Generally it is appropriate to use these studies for the RfDs.

1.2 Are the Eriksson et al., 2001 (BDE-47), Viberg et al., 2004 (BDE-99), Viberg et al., 2003a (BDE-153) and the Viberg et al., 2003b (BDE-209) studies appropriate for determining the point of departure?

1.3 Have the most appropriate critical effect and point of departure been selected? And hasthe rationale for the point of departure been transparently and objectively described?

1.4 Have the rationale and justification for each uncertainty factors (UFs) selected in the draft Toxicological Reviews of BDE-47, BDE-99, BDE-153 and BDE-209 been transparently described? If the selected UFs are not appropriate, what alternative UFs would you suggest and what are the scientific rationales for those suggested?

2. BODY BURDEN APPROACH

2.1 Are there adequate data for considering body burden as an alternative dose metric to administered doses in any of the RfD derivations?

The Birnbaum and Burka references on TK of the PBDEs need to be added and analyzed.

Sanders JM, Burka LT, Smith CS, Black W, James R, Cunningham, ML. 2005. Differential expression of *CYP1A*, *2B*, and *3A* genes in the F344 rat following exposure to a polybrominated diphenyl ether mixture or individual components. Toxicological Sciences, 88:127-33.

Sanders JM, Chen L-J, Lebetkin EH, Burka LT. 2006. Metabolism and disposition of 2,2',4,4'-tetrabromodiphenyl ether following administration of single or multiple doses to rats and mice. Xenobiotica (in press).

2.2 Do you agree with the rationale described in the Toxicological Review of BDE-99 that the data on the window of susceptibility of the cholinergic receptors to BDE-99 tend to minimize body burden concerns?

3. QUESTIONS RELATED TO THE CARCINOGENICITY ASSESSMENT OF BDE-209

3.1 Is the weight of evidence for the carcinogenicity of BDE-209 in the draft Toxicological Review appropriately described? Are there additional studies that should be included?

No – see additional comments below.

3.2 Do the available data support the descriptor *Suggestive evidence of carcinogenic potential* for BDE-209 according to the U.S. EPA. (2005) Guidelines for Carcinogen Risk Assessment? If not, what alternative descriptor would be supported by the existing data and what is the scientific rationale?
OK, but not complete.

3.3 Is the estimation of a cancer slope factor for BDE-209 in the Toxicological Review appropriate? Have the rationale and justification for the use of linear low-dose extrapolation been objectively and transparently presented?

3.4 Are there alternative modeling approaches that should have been considered instead of or in addition to the low-dose extrapolation approach?

See comment on added references.

1-09-06 - EPA Review of PBDEs

The major data gap in our knowledge on the toxicity of the polybrominated diphenyl ethers, is the toxic/cancer potential after long term exposures to these chemicals. The NTP's studies of these compounds is focused on filling this datagap, particularly after in utero/postnatal/adult exposures. It will be several years before these studies are completed.

I. EPA Toxicological Review of BDE-209, BDE-47, BDD-99, and BDE-153

a. The carcinogenicity assessment of BDE-209 is primarily based on the 1986 NTP TR study of decabromodiphenyl ether. The NTP TR reference (and also the NTP web site reference) should be added to the reference list for this report. This NTP study is used for the EPA Benchmark dose modeling.

The oral RfD for BDE-209 is 7 ug/kg/day (NTP Study, 1986); Viberg 2003).

The oral RfD for BDE-47 is 0.1 ug/kg/day (Eriksson, 2001; neurobehavioral study in mice).

The oral Rfd for BDE-99 is 0.1 ug/kg/day (Viberg, 2004 reference – locomotion and rearing habituation in mice).

The oral Rfd for BDE-153 is 0.2 ug/kg/day (Viberg 2003 reference – spontaneous motor behavior, learning, and memory endpoints in mice).

b. Missing from the EPA Toxicologic review of decabromodiphenyl ether (BDE-209) is a complete analysis of BDE-209 to the environment and the resultant chemical exposures.. When decabromodiphenyl ether is released into the environment does the chemical break down to lower brominated diphenyl ethers? If so, the hazard from exposure may be more extensive.

Decabromodiphenyl ether - does this chemical break down to lower brominated diphenyl ethers?

1. Stapleton, H.M., R.J. Letcher, and J.E. Baker, *Debromination of polyhrominated diphenyl ether congeners BDE 99 and BDE 183 in the intestinal tract of the common carp (Cyprinus carpio).* Environmental Science & Technology, 2004. **38**(4): p. 1054-1061.
2. Eriksson, J., et al., *Photochemical decomposition of 15 polybrominated diphenyl ether congeners in methanol/water.* Environmental Science & Technology, 2004. **38**(11): p. 3119-3125.
3. Bezares-Cruz, J., C.T. Jafvert, and I. Hua, *Solar photodecomposition of decabromodiphenyl ether: Products and quantum yield.* Environmental Science & Technology, 2004. **38**(15): p. 4149-4156.

4. Watanabe, I. and S. Sakai, *Environmental release and behavior of brominated flame retardants.* Environment International, 2003. **29**(6): p. 665-682.
5. Gouin, T. and T. Harner, *Modelling the environmental fate of the polybrominated diphenyl ethers.* Environment International, 2003. **29**(6): p. 717-724.
6. Keum and Li. *Reductive debromination of polybrominated diphenyl ethers by zerovalaent iron.* Environ Sci Techonology, 2005.
7. Hites, *Global assessment of polybrominated diphenyl ethers in farmed and wild salmon.* Environ Sci Technol. 38: 4945-9, 2004

c. Calculations to determine the amount of PBDEs released into the environment, and how this correlates to environmental concentrations should be calculated. An update on the CDC nhanes data for the PBDE monitoring program would be helpful.

d. The EPA reviews of PBDEs omit the ATSDR Reference for the Toxicologic Profiles for these chemical: ATSDR Profile on PBDEs

http://www.atsdr.cdc.gov/toxprofiles/tp68.html

d. Other References:

McDonald, T. A. Polybrominated diphenylether levels among United States residents: daily intake and risk of harm to the developing brain and reproductive organs, Integrated Enviroinmental Assessment and Management 1: 343-354, 2005.

D'Silva et al. Brominated organic micropollutants – igniting the flame retardant issu. Critical Reviews in Environmental Science and Technology 34: 141-207, 2004.

Other References:

Kodavanti and Ward, Differenctial effects of commercial polybrominated diphenyl ether and polychlorinated biphenyl mixtures on intracellular signaling in rat brain in vitro Toxicologic Sciences 85: 952-962, 2005.

Stapleton et al Polybominated diphenyl ethers in house duse and chlotes dryer lint, Envi Science Technology 39: 925-931,2005.

Brown et al. Analysis of AH receptor pathway activation by brominated flame retardants. Chemosphere 55: 1509-1518,2004.

Weber and Kuch. Relevance of BFRs and thermal conditions of the formation pathways of brominated and bromanted-chlorinated dibenzodioxins and dibenxofurans. Environmental Internation 29: 699-710, 2003.

Gallard et al Rate contants of reactions of bromine with phenols in aqueous solution. Water Research 37: 2883-2892, 2003.

Talsness et al Ultrastructural changes observed in rat ovaries following in utero and lactational exposure to low doses of a polybrmonated flame retardant. Tox. Let 157: 189-205, 2005 .

Kuriyama et al. Developmental exposure to low-dose PBDE-99 effects on male fertility and neurobehaviro in rat offspring. Envi Health Persp. 113:149-154, 2005.

Smeds and Saukko. Brominated flame retardants and phenolic endocrine disrupters in Finnish human adipose tissue. Chemosphere 53: 1123-1130, 2003.

Darnerud and Risberg. Tissue localization of tetra- and pentabromodiphenyl ether congeners 9BDE-47,-85-, and -99) in perinatal and adult C57Bl mice. Chemosphere 62; 485-93, 2006.

Jones-Otazo et al Is house dust the missing exposure pathway for PBDEs? An analysis of the urban fate and human exposure to PBDEs. Enviroin Sci Technol 39: 5121-30. 2005.

Darnerud et al. Common viral infection affects pentabrominated diphenyl ether distribution and metabolic and hormonal activities in mice Toxicology 210: 159-167, 2005.

Staskal et al Toxicokinetics of BDED47 in female mice; effect of dose, route of exposure, and time. Tox Sci 83: 215-223, 2005.

Sjodin et al Retrospective time-trend study of polybrominated diphenyl ether and polybrominated and polychrorinated biphenyl levels in human serum from the United States. Env Health Persp 112: 654-658, 2004.

Background Information on Chemicals with hormone action

Book I

I. General Background

1. de Wit, C.A., *An overview of brominated flame retardants in the environment.* Chemosphere, 2002. **46**: p. 583-624.
2. Birnbaum, L.S. and D.F. Staskal, *Brominated flame retardants: Cause for concern?* Environmental Health Perspectives, 2004. **112**(1): p. 9-17.
3. Darnerud, P.O., *Toxic effects of brominated flame retardants in man and in wildlife.* Environment International, 2003. **29**(6): p. 841-853.
4. Legler, J. and A. Brouwer, *Are brominated flame retardants endocrine disruptors?* Environment International, 2003. **29**(6): p. 879-885.
5. Vos, J.G., et al., *Brominated flame retardants and endocrine disruption.* Pure and Applied Chemistry, 2003. **75**(11-12): p. 2039-2046.
6. Alaee, M., et al., *An overview of commercially used brominated flame retardants, their applications, their use patterns in different countries/regions and possible modes of release.* Environment International, 2003. **29**(6): p. 683-689.

II. Polybrominated Diphenyl Ethers

A. PBDE Hormone action

1. Zhou, T., et al., *Effects of short-term in vivo exposure to polybrominated diphenyl ethers on thyroid hormones and hepatic enzyme activities in weanling rats.* Toxicologic Sciences, 2001. **61**: p. 76-82.
2. Zhou, T., et al., *Developmental exposure to brominated diphenyl ethers results in thyroid hormone disruption.* Toxicological Sciences, 2002. **66**: p. 105-116.
3. Stoker, T.E., et al., *Assessment of DE-71, a commercial polybrominated diphenyl ether (PBDE) mixture, in the EDSP male and female pubertal protocols.* Toxicological Sciences, 2004. **78**(1): p. 144-155.
4. Meerts, I.A.T.M., et al., *In vitro estrogenicity of polybrominated diphenyl ethers, hydroxylated PBDEs, and polybrominated bisphenol A compounds.* Environ. Health Perspect., 2001. **109**: p. 399-407.

B. PBDE General Exposure information

1. Sjodin, A., et al., *Retrospective time-trend study of polybrominated diphenyl ether and polybrominated and polychlorinated biphenyl levels in human serum from the United States.* Environmental Health Perspectives, 2004. **112**(6): p. 654-658.
2. Hites, R.A., *Polyhrominated diphenyl ethers in the environment and in people: A meta-analysis of concentrations.* Environmental Science & Technology, 2004. **38**(4): p. 945-956.
3. Petreas, M., et al., *High body burdens of 2,2 ',4,4 '-tetrabromodiphenyl ether (BDE-47) in California women.* Environmental Health Perspectives, 2003. **111**(9): p. 1175-1179.
4. Alcock, R.E., et al., *Understanding levels and trends of BDE-47 in the UK and North America: an assessment of principal reservoirs and source inputs.* Environment International, 2003. **29**(6): p. 691-698.
5. Covaci, A., S. Voorspoels, and J. de Boer, *Determination of brominated flame retardants, with emphasis on polybrominated diphenyl ethers (PBDEs) in environmental and human samples - a review.* Environment International, 2003. **29**(6): p. 735-756.
6. Law, R.J., et al., *Levels and trends of polybrominated diphenylethers and other brominated flame retardants in wildlife.* Environment International, 2003. **29**(6): p. 757-770.
7. Hale, R.C., et al., *Polybrominated diphenyl ether flame retardants in the North American environment.* Environment International, 2003. **29**(6): p. 771-779.
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9. Hooper, K. and J.W. She, *Lessons from the polybrominated diphenyl ethers (PBDEs): Precautionary principle, primary prevention, and the value of community-based body-burden monitoring using breast milk.* Environmental Health Perspectives, 2003. **111**(1): p. 109-114.

Book II

C. Other PBDE biological effects

1. Helleday, T., et al., *Brominated flame retardants induce intragenic recombination in mammalian cellsMutation Research.* Mutation Research, 1999. **439**: p. 137-147.
2. Kemmlein, S., D. Herzke, and R.J. Law, *BFR - governmental testing programme.* Environment International, 2003. **29**(6): p. 781-792.
3. Hakk, H. and R.J. Letcher, *Metabolism in the toxicokinetics and fate of brominated flame retardants - a review.* Environment International, 2003. **29**(6): p. 801-828.
4. Viberg, H., A. Fredriksson, and P. Eriksson, *Neonatal exposure to polybrominated diphenyl ether (PBDE 153) disrupts spontaneous behaviour, impairs learning and memory, and decreases hippocampal cholinergic receptors in adult mice.* Toxicology and Applied Pharmacology, 2003. **192**(2): p. 95-106.
5. Viberg, H., A. Fredriksson, and P. Eriksson, *Investigations of strain and/or gender differences in developmental neurotoxic effects of polybrominated diphenyl ethers in mice.* Toxicological Sciences, 2004. **81**(2): p. 344-353.
6. Chen, G.S. and N.J. Bunce, *Polybrominated diphenyl ethers as Ah receptor agonists and antagonists.* Toxicological Sciences, 2003. **76**(2): p. 310-320.
7. Branchi, I., et al., *Polybrominated diphenyl ethers: Neurobehavioral effects following developmental exposure.* Neurotoxicology, 2003. **24**(3): p. 449-462.

III. Tetrabromobisphenol A

1. Meerts, I.A.T.M., et al., *Potent competitive interactions of some brominated flame retardants and related compounds with human transthyretin in vitro.* Toxicologic Sciences, 2000. **56**: p. 95-104.
2. Kitamura, S., et al., *Thyroid hormonal activity of the flame retardants tetrabromobisphenol A and tetrachlorobisphenol A.* Biochemical and Biophysica Research Communications, 2002. **293**: p. 554-559.
3. Hakk, H., et al., *Metabolism, excretion and distribution of the flame retardant tetrabromobisphenol-A in conventional and bile-duct cannulated rats.* Xenobiotica, 2000. **30**: p. 881-890.
4. Samuelsen, M., et al., *Estrogen-like properties of brominated analogs of bisphenol A in the MCF-7 human breast cancer cell lines.* Cell Biology and Toxicology, 2001. **17**: p. 139-151.
5. Brown, D.J., et al., *Analysis of Ah receptor pathway activation by brominated flame retardants.* Chemosphere, 2004. **55**: p. 1509-1518.
6. Hayama, T., et al., *Determination of tetrabromobisphenol A in human serum by liquid chromatography-electrospray ionization tandem mass spectrometry.* Journal of Chromatography B-Analytical Technologies in the Biomedical and Life Sciences, 2004. **809**(1): p. 131-136.
7. Szymanska, J.A., J.K. Iotrowski, and B. Frydrych, *Hepatotoxicity of tetrabrombisphenol-A: effects of repeated dosage in rats.* Toxicology, 2000. **142**: p. 87-95.

8. Inouye, B., et al., *Effects of aromatic bromine compounds on the function of biological membranes.* Toxicol Appl. Pharmacol, 1979. **48**: p. 467-477.

IV. Sodium chlorate

1. Hooth, M.J., et al., *Subchronic sodium chlorate exposure in drinking water results in a concentatio-dependent increase in rat thyroid follicular cell hyperplasia.* Toxicol Pathol, 2001. **29**: p. 250-259.

Book III

V. Hexachlorobenzene

1. National Toxicology Program, *Final Report on the 13-Week toxicity study of Hexachlorobenzene.* Battelle Columbus, 2001.

VI. 3,3',4.'-Tetrachlorazobenzene

1. National Toxicology Program, *Final Report on the 13-Week toxicity study of 3,3",4,4'-tetracloroazobenzene.* Battelle Columbus, 2001.

VII. Decabromodiphenyl ether - does this chemical break down to lower brominated diphenyl ethers?

1. Stapleton, H.M., R.J. Letcher, and J.E. Baker, *Debromination of polyhrominated diphenyl ether congeners BDE 99 and BDE 183 in the intestinal tract of the common carp (Cyprinus carpio).* Environmental Science & Technology, 2004. **38**(4): p. 1054-1061.
2. Eriksson, J., et al., *Photochemical decomposition of 15 polybrominated diphenyl ether congeners in methanol/water.* Environmental Science & Technology, 2004. **38**(11): p. 3119-3125.
3. Bezares-Cruz, J., C.T. Jafvert, and I. Hua, *Solar photodecomposition of decabromodiphenyl ether: Products and quantum yield.* Environmental Science & Technology, 2004. **38**(15): p. 4149-4156.
4. Watanabe, I. and S. Sakai, *Environmental release and behavior of brominated flame retardants.* Environment International, 2003. **29**(6): p. 665-682.
5. Gouin, T. and T. Harner, *Modelling the environmental fate of the polybrominated diphenyl ethers.* Environment International, 2003. **29**(6): p. 717-724.

CDC comments:

CDC/ATSDR General Comments:

We have very few comments concerning the approach taken for the assessment of the

new RfD for BDE-47, BDE-99 and BDE-153. We are happy to see that EPA is now basing the risk assessment to a large extent on the work of Erikson and co-workers as the most sensitive endpoint of PBDE exposure, while at the same time describing in an objective manner the limitations of these studies.

Page 1, line 3 in the BDE-153 document: At this location please change BDE-99 to BDE-153.

DBT

John Vandenberg /DC/USEPA/US
02/07/2006 02:34 PM

To: Bob Benson/P2/R8/USEPA/US@EPA, Mary Manibusan/DC/USEPA/US@EPA, Amy Mills/DC/USEPA/US@EPA, Karen preuss.peter@epa.gov, George Alapas/DC/USEPA/US@EPA
cc:
bcc:
Subject: Interagency/OMB comments on Draft IRIS assessment of Dibutyl Phthalate

Please see below for a number of specific comments from CDC and also OMB, it is possible other comments from CPSC will be provided later. In general, I see many technical edits and corrections, with a few bigger issues as well (e.g., the comments on pages 74-85).

Our approach to these interagency comments (for perc and dichlorobenzenes) has been to carefully evaluate the comments and to develop a response to comments document. I recommend you create a document that addresses each comment (include their "comment" and our "responses" as one file) and provide a point-by-point evaluation. I encourage that the tone of our 'responses' be thoughtful and that we make such changes as we deem warranted. If there are some larger science-policy issues or points made where it is unclear how to respond, then flag these for discussion.

Please give me a sense of the time it may take you to respond to these comments (I'd expect a few weeks). Thank you for all your hard work on this document, it seems we'll soon be able to move ahead!

John

John Vandenberg
Associate Director for Health
National Center for Environmental Assessment B243-01
Office of Research and Development, USEPA
Research Triangle Park, NC 27711

DC Research Triangle Park, NC
Tel: 202 564 3407 919 541 4527
Fax: 202 565 0090 919 541 5078

---- Forwarded by John Vandenberg/DC/USEPA/US on 02/07/2006 02:21 PM ----

"Beck, Nancy" <Nancy_Beck@omb.eop.gov>
02/07/2006 09:50 AM

To: John Vandenberg/DC/USEPA/US@EPA
cc: Peter Preuss/DC/USEPA/US@EPA
Subject: RE: Draft IRIS assessment of Dibutyl Phthalate

OMB coms
- sim to OMB rags
- precursor events & adversity. Reduced testosterone · Biochem. change.
- moa rel to humans? (Ag. trad'y assumes relevance). (Hormone)
(what level in rodent rel. to humans??) ---→ clinical link to change.
- concordance
(need epi data?)
(- precursor effects OK via cancer g'lines.)
- where's data coming from - rodent only?

Hi John,
Attached are agency comments on the draft. Its possible CPSC may have some comments as well, but here are some to get you started.

Please let me know if you would like to talk through EPA responses to comments or if EPA will provide a written response. I'm happy to answer and questions and facilitate any needed dialogue with CDC as well. Otherwise, we will look forward to seeing a revised draft and responses to comments.

Many thanks,
Nancy

-----Original Message-----
From: Vandenberg.John@epamail.epa.gov
[mailto:Vandenberg.John@epamail.epa.gov]
Sent: Friday, December 02, 2005 12:34 PM
To: Beck, Nancy
Cc: Boone.Amanda@epamail.epa.gov; Mills.Amy@epamail.epa.gov; preuss.peter@epamail.epa.gov
Subject: Draft IRIS assessment of Dibutyl Phthalate

Hi Nancy,
Here is the next draft IRIS assessment for you to look at (if you want!). Attached is the draft dibutyl phthalate tox review and draft charge questions.
This has been developed within the agency and has completed intra-agency review by the IRIS reviewers. It has not been shared with other agencies and we are not aware of any particular interest by other agencies. Our plan is to announce the availability of the document in the FR and have the document externally reviewed through a panel review (organized and managed by a contractor, timed to allow public comments to be provided prior to panel meeting).
Let me know if you have any questions about the draft.
Thanks,
John
(See attached file: Charge DiBP ext peer review3.wpd) (See attached file: Tox R DiBP ext peer review2.wpd)

John Vandenberg
Associate Director for Health
National Center for Environmental Assessment B243-01 Office of Research and Development, USEPA Research Triangle Park, NC 27711

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Dibutyl PhthalateAgencycomments.doc

February 6, 2006 (there may be more comments coming from CPSC)

CDC Comments

Page 6, 2nd paragraph, 2nd sentence: It needs to be mentioned that there are esterases in some biological matrices, including amniotic fluid, saliva, and breast milk, that could hydrolyze DBP to MBP. Therefore, MBP could be detected in some tissues as a result of contamination with DBP that it is hydrolyzed to MBP by esterases.

Page 7, section 3.2: The Silva et al., 2003 ref (2nd line of 1st paragraph) doesn't have rats data: It should be deleted.
Last sentence of paragraph: It is not that the omega and omega-1 oxidation products of MBP were not detected, but that they were not measured. The sentence should be rewritten: Monobutyl phthalate and monobutyl phthalate glucuronide have been found in human blood and urine, but the products of omega and omega-1 oxidation have not been MEASURED (Silva et al., 2003).

Page 8, Figure 1: The correct name of the structure at the bottom right of the scheme is: 3-carboxypropyl NOT 4-carboxypropyl

Page 9, 1st paragraph: The concentrations reported in the draft from the Silva et al., 2003 paper are MEDIAN, not mean (as stated). Also, indicate the number of human samples analyzed: 283.

Page 16, 2nd paragraph, line 7: As written, it appears that in the Silva et al., 2003 paper the concentration values 14.4 and 4.2 were given. However, this statement is incorrect: The value 14.4 was given in Silva et al., 2003 (Table 2 of the manuscript). The value of 4.2 was not. If this value was calculated by EPA from data provided in Silva et al., 2003, this should be clearly indicated.

Page 16, 2nd paragraph, line 4: The presence of MBP in tissues other than urine could come, at least partially, from the hydrolysis by esterases present in the tissues of the ubiquitous DBP introduced in the sample during sampling or storage. Furthermore, the concentrations of MBP in tissues/fluids other than urine in humans are relatively low when compared to urinary concentrations. For these reasons, urinary data may be more reliable than serum data for MBP: higher MBP concentrations in urine than in serum, and minimal esterase activity in urine compared to serum. Urine, however, unlike blood/serum, is a non-regulated fluid, so dilution of urine due to hydration status may complicate calculations.

Page 17, 2nd paragraph: The Calafat et al. (2005) reference (in press at the time the draft was written) has been published. The correct citation is Calafat et al. (2006):
Calafat, A.M., Brock, J.W., Silva, M.J., Gray, L.E., Reidy, J.A., Barr, D.B., Needham, L.L., 2006 Urinary and Amniotic Fluid Levels of Phthalate Monoesters in Rats after the Oral Administration of Di(2-ethylhexyl) Phthalate and Di-n-butyl Phthalate. Toxicology 217, 22-30.
This citation can also be updated in page 90 (reference list)

Page 19, 1st line: Colon et al. (2000) didn't measure monobutyl phthalate in serum. They measured the parent compound, dibutyl phthalate (DBP). Therefore, the reference to this study should be deleted.
Page 19, 2nd paragraph: Data from NHANES 2001-2002 are available at www.cdc.gov/exposurereport/, so Table 3-5 could be updated to also include these data.

Page 19, 2nd paragraph: In CDC's publication using the NHANES 1999-2000 data (Silva et al, 2004a), it was shown that women of reproductive age (30-39 years old) DID NOT have higher concentrations of MBP than younger or older women. This is shown in Figure 4 of the Silva et al., 2004a paper. This finding is not mentioned in this draft and it should, especially because the draft does mention the findings from the NHANES III dataset in the 1st paragraph of this page regarding pregnant women.

Page 21: The calculation of the estimated dose conducted by Kohn et al. in 2000, used the phthalates NHANES III dataset, which was NOT representative of the U.S. population. Therefore, in page 21, the 7 microg/Kg-day dose for the general U.S. population was taken from 192 individuals and the 32 microg/kg-day for U.S. women of childbearing age was taken from only 97 women. I think here it would be a good place again to indicate the estimated exposure from the NHANES 1999-2000 and NHANES 2001-2002 data.

Page 24, last line of 1st paragraph: Specify that the NHANES samples are from NHANES 1999-2000.

Page 67, 1st paragraph, 3rd line: Delete Silva et al. 2003. In this manuscript no attempt was made to measure analytes other than MBP.

Page 67, 4th paragraph: Rewrite sentence as follows: Two studies have documented an association between some adult human semen measures with exposure to dibutyl phthalate (Murature et al., 1987) and phthalate monoesters (Duty et al., 2003a).

Page 89, end of 1st paragraph: There is only one study that suggests that "the 95th percentile for the general population is approximately 7 µg/kg-day and for women of childbearing age approximately 32 µg/kg-day." Insert the Kohn et al. 2000 reference at the end of the last sentence of the paragraph: this will indicate to the reader the source of the data. I would also suggest that the dose is calculated for the U.S. general population and for women of childbearing age using the NHANES 1999-2000 data presented in Silva et al. 2004a. The phthalates NHANES 1999-2000 and 2001-2002 were representative of the general U.S. population, the NHANES III dataset was not.

OMB Comments

- Page 1 and throughout- please use original, not 2002 recommended RfD definition.

- Page 5, the Anderson 2001 study is referred to as being 'conducted with an ethically approved protocol'. Please clarify in the text what it is that this means.

- Page 9, in discussing Silva 2003 and elimination, the text should state what the dose (exposure) was otherwise the urine value is not informative regarding elimination rates.

- Page 14 states: "*Although a completed physiologically based pharmacokinetic model for both the rat and human is not yet available, it might be possible to use other data to provide an estimate of the relative exposure of the rat and human fetus to the toxicologically active metabolite, monobutyl phthalate, during the critical window for development of the male reproductive tract. Information on relative exposure could be used to inform the selection of the interspecies uncertainty factor used to derive a reference value.*" These statements are very broad. What is meant by "other data" and in 1st sentence? In the 2nd sentence how might relative exposure information be used to inform an UF? Its not clear how UF's take relative exposure into account-do you mean organ specific internal dose?

- Page 15, how significant is the variability of monobutyl phthalate glucuronide, as discussed in Silva 2003?

- Page 17, for monobutyl phthalate, the range of partition coefficients is 1.9-2.8. Is there a citation for this? Its not clear where the numbers come from.

- Page 18, plots from Kremer 2005a are referred to. This citation is only an abstract. Did it really contain plots?

- Page 19, please state that the 289 samples from Blount, although part of NHANES, should not be considered to be representative as it is not a full NHANES dataset.

- Page 19, table 3-5 is confusing. Its not clear what data is being referred to-is it from the Blount study or Silva or DHHS? Also it would be useful to know if the values are for males or females or both.

- Page 20/21, its not clear at all where the values of 7ug/kg for a 95th percentile and 32 ug/kg for US women comes from. Please clarify. This is very confusing. Also, is the 32ug/kg data a mean or a 95th percentile?

- Page 22, please state whether or not the decrease in mean sperm density seen in Murature was statistically significant?

- Page 22, please state the sample size for the comparison group in Duty et al.

- Page 23, in discussing Duty, 2004, it says the dose response was 'suggestive negative'. Please clarify what this means-was it not statistically significant?

- Page 26, please state whether or not the associations with enzyme levels in Fukuoka and the decreases in Zhou were statistically significant.

- Page 28, in discussion of Fukuoka please state whether or not changes in testicular fructose and glucose were statistically significant. Also, what may explain the fact that blood concentrations did not change? Is this to be expected?

- Page 35, why are no NOAELs and LOAELs provided for the Gray study?

- Page 43, a NTP 2002 abstract is referred to. Is there no final report to update these data?

- Page 54, refers to a weight of evidence pointing to a dec. in testosterone in leydig cells. Where is this weight of evidence coming from? Its not clear what studies are being referred to here as the 2 most recently cited studies in the text are both abstracts.

- Page 61, its not clear where or how the studies in 4.3.2 clearly show that monbutyl phthalate is responsible for the toxic effect. Please clarify the reasoning behind this.

- Page 66, states that Dibutyl phthalate is metabolized to monobutyl phthalate and n-butanol. How come n-butanol is never mentioned in section 3.2?

- Page 68, please insert the language in bold in the following 2 sentences:
There are extensive studies documenting developmental toxicity of dibutyl and monobutyl phthalate **in rodents**. A number of studies have examined gene expression for the enzymes involved in steroid biosynthesis **in rodents**.

- Page 69, discussion of MOA should be clear that this is for rodents. Also, there seems to be no discussion about the relevance of this in humans. Is it known that the pathways in humans are the same and that levels of hormones and hormone reserves are similar?

- Page 72, please clarify that this is a proposed MOA in rodents. Also in the figure suggest saying that reduced testosterone and dihydrotestoterone **can** result in... Also reduced Ins3 **may** result in...unless all these effects are proven-although the language in the text makes it sound as though causality is possible but not known with certainty. Also in the figure its not clear if the MOA is for the testis or leydig cell?

- Page 74, why is the decrease in testosterone levels throughout the document referred to as a NOAEL and LOAEL? Isn't it really an NOEL? this should be changed throughout the document (page 85 etc) Even the Lehmann paper itself talks about a NOEL and a LOEL. Page 75 is clear that this is not an adverse effect but is a precursor for all other effects. Is it clear that all adverse developmental effects stem from the decrease in testosterone? From figure 2 it seems as though Ins3 effects are independent of testosterone.

- Page 74, is there a developmental effect in humans that is predicted by retained areolas or nipples in the male fetus? Has EPA relied on this endpoint before?

- Page 75, in perchlorate there is a precedent for regulating based on an upstream precursor effect in humans. However, here EPA is using a precursor effect in rats. A discussion of how levels of testosterone in humans and rodents may be similar in levels, reserves, metabolism, or

stores is not provided at all. In order to justify using this endpoint, EPA needs to discuss this thoroughly and there needs to be strong evidence that pathways and regulation in humans and rodents, not just for testosterone but also for dibutyl phthalate metabolism are similar.

- Page 75, its not clear how the effect could be due to a single exposure. Text cites Carruthers and Foster, which was a multiday exposure, Thompson was an abstract only which used a 2 day exposure, and its not clear what in EPA 1991 is being referred to. The Developmental guidelines are getting pretty old and the endpoint of changes in hormone levels is not even referred to in this document-the guidelines do not discuss whether or not exposure to a precursor on a single day could justify an adverse effect.

- Page 76, figure 3 and 4 should be made more clear. It would be helpful to perhaps break these into 2 arrays—one showing responses in the 0-400 range and the other showing higher levels. The resolution at the low exposures is what is important here and it is lacking most. Also please be clear about which effects are not adverse.

- Page 79, regarding the # notation, please see the comments for page 75 regarding the exposure window.

- Page 85, in table 5-4, why is BMDL 1SD shown? Its not clear why this endpoint was chosen.

- Page 85, there is discussion as to why the BMD approach was not used and this seems to depend on limitations of the study (position in litter was not considered, gender effects, etc). How do these limitations affect the confidence in the NOEL? It seems that they likely lead to an increase in variability. Also this section is the first time the biological significance of testosterone changes is mentioned. Shouldn't there be more discussion of the levels required for significance in the MOA section of the chapter?

- Page 86, see comment on page 75 regarding single exposures. Suggest deleting this sentence.

- Page 87, its not clear why there is a discussion in the database UF section that is talking about the lack of cancer bioassays and the mode of action for tumors. Suggest deleting this language.

- Page 87, its not clear that the data support an acute, short term, or subchronic RfD. Discussion is not sufficient to support this (see comment regarding page 75).

- Page 88, besides the old RfD, are there any other safety values in existence (ATSDR or CALEPA or other?). It would be useful to mention these.

- Page 89, please change NOAEL to NOEL; please clarify where 7 and 32ug/kg come from and discuss how representative they are; why is the confidence high when there are no human developmental or reproductive data—how dose data in 7 animals translate to high confidence for the RfD?

- B-1, is it normal to use a nested model? What does this imply about the data?

- B-5, Were the data used based on the F1 litter 3 or results from all 5 litters analyzed together?

editorial comments:

Page 16- Saliva 2005 should be Silva 2005

Page 17- in discussing the boron assessment, the ref given is to the cancer guidelines, which does not seem correct

Page 19- refers to "thelarche", do you mean "menarche"?

Page 44- refers to a 10,000ppm:0ppm exposure group. Is this a common way to describe this treatment group?

Other comments:

- What expertise will EPA have on the review panel? How many reviewers in each area?
- Has EPA set an RfD before based on a precursor effect in rodents? Based on retained nipples?
- The charge should be modified to reflect that there is no discussion of an RfC or quantitative cancer assessment
- If EPA continues to rely on the NOEL, the charge will have to have some questions asking about relevance of this precursor to humans, MOA in humans, whether or not this is adverse and at what levels, whether or not this prevents all developmental effects, etc.

Comments from OMB (Margo Schwab)
4-19-05

Comments on the Toxicological Review of Toluene (Feb 2005 draft)

General Comments on RfC

1. Clarity:

We suggest improving the clarity of presentation for both this document and the actual IRIS entry file. Specifically, the document reads like a hybrid of the old focus on "color vision" and the new focus on a suite of "neurological effects."

We suggest a stronger first paragraph that reviews the potential options for the critical endpoint and clearly states that you are using an array or suite of effects, considered together as the critical endpoint. The reasons EPA determined it makes sense to use a suite of endpoints should be more clearly stated here as well.

The detailed comments below provide additional comments designed to help improve the clarity of the document.

2. Description of the Methods Used:

The "Weight of Evidence" method should be clearly explained before presenting the results (although a weight of evidence approach is common for hazard ID, but not for dose-response, thus the need for an explanation). The actual criteria that are used should be described as well. See comments below for page 75.

Some confusion might be due the apparent disconnect between the usual use of "weight of evidence," which describes an approach which weighs all of the evidence, versus it use here to describe a method of classifying available studies based on adequacy. It may be better to describe the choice of the critical endpoint as based on "weight of evidence" approach rather than the choice of the principal study. That is, EPA reviewed all of the studies, and determined that as a whole they present evidence of the potential for neurological effects. However, in determining a point of departure, EPA selected a subset of the highest quality studies to determine an "average" or "typical" level of effect.

3. Transparency with Respect to the Limitations of the Methods:

We suggest adding discussions that clearly lay out the limitations/caveats/concerns and utility associated use of **both** 1) a suite of neurological endpoints as the critical effect and 2) an average or typical metric as the point of departure. Both of these discussions would provide risk managers with the information that they need to understand what she/he is protecting against when they use this RfC.

With respect to the former, the discussion could be added to the paragraph that initially introduces the use of a **suite of endpoints**. The added discussion should highlight (based in part on peer reviewers comments) that some of these neurological endpoints may not actually be "adverse" and others may exhibit fairly high baseline population variability.

With respect to the latter, use of an average **point of departure** from a group of studies that are not strong enough in and of themselves begs the question as to meaning of the relationship being described. The reader needs some guidance as to what it means to

be "above" or "below" this number since it is not a simple NOAEL or BMD. Perhaps it would be helpful to explain it as a range: "we expect the NOAEL for this suite of neurological effects to be between x and y ppbs." Then go on to explain that you are using the average as a surrogate because of the instability of each of the individual numbers (given both EPA's and the peer reviewer concerns about utility of the individual studies). Perhaps you can show how sensitive the average is to the inclusion of certain studies or the similarity of the average with the use of specific principal studies.

Specific edits re: RfC section:

pg 73, 1st paragraph, line 2: documentation of the "developmental effect in newborn children" is not provided in the prior literature review. pls add cites to the "numerous cases" or delete

pg 73, 2nd paragraph, end of second sentence add "for individual neurological effects"

pg 73, 2nd paragraph, fourth sentence: add "at least one of the following neurological effects" between "on" and "color vision, auditory evoked....."

pg 73, 2nd paragraph, last sentence: it is not clear what the connection is between the two parts of the sentence. Should the Campagna et al 2001 study be cited in with the lower exposure studies at the beginning of the paragraph? Also, isn't this the same thought that is in the second sentence of the next paragraph?

pg 73, 3rd paragraph, second line, add "have" between "or" and "inadequate" (or change it to "do not have adequate").

pg 74, paragraph beginning on prior page: rework 1st sentence on page to focus on the key point: "For example, the study that showed effects at the lowest level of exposure (i.e., color vision at 8 ppb) included individuals who had substantial exposure to compounds other than toluene (Compagna et al. 2001).

pg 74, paragraph beginning on prior page: how does this sentence relate to the theme re: confounding? are you implying that effects were not found due to confounding? If this is so, say so and present the specific ways in which these studies were confounded that the positive studies were not. The sentence, as is, however, could just be moved to the end of the prior paragraph (it would provide the balance to the positive studies listed there.)

pg 75, line 2, insert "the potential for" or "the relationship between" after the phrase "evidence indicating"

pg 75, line 3: see comment above re: term weight of evidence. Since this is the first place this concept is introduced, please clearly define the method used to review and categorize the literature here.

pg 75, 1st full paragraph: please define the basis for determining "adequacy" here - lay out the criteria that used.

pg 75, 2nd full paragraph: suggest not using the term "discounted" (either here or in the subsequent paragraphs and summary document) because a weight of evidence approach weighs ALL of the evidence. It does not "discount" studies. It does give more weight to stronger studies, but the way the term is being used in this and subsequent pages, it implies the studies were not included. A more appropriate way of explaining would be to describe why lesser weight was given to certain studies (e.g., lower quality or strength, etc).

Table 2: Suggest a more balanced presentation in which highlights both the positive and negative results from the 10 studies are presented - that is, if several endpoints were explored, it is inadequate to just present the positive results given the impact of problem of multiple comparisons on the statistical significance of findings. Some of the information appears to be in the tables, perhaps it is an issue of re-labeling the columns?

Pg 81: 1st paragraph, line 2: not sure why effects other than neurological are being discussed here within the context of the "principal study" given that principal effect has been determined (this whole paragraph seems misplaced – perhaps it belongs as part of the first paragraph on page 72?)

Pg 81: 2nd and 3rd paragraphs, and the 1st paragraph on the next page: all three of these paragraphs discuss on deficits in visual perception, but the context for that discussion is not clear – since the "critical effect" is now a suite of neurological effects, please indicate why one set of effects is discussed.

Comments on the RfD

- It is unclear why the UF of 3 for data base sufficiency is necessary, especially given peer reviewer comments to the contrary.
- If the UF is 3000, it is unclear how the confidence could be "medium"

December 30, 2003

Summary of OMB comments and EPA responses -
External review draft of the Toxicological Review of Toluene (December 2003)
Prepared by Lynn Flowers, chemical manager for toluene

OMB comment #1: There is concern about precedent being set by using color vision as a critical endpoint and a related concern that there is not sufficient reviewer expertise to address this, particularly the biological relevance. Specific comments included:

-Are there appropriate reviewers to look at this?
-Only 50% of reviewers on previous panel were ok with this and one of these reviewers did not think documentation was sufficient.
-Others asked for increased discussion on biological relevance. This still seems to be missing from the draft.
-The added reviewer with this expertise is an author whom EPA cites for having used this test for environmental relevance in the past, thus he may not be seen as an unbiased reviewer.
-The charge question 2b should directly ask "Is this effect biologically relevant"? This would mean there needs to be experts on the panel that can answer the question. Reviewers from the previous panel sounded like they could not and these same reviewers are on the panel again.

EPA response: The peer review contractor is trying to find another color vision expert and has contacted the panel members with neurotoxicity expertise to inquire about their capability to review/comment on color vision. Additional discussion on the choice of color vision as the critical effect and biological relevance of this endpoint has been added to Section 5.2.1 of the Toxicological Review. The charge question (2b) has been clarified as follows: "The critical effect is identified as impaired color vision. Is this the correct critical effect and is it adequately described? Is the biological basis for choosing this effect adequately explained?"

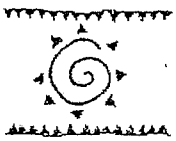
OMB comment #2: Appendix A is unclear in that all reviewers agreed with the RfD principal study, yet it was changed anyway. Reads as very contradictory and needs to be clarified. Uncertainty factor discussion needs to be clarified.
EPA response: The rationale for the change in the principal study for the RfD has been clarified in Appendix A to better explain that additional key studies were identified as a result of public comment. The discussion on the application of uncertainty factors to the point of departure for the RfD has been corrected.

OMB comment #3: It is unclear why kidney weight changes are used instead of liver weight changes or in addition to liver changes. This is not explained well (especially considering distribution of toluene in the body).
EPA response: The rationale for selecting kidney weight changes as the critical effect for the derivation of the RfD has been further clarified in Section 5.1.1 of the Toxicological Review.

OMB comment #4: It is unclear if discussion of immunological studies belongs in Section 1.A.2 or 1.A.4 of the IRIS summary.
EPA response: The discussion of immunological effects from toluene exposure has been moved to Section 1.A.4 of the IRIS Summary.

OMB comment #5: Use of male rat data instead of male and female data for the RfD does not appear to be supported well, especially considering Section 4.7.2 of the Toxicological Review. If both sexes were used, how different would the value be?
EPA response: Male rat data were used for the derivation of the RfD. The response in male rats was greater than that seen in female rats as indicated in Section 4.2.1.1 of the Toxicological Review. As indicated in Section 4.7.2, male rats and mice have been shown to be more sensitive, in general, to the effects of toluene than females. Thus, the use of data from male rats is supported by the available studies.

John Vandenberg/DC/USEPA/US



John
Vandenberg/DC/USEPA/US
09/13/2004 10:39 AM

To Peter Preuss/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US
cc George Alapas/DC/USEPA/US@EPA, Amy Mills/DC/USEPA/US@EPA
Subject naphthalene - OMB request for briefing

Nancy Beck called me this morning and conveyed several things:

1) John Graham wants a briefing on the naphthalene assessment, focused on process from here (e.g., interagency review, consideration of peer review comments). We should arrange in next couple of weeks if possible.

2) She (Nancy) considers some of the external peer review comments to be significant.

3) they've heard a rumor we plan to have the document out by end of September.

I told her we're evaluating the draft in light of peer review comments, that we've heard DOD plans to comment but we have not received any commentsfrom them and I urged her to get them to share their comments. I sketched out the IRIS process insofar as it would normally proceed, noting that a formal interagency review would change the process (and that we'd share a document that reflects our revisions following external peer review). I mentioned IRIS Track (Paul Gilman had also mentioned it, they're interested in seeing it). I didn't give any specific dates to her (perhaps fortunately IRIS track was offline this morning!)

We should talk through how we want interagency review to occur, including any groundrules we want to get set up front to avoid paralysis (e.g., fixed time for other agencies to provide review comments; final disposition/decisionmaking by EPA/ORD on assessment document completion; criteria or conditions calling for additional external peer review). Especially for "biggies" that have interagency review we need to stake out a process that will lead us to be successful in terms of timeliness, clarity, consistency, etc.

John

John Vandenberg
Associate Director for Health
National Center for Environmental Assessment B240-01
Office of Research and Development, USEPA
Research Triangle Park, NC 27711

DC Research Triangle Park, NC

John
Vandenberg/DC/USEPA/US
05/24/2005 02:52 PM

To: Amy Mills/DC/USEPA/US@EPA, preuss.peter@epa.gov, George Alapas/DC/USEPA/US@EPA, Bettyjo Overton/DC/USEPA/US@EPA, Linda
cc:
bcc:
Subject: IRIS process comments from OMB, next steps

In brief, Nancy Beck (and, she says, Dr. Graham) were expecting more detail than provided in the flow chart and 2-pager to address the 'details'. I pushed back, not wanting to have us wait several months to develop new SOPs, as this is premature. Nancy seemed to concur, though she is checking with Dr. Graham.

We ended up agreeing to slightly revise the 2-pager to add a bullet on next steps (i.e., public workshop to discuss process and details/issues) and to emphasize or elaborate on the improvements the process will bring. I've discussed these changes with Amy and she'll revise the 2-pager sent to OMB in preparation for Amy Farrell. Nancy will send over her comments by fax by tomorrow (to DC office, BettyJo - please keep an eye out for this and give copies to addressees here).

Further, I agreed that in our Federal Register notice announcing the workshop, we'll identify some of the topics and issues for discussion including, for example, the attribution of comments to specific reviewers, the criteria for selection of QA Check reviewers, the proposal with respect to a NAS risk assessment panel, the availability of relevant information on web sites, etc. OMB wants to review this FR notice. I emphasized the FR notice will not be exhaustive on what issues will be raised and discussed at the workshop but it will be sufficiently illustrative to inform potential participants as to the details that we will likely seek input on.

We discussed Interagency review and I informed her perc was soon to arrive for interagency review (estimate about a month from now). She clearly is concerned that OMB/OSTP have not worked out a plan for interagency review. I offered that we could help in getting materials prepared for the review process, but it is essential that the request for review come from OMB/OSTP. She asked that the bullet on interagency review refer to EOP rather than "OMB and OSTP will manage interagency review".

Next steps:
1) Amy will revise 2-pager and look also at Nancy's comments to see if any final changes are needed before 2-pager and flowchart are sent to Amy Farrell
2) I'll send a note to Amy Farrell noting that we've discussed with OMB and expect to make final draft revisions to information by end of this week and offer to brief her
3) George, please send (or have BettyJo send) revised 2-pager and flow chart to Amy Farrell later this week.
4) Linda, Amy and IRIS staff should initiate or continue FR development and workshop planning.

John

John Vandenberg
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OSD-ATL"
<Shannon.Cunniff@osd.mil>
02/02/2006 10:18 AM

To Peter Preuss/DC/USEPA/US@EPA

cc "'Beck, Nancy'" <Nancy_Beck@omb.eop.gov>, "Noe, Paul R." <Paul_R._Noe@omb.eop.gov>, "Beehler, Alex, Mr, OSD-ATL" <Alex.Beehler@osd.mil>, John Vandenberg/DC/USEPA/US@EPA, "Richard Wickman (richard.a.wickman@nasa.gov)" <richard.a.wickman@nasa.gov>, "Bill McGovern (bill.mcgovern@dhs.gov)" <bill.mcgovern@dhs.gov>, "Blaine Rowley (blaine.rowley@em.doe.gov)" <blaine.rowley@em.doe.gov>, Carl Ma <carl.ma@faa.gov>, "Dave Belluck (David.Belluck@fhwa.dot.gov)" <David.Belluck@fhwa.dot.gov>, "James Leatherwood (James.Leatherwood-1@nasa.gov)" <James.Leatherwood-1@nasa.gov>, "'JLeather@hq.nasa.gov'" <JLeather@hq.nasa.gov>, "Juan Reyes (juan.reyes@dhs.gov)" <juan.reyes@dhs.gov>, Keith Holman <keith.holman@sba.gov>, "Martin, Mary" <Mary.Martin@nnsa.doe.gov>, Mike Savonis <michael.savonis@dot.gov>, Paul Atelsek <patelsek@comdt.uscg.mil>, David Moses <David.Moses@hq.doe.gov>

Subject DoD, NASA, DoE comments on IRIS revisions

Peter,
OSD, NASA and DOE Sr. staff have reviewed ORD's proposed IRIS revisions chart and detailed explanation of some of the boxes and attached are our comments and suggestions. DHS and DOT were not on our last calls due to scheduling conflicts, so I can not assert to what degree they support these comments. I will get you a confirmation on that.

What you have attached is a) the flow chart - we added numbers to all the boxes but also retained your numbering of the latter 10 boxes that correspond to your detailed explanation -- and b) an expanded detailed explanation of the boxes that includes, as we discussed, an proposed explanation for every step to help us all achieve clarity and eventually agreement.

These inserts and changes were drafted by a committee of federal staff and recorded by Mitretek (so you might see Mitretek identified as a "commentor". All of our insertions or changes are in color and underlined.

We suggest that after you look this over that we set up another multi-agency meeting to bring all the interested federal agencies together to discuss the process steps and see if together can reach consensus on the process, understand how or if this effort fits with Dr. Gray's visions for IRIS, and develop a plan for next steps.

Please call me if you have any questions or comments.

Shannon E. Cunniff
Executive Lead, MERIT
Special Assistant for Emerging Contaminants

Proposed IRIS Process 012406.ppt Detailed Steps 0202061.doc

January 28, 2013

John Cowden, Ph.D.
Janice Lee, Ph.D.
U.S. EPA
National Center for Environmental Assessment
Mail Code: B243-01
109 T.W. Alexander Drive,
Durham, N.C, 27711
Submitted via email to: Docket_ORD@epa.gov; cowden.john@epa.gov; lee.janices@epa.gov

Regarding: Submission to docket EPA-HQ-ORD-2012-0830; comments on the Planning and Scoping Summary for the Toxicological Review of Inorganic Arsenic.

Dear Drs. Cowden and Lee:

The American Chemistry Council (ACC)[1] and its Center for Advancing Risk Assessment Science and Policy (ARASP)[2] appreciate the opportunity to provide comments to the Environmental Protection Agency (EPA) on the draft Planning and Scoping Summary for the Toxicological Review of Inorganic Arsenic (hereinafter referred to as draft Scope).

We applaud EPA for holding a two-day stakeholder workshop to begin addressing important scientific issues that will inform the toxicological review as well as the National Academies review of inorganic arsenic. ACC participated remotely via webinar and we found the technology to be easily accessible and generally user-friendly. While there were some small glitches, we are confident that EPA will work to improve them in the future. To further improve transparency, it would be very helpful if EPA could share the presentations with the meeting participants in advance of the meeting or in real-time via email. While we understand that web posting may take longer, it is unfortunate that this delays active participation from engaged stakeholders.

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $760 billion enterprise and a key element of the nation's economy. It is the largest exporting sector in the U.S., accounting for 12 percent of U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against threats to the nation's critical infrastructure.

[2] Within ACC, the Center for Advancing Risk Assessment Science and Policy (ARASP) is a coalition of independent groups and associations that promotes the development and application of up-to-date, scientifically sound methods for conducting chemical assessments.

Additionally, it would be helpful to give the public sufficient advance notice of upcoming stakeholder meetings to provide all stakeholders with an opportunity to suggest panelists for the workshops. Unfortunately, scientific experts with industry experience and perspectives were not sufficiently represented at the stakeholder workshop. To the extent possible, the panels should be balanced to represent as many scientific perspectives as possible. Going forward, if the IRIS Program needs assistance in identifying experts with industry experience, ACC would be glad to provide suggestions.

As was discussed at the workshop, it is clear that there is already a great deal of scientific information, as well as consensus, regarding the effects of inorganic arsenic at high doses which are not relevant to today's environmental exposures in the U.S. However, there did not appear to be agreement regarding human health risks at low dose exposures. We were thus disappointed that the draft Scope does not specifically focus on evaluating cancer and non-cancer health effects in the exposure range relevant to U.S. citizens. As part of scoping and planning, EPA could conduct surveys, review literature, and take public comment on what the appropriate range of exposures should be to conduct a focused and targeted assessment.

In addition, we suggest that mode of action be considered as a central organizing principle of the assessment. In this manner, data from laboratory experiments, epidemiological investigations, and cutting-edge mechanistic research from all relevant studies and from all investigators, regardless of affiliation or funding source, can be comprehensively reviewed, given appropriate weight, and integrated in a manner that provides a robust, biologically plausible understanding of the potential hazards and risks that environmentally relevant exposures could pose. The extent to which the data do or do not support specific hypothesized modes of action can then be compared.

The draft Scope should also describe the approaches that will be used for developing the dose response relationships for evaluating potential risks to humans at environmentally relevant levels of exposure. ACC encourages EPA to evaluate and include alternative extrapolation models, including scientifically plausible threshold models for the analysis of cancer data in addition to a default linear model to account for the uncertainties associated with the dose response extrapolation. Such an approach would be consistent with the EPA 2005 Guidelines for Carcinogen Risk Assessment as well as the recommendations provided to EPA in the 2011 National Academies Review of the EPA's Draft IRIS Assessment of Formaldehyde. Furthermore, to ensure appropriate context for risk managers and policymakers and to promote a more complete characterization of potential hazards and risks, the scoping document should contain plans for including in the assessment 1) central tendency estimates of dose-response curves in addition to upper bound estimates and 2) a plausibility check to compare the resulting reference values and cancer risk value estimates with data on the actual health outcomes at environmentally relevant levels of exposures. It would also be useful for the draft scope to describe the qualitative and quantitative approaches that will be used to evaluate uncertainties associated with the risk values that will be derived.

In conclusion, we believe sharpening the focus of the scope of the hazard identification and dose-response analyses to the most relevant range of exposures and on the key scientific issues such as

mode of action and dose response will help EPA to 1) streamline the toxicological review process; 2) focus resources on evaluating the most relevant hazards and risks of inorganic arsenic; and 3) provide risk assessors and risk managers with the tools needed to most accurately characterize the nature and range of potential risks in populations throughout the U.S.

Thank you for considering our comments and suggestions. We look forward to receiving EPA's revised scoping document. If we can provide additional information, or if you have any questions regarding our comments, please feel free to contact Dr. Kimberly Wise at Kimberly_Wise@americanchemistry.com or Dr. Nancy Beck at Nancy_Beck@americanchemistry.com.

Sincerely,

Kimberly Wise, Ph.D.
Senior Director
ARASP

Nancy Beck, Ph.D., DABT
Senior Director
Regulatory and Technical Affairs.

cc:
Vincent Cogliano, Ph.D.
Ken Olden, Ph.D.

"Beck, Nancy"
<Nancy_Beck@americanchemistry.com>
02/04/2013 05:57 PM

To John Cowden/RTP/USEPA/US@EPA
cc JaniceS Lee/RTP/USEPA/US@EPA, Docket ORD@EPA
bcc
Subject Mode of Action in WoE reviews ORD-2012-0830

Hi John,

Attached is the letter we sent to the NAS Arsenic Committee. Its appendix contains a list of publications and presentations that are related to using a weight of evidence approach that has mode of action as an organizing principle. I hope this is what you were looking for-- if not just let me know! Hopefully the publications will be useful for the arsenic assessment as well as other IRIS assessments. I have also attached a white paper that was developed for ACC that addresses toxicity data evaluation for hazard and risk assessments. As the NTP systematic review framework is thus far silent on evaluating *in vitro* and *in vivo* data, we thought this may also be useful for you.

Please let me know if there are any steps I need to be taking to ensure that our comments make it into the official docket (such that they will be available to peer reviewers when the document reaches that stage) for the Arsenic assessment.

Also if you could confirm receipt of this letter, and the one I sent you on 1/28/13, that would also be very helpful as I don't want to keep unnecessarily spamming you. Thanks!!

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Senior Director- Regulatory Science Policy
Regulatory and Technical Affairs

American Chemistry Council|700 2nd St NE|Washington DC 20002

Email: Nancy_Beck@americanchemistry.com

Office: 202-249-6417

www.americanchemistry.com

- ACC letter to NAS Jan 31 2013.pdf - Data Quality Evaluation White Paper ARASP December 2012.pdf

December 13, 2013

Comments submitted to EPA docket: EPA-HQ-OPPT-2012-0725

Public comments from Dr. Nancy Beck on behalf of the American Chemistry Council to the EPA N-Methylpyrrolidone (NMP) and Methylene Chloride (DCM) peer review panelists at the December 13, 2013, peer review meeting.

Good Afternoon.

I am providing comments today on behalf of the American Chemistry Council (ACC). My brief comments today will address both NMP and DCM.

As ACC has noted previously, we appreciate the opportunity to provide comments to the peer reviewers. ACC welcomes the general direction that EPA has taken in the Work Plan Chemicals program to prioritize chemicals for further review and to conduct targeted assessments that may then be used to consider whether additional regulatory action is warranted. ACC strongly supports EPA's effort to conduct these targeted assessments on specific uses and applications that may raise concerns for the agency. We also support the Agency's use of a Margin of Exposure Approach, which will allow the Agency to do screening level assessments quickly to determine if further refined assessments are necessary based on exposure or hazard concerns.

We have provided detailed comments to the docket, which are also available on the SCG webpage. Those written comments address both DCM and NMP and were offered to the Agency in the spirit of constructive engagement. On previous peer review calls, we have presented our constructive recommendations for improving the assessment, and also suggested areas where peer review comments on the assessment would be particularly helpful. These comments should be available in the docket and on the SCG webpage.

As experts, you all have a lot on your plate and the time you have dedicated to reviewing these assessments is greatly appreciated. To fully capitalize on your expertise, we hope that as you finalize your comments you will keep in mind that EPA is not seeking consensus, but is instead seeking input from a diverse group of experts. Therefore, we encourage each of you to respond clearly to every one of the charge questions for which you have expertise, rather than relying on

your peers to provide a response. The feedback EPA receives, regardless of whether it is consistent or diverse, will help strengthen the assessment.

ACC continues to believe, in particular due to the exposure scenarios selected, that these assessments should be treated as screening-level assessments that require further refinements before they can properly be relied upon to pursue regulatory actions. Strong science must be the basis of EPA regulatory action and your input will be critical to assist EPA as it improves its scientific assessments.

Thank you again for the time and effort you have spent reviewing and discussing EPA's draft assessments.

About Nancy Beck, Ph.D., D.A.B.T.
Senior Director, Regulatory Science Policy | American Chemistry Council

Author Archive: Nancy Beck, Ph.D., D.A.B.T.

Carcinogen or not a carcinogen? A tale of two WHO Agencies, and the importance of evaluating study quality and human relevance

by Nancy Beck, Ph.D., D.A.B.T. on SEPTEMBER 23, 2016 in POLICY

How is it possible that two World Health Organization (WHO) agencies could evaluate the same chemical's potential to cause cancer and come to seemingly opposite conclusions? Dr. David Eastmond explored this question in a presentation at the Summer Toxicology Forum meeting comparing the approaches taken by the International Agency for Research on Cancer (IARC) and […]

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The pursuit of quality in risk assessment

by Nancy Beck, Ph.D., D.A.B.T. on SEPTEMBER 16, 2016 in POLICY

The Toxicology Forum is an international organization that encourages dialogue among government agencies, industry, academia, policymakers, and NGOs concerned with public health issues. Following Congress's recent passage of the Lautenberg Chemical Safety Act, the Toxicology Forum's summer meeting in Salt Lake City, featured a particularly interesting and timely session on "the pursuit of quality and […]

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about improving chemical risk assessments

by Nancy Beck, Ph.D., D.A.B.T. on APRIL 28, 2016 in POLICY

Wall Street Journal editorial board member Holman W. Jenkins, Jr. seems to have a knack for battling bad science – especially what he perceives to be misguided reporting and alarmist stories about climate change. In his most recent piece, Jenkins laments the fact that some activists have used faulty research to overstate the risks associated […]

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Fixing EPA's chemical assessment program – Latest reviews show IRIS is still a work in progress

by Nancy Beck, Ph.D., D.A.B.T. on FEBRUARY 22, 2016 in INDUSTRY

It's hard to believe but this year marks the fifth anniversary of the National Academy of Sciences' (NAS) 2011 report on the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program. The report identified systemic problems and offered sweeping recommendations to overhaul the program. So what has happened in the five years since the […]

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Grappling with uncertainty: New paper offers a better approach

by Nancy Beck, Ph.D., D.A.B.T. on FEBRUARY 16, 2016 in INDUSTRY

As Donald Rumsfeld taught us, how you handle and communicate what you don't know is just as important as dealing with what you do know. A new paper recently published by the scientific journal Environment International offers several different ways to help better address the uncertainty conundrum when it comes to sharing the results of […]

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Had we been given the opportunity, here's what we would have offered the NIEHS on its new NTP RoC Handbook

by Nancy Beck, Ph.D., D.A.B.T. on SEPTEMBER 28, 2015 in INDUSTRY

One way in which the National Institute of Environmental Health Sciences (NIEHS) National Toxicology Program (NTP) could demonstrate its commitment to transparency is by seeking public comment on its guidance documents prior to finalizing and implementing them. Not only would this help NTP to develop a robust approach, but it would also allow outside experts, […]

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IRIS progress report details key improvements, but the

bar must be raised higher

by Nancy Beck, Ph.D., D.A.B.T. on MAY 13, 2015 in POLICY

According to a May 2015 progress report to Congress, the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) is better off than it was a year ago, but not as effective as it needs to be to deliver timely, high-quality and credible chemical risk assessments. EPA does deserve credit, first and foremost, for following […]

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Returning to fundamental principles can help science live up to the public trust

by Nancy Beck, Ph.D., D.A.B.T. on NOVEMBER 24, 2014 in POLICY

A revised approach in the biomedical sciences for reporting research should set a strong precedent for researchers, publishers, and regulators around the U.S. who are committed to improving the science that guides public health decisions. Scientists today are more prolific than ever. The sheer body of research published every year can be overwhelming—from breakthroughs in […]

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Two keys to a stronger chemical assessment program: Planning for success and avoiding pitfalls

by Nancy Beck, Ph.D., D.A.B.T. on OCTOBER 14, 2014 in INDUSTRY

This week's Integrated Risk Information System (IRIS) workshop on the National Research Council's (NRC) recommendations for improving federal chemical assessments gives the U.S. Environmental Protection Agency (EPA) an opportunity to build on the progress it has already made in creating a sound, more transparent, and objective assessment program. While the agenda for the workshop covers […]

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What are the key challenges for improving risk assessments? Two experts weigh in

by Nancy Beck, Ph.D., D.A.B.T. on MAY 2, 2014 in POLICY

Two recurring themes at the 53rd meeting of the Society of Toxicology (SOT) in Phoenix, Arizona, were enhancing strategies for risk assessment and finding new ways to conduct safety assessments. Here are three questions (and some potential answers) that continue to drive the debate. What are the biggest issues for the future of risk assessment? […]

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ACC's Principles for Improving Chemical Hazard and Risk Assessments

Assessments should focus on understanding the inherent properties of substances in order to determine the likelihood of harm from a specific exposure. The public, businesses and regulators look to government assessments for reliable information about the potential hazards and risks associated with chemicals.

Identify Key Science Issues Prior to Initiation of Assessment

- Discuss the purpose, scope and technical approaches
- Engage stakeholders

Apply Objective Criteria

- Develop and apply consistent criteria for selecting and evaluating a study, before an assessment begins
- Evaluate all studies to determine their quality, relevance and reliability

Ensure Assessments are Transparent

- Disclose key information and assumptions used to develop assessments and reach conclusions
- Make materials, including important data sets, publicly available

Conduct Scientific Peer Review by Independent Experts

- Ensure peer reviewers are fully independent from the program office issuing the assessment
- Evaluate peer review panels for conflicts of interest; ensure panels contain a balance of perspectives and appropriate technical expertise

Use Modern Science and Tools

- Use relevant data
- Consider how chemicals act in the body
- Evaluate chemicals at relevant exposure levels

Integrate Evidence

- Give the greatest weight to information from the highest-quality and most-relevant studies
- Transparently and objectively integrate evidence to make realistic determinations of hazards and risks; consider all types of evidence

Characterize Hazards and Risks Fully and Accurately

- Present hazards and risks in an easy-to- understand manner to stakeholders and risk managers
- Present a range of plausible values, including central estimates when going beyond a screening level assessment

Improve Accountability

- Use an independent accountability procedure to verify that revised assessments are accurate and responsive to scientific and peer review

RESULT: Public Trust in High-Quality Risk Assessment

Data and Methods

Formaldehyde Assessments Must Properly Evaluate and Integrate All Available Evidence

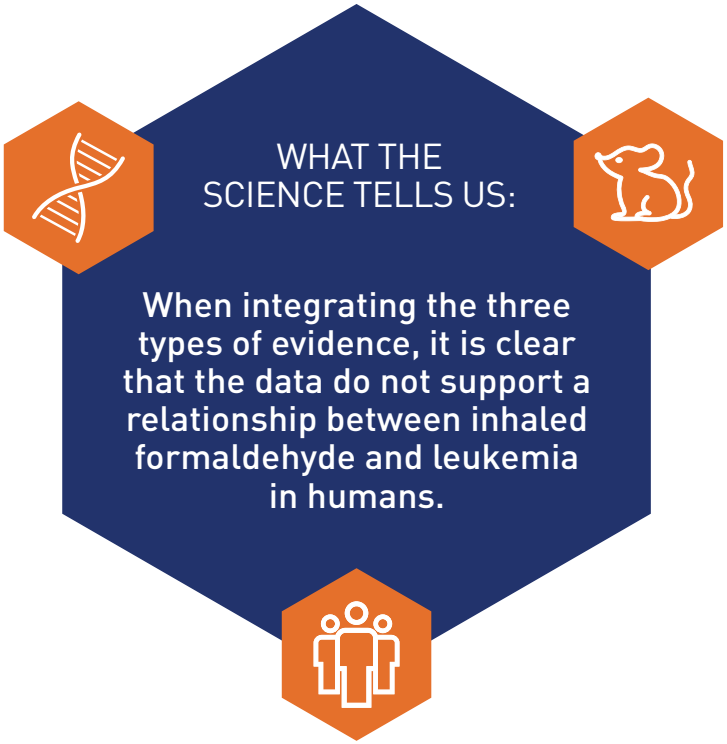
A fully integrated chemical assessment requires that all available scientific evidence is evaluated for quality and relevance, then analyzed together to make an informed decision.

Mechanistic Data

(Studies about what a chemical does in the human body and how it does it)

Compelling evidence shows that inhaled formaldehyde does not reach bone marrow (Swenberg et al. 2011).

There are no reliable, high-quality mechanistic data available to support speculation that formaldehyde causes leukemia.



Animal Data

(Experimental data from animal lab studies)

The best-available studies show that inhaled formaldehyde has no effect on blood or bone marrow.

A recent NTP study on two strains of mice genetically predisposed to develop leukemia to high doses of inhaled formaldehyde and confirmed no leukemia effects.

Epidemiological Data

(Studies of select human populations)

Extensive and detailed critical reviews of epidemiological literature do not support a causal relationship between formaldehyde exposure and leukemia.

When data from three large, high-quality studies are combined, the number of leukemia cases in the studied occupationally-exposed populations is essentially the same as what is expected in the U.S. population (152 v. 153), indicating there is no appreciable risk for developing leukemia.

Returning to fundamental principles can help science live up to the public trust

by Nancy Beck, Ph.D., D.A.B.T. on NOVEMBER 24, 2014 in POLICY

A revised approach in the biomedical sciences for reporting research should set a strong precedent for researchers, publishers, and regulators around the U.S. who are committed to improving the science that guides public health decisions.

Scientists today are more prolific than ever. The sheer body of research published every year can be overwhelming—from breakthroughs in innovation, to new health and safety studies, to novel solutions to improve environmental health. If there is one thing that should ground them all in the public trust, it should be a commitment to adhering to an established sound scientific process.

Unfortunately, many of the scientific studies we read about in the news were not quite ready for prime time. Forbes contributor Geoffrey Kabat wrote in a November 15 piece that often it is the "anomalous, and almost certainly wrong, results" that can get the most attention. As Kabat points out, these inconsistent results can have serious ramifications for public health:

> *This phenomenon leads to an enormous waste of resources, which comes at the expense of research that might actually lead to saving lives. It also confuses the public and leads people to mistrust science generally.*

Many in the scientific community agree, and at least one group of editors has already begun to lead a return to the fundamental principles of science to restore public confidence.

Journals stand up for science

"Reproducibility, rigor, transparency, and independent verification are cornerstones of the scientific method," Editor-in-Chief Marcia McNutt made clear at the opening of a November 7 editorial published in the journal Science.

According to McNutt, a swath of editors from more than 30 major journals, together with funding agencies and other scientific leaders met at the American Association for the Advancement of Science headquarters earlier this year to tackle the reproducibility issue plaguing so many preclinical studies of late. Below is a list of guidelines they agreed to as first big step toward improving the integrity of the biomedical sciences:

- Journals should make it clear to authors the policies for statistical analysis and how they review the statistical accuracy of work under consideration

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- Any imposed page limits should not discourage reproducibility (in other words, researchers should be given the time and space to show their work)
- Researchers should use a checklist to ensure the reporting of important experimental parameters: standards used, number and type of replicates, statistics, method of randomization, whether experimenters were blind to the conduct of the experiment, how the sample size was determined, and what criteria were used to include or exclude any data
- Journals should recommend that data be placed in public repositories, where available, and linked to the paper to ensure proper attribution
- Journals should ensure that all datasets relied upon for conclusions in the paper are made available upon request, where ethically appropriate, by editors and reviewers; in addition, journals should encourage the release of data for sharing after publication
- Once a journal publishes a paper, it should assume the obligation to consider publication of a refutation of that paper, subject to its usual standards of quality
- Journals should consider establishing best practices guidelines for images and biological material use.

Valuable lessons for improving chemical assessments

Because of their fundamental nature, the guidelines have tremendous potential to help the public beyond their use by journals and beyond the biomedical science field. For example, many of the guidelines proposed in McNutt's editorial are consistent with the recommendations that have been recently offered to improve how federal programs are evaluating chemicals.

For example, there are many parallels when it comes to improving the review and transparency of the research used in chemical assessment programs. In several cases, these concepts are in line with ACC's principles for enhancing federal risk assessment, especially when it comes to evaluating data and selecting studies used in assessments and providing full disclosure of underlying data and key information used to develop assessments.

Fully implementing these improvements to chemical assessments will provide regulators, the public, and industry with more accurate and useful information to help guide better decisions for protecting human health and the environment.

Call to action

Now that leaders in the biomedical sciences have acknowledged that their journals may not always meet scientific standards of reproducibility, rigor, transparency and independent verification, it's time that researchers and journals that examine chemicals do the same.

The American Association for the Advancement of Science (AAAS) pledge should serve as a wake-up call to researchers and journals across the toxicological sciences to step up their game by renewing their commitment to the scientific method. And regulators can help facilitate this "return to the science" by rigorously reviewing existing published studies to ensure they meet these core tenets of the scientific method and calling on journals to publish more robust, independently verified studies going forward.

As McNutt concludes, "The hope is that these guidelines will not be viewed as onerous, but as part of the quality control that justifies the public trust in science."

American Association for the Advancement of Science, Chemical Assessment, Geoffrey Kabat, Marcia McNutt, Risk, Safety

NANOSAFE 2014 conference in France features paper sponsored by ACC's Nanotechnology Panel
Versatile. Durable. Incredible… Macy's Thanksgiving Day Parade Balloons!

About the Acting Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention

Wendy Cleland-Hamnett

Wendy Cleland-Hamnett

- Phone: 202-564- 2902
- About the Office of Chemical Safety and Pollution Prevention

Wendy Cleland-Hamnett

Wendy Cleland-Hamnett is the Acting Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). Previously, she was the Principal Deputy Assistant Administrator for OCSPP and the Director of the Office of Pollution Prevention and Toxics, where she led EPA's chemical safety program under the Toxic Substances Control Act; numerous safer chemical and pollution prevention activities; efforts to manage risks from several legacy chemicals; and the Toxics Release Inventory Program. She is also responsible for EPA's pesticides program.

Ms. Cleland-Hamnett has worked in a number of EPA offices, including the Office of Environmental Information, the Office of Policy, and the Administrator's Office. She received her law degree from George Washington University.

Location: Capitol Hill TBD

11:00 AM-12:00 PM FLOTUS Reception
Ct: Cheryl Andrews 703-556-9401

The reception begins at 11 AM, followed by the Luncheon at 12 PM.

Location: Hilton Washington Hotel-Georegtown Room on the Concourse Level
1919 Connecticut Ave, NW

12:00 PM-01:00 PM FLOTUS Luncheon
Location: International Ballroom at the Hilton Washington Hotel
---
02:00 PM-02:45 PM Meeting with Health Organization Leaders to discuss TSCA Reform
Ct: Maureen Swanson (Learning Disabilities Association of America) 724-813-9684

Staff:
Bob Sussman, Peter Grevatt, Robert Goulding (OA)
Steve Owens, Jim Jones, Wendy Cleland-Hamnett (OPPTS)
Arvin Ganesan (OCIR)
Stephanie Owens (OPA)
Optional: Diane Thompson (OA), Lisa Garcia (OECA)

Attendees:

M. Doreen Croser, Executive Director - American Association on Intellectual and Developmental Disabilities
Marla Weston, PhD, RN, Chief Executive Officer -American Nurses Association
Wayne C. Shields, President and CEO - Association of Reproductive Health Professionals
Lee Grossman, President and CEO - Autism Society
Janet Gray, Science Advisor - Breast Cancer Fund
Patricia Lillie, President - Learning Disabilities Association of America
Vanessa Collins, MD - Planned Parenthood Federation of America
Kirsten Moore, President and CEO - Reproductive Health Technologies Project
Maureen Swanson - National Coordinator, Healthy Children Project - Learning Disabilities Association of America
Location: Bullet Room

02:45 PM-03:00 PM Stop by K. Petrucelli Retirement Celebration
Ct: Gary Waxmonsky (OIA) 564-6428

The Administrator will stop by briefly.
Location: Green Room

03:00 PM-03:45 PM 1 on 1 with Chuck Fox
Ct: Julie Winters (CBPO) 410-267-5754

Staff:
Shawn Garvin + 1 (R3)
Pete Silva, Nancy Stoner, Tom Wall +1 (OW)
Steve Neugeboren +1 (OGC)
Optional attendees:
Bob Perciasepe, Bob Sussman, Diane Thompson (OA)
Location: Administrator's Office

From: Jones, Jim
Sent: Friday, November 07, 2014 2:00 PM
To: Andy Igrejas
Cc: Milhouse, Gloria; Wallace, Ryan; Sterling, Sherry
Subject: Re: checking in

Andy, I am happy to. I am out Mon and Tues but we should be able to find time later in the week. Gloria will find some time. Thx

Jim Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Andy Igrejas
Sent: Friday, November 7, 2014 11:27 AM
To: Jones, Jim
Subject: checking in

Jim,

Do you have time next week to check in? I could swing by in person or we could just do it by phone.

-Andy

Andy Igrejas, Director
Safer Chemicals, Healthy Families
[redacted]
andyigrejas@saferchemicals.org

From: Jones, Jim
Sent: Friday, November 14, 2014 10:05 AM
To: Cleland-Hamnett, Wendy
Subject: TSCA Reform

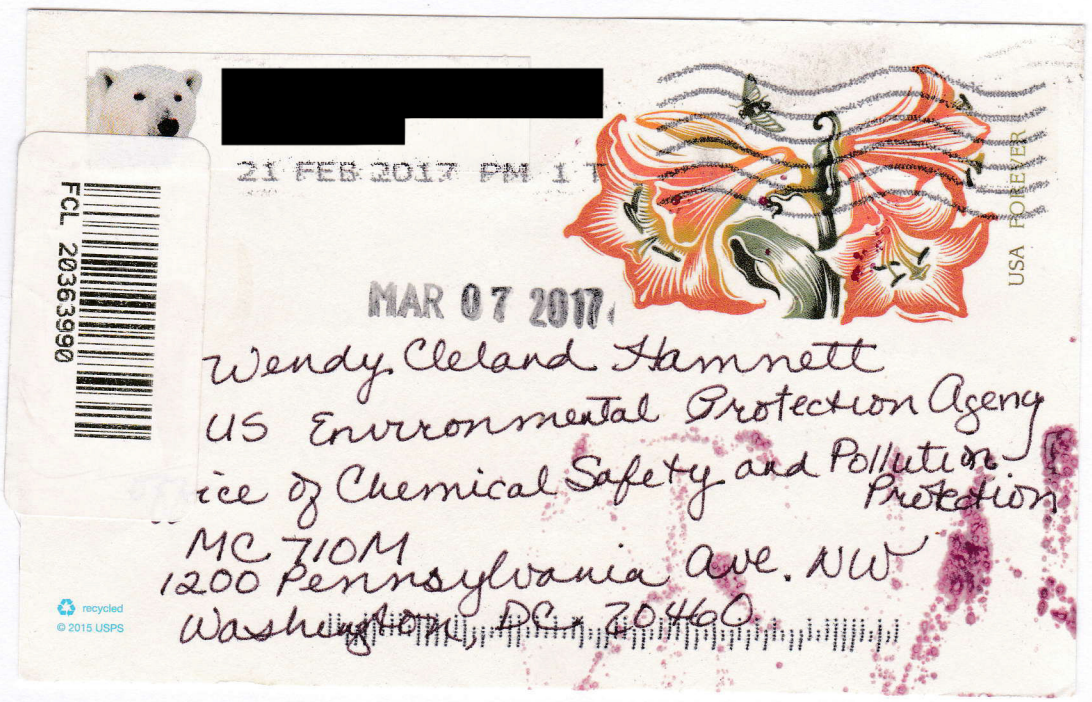
Andy Igrejas is coming by at 2. Feel free to join us. Thx

Jim Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
US EPA
202 564-0342

Hello,

You do not know me. However, I would expect that your job possibly has become more difficult under this new administration. I want you to know that I support you in any endeavors to help protect our environment from toxics and pesticides, backed up by actual scientific facts. I applaud you, and hope your office prevails.

Thank you, [redacted]



Tom Udall
New Mexico

531 Hart Senate Office Building
(202) 224-6621

United States Senate

WASHINGTON, DC 20510-3103

April 29, 2015

Ms. Wendy Cleland-Hamnett
Director, Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

Dear Wendy:

As you know, yesterday the U.S. Senate Committee on Environment and Public Works reported out S.697, The Frank R. Lautenberg Chemical Safety for the 21st Century Act on a very bipartisan basis. I want to personally thank you for your commitment to chemical safety reform and for all of the attention you have given this issue.

You have worked so hard to be available and responsive to us as we crafted and wrote this legislation. I know that EPA was fielding requests from many different offices and you did a masterful job of navigating it all. You have been a resource to us from day-one and continued that professionalism through the weekend - going above and beyond the call of duty and representing the best tradition of government service. It makes me proud to be a Member of Congress and to work so collaboratively with the Executive Branch.

Senator Frank Lautenberg had a long and successful career fighting for the environment and public health. Despite all he accomplished, he told his wife that his work on chemical safety could be the most important work he had ever done, even more important than banning smoking on airlines. I believe S.697 embodies that work and, while there is still a long road ahead of us, I believe we have achieved a major milestone for which I am grateful to you for your assistance.

S.697 has had input from many Members of Congress and vested stakeholders, but the ultimate responsibility to ensure the safety of our citizens through chemical safety will reside with the professionals and experts at EPA. This exercise has given me the confidence and assurance you are among the best possible staff to do so. Thank you very much for the work that you do.

Sincerely yours,

Tom

Tom Udall
United States Senator

The Frank R. Lautenberg Chemical Safety for the 21st Century Act

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law.

The new law, which received bipartisan support in both the U.S. House of Representatives and the Senate, includes much needed improvements such as:

- Mandatory requirement for EPA to evaluate existing chemicals with clear and enforceable deadlines;
- New risk-based safety standard;
- Increased public transparency for chemical information; and
- Consistent source of funding for EPA to carry out the responsibilities under the new law.

August 24, 2016

Wendy Cleland-Hamnett
Director, Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001
Sent electronically to www.regulations.gov docket # EPA-HQ-OPPT-2016-0400

Re: ACC Comments to Inform EPA's Rulemaking on the Conduct of Risk Evaluations under the Lautenberg Chemical Safety Act

Dear Ms. Cleland-Hamnett:

The American Chemistry Council (ACC)[1] appreciates the opportunity to provide input to the Office of Pollution Prevention and Toxics to inform the Agency's development of a risk evaluation rulemaking under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). ACC has a long-standing commitment to a robust, science-based approach to evaluation of human and environmental risk. ACC is committed to the effective implementation of the LCSA and supports a workable, rigorous process that allows for timely, high quality reviews. Given the strong emphasis on a risk-based approach in the LCSA, the Section 6(b)(4) rulemaking is particularly important because it will guide the conduct of future risk evaluations that will then inform risk management activities.

ACC is committed to being a constructive stakeholder throughout the implementation of LCSA. We will continue to draw from the breadth and depth of our member companies' expertise to ensure that our recommendations are not only science-based, but also allow for the efficient and effective implementation of the LCSA. In doing so, ACC will continue to consider the high quality science standards in the LCSA as well as the timeframes and deadlines imposed therein. The enclosed recommendations were developed with these important considerations in mind.

If EPA has any questions, please contact me at nancy_beck@americanchemistry.com or 202-249-6417.

Sincerely,

Nancy B. Beck, PhD, DABT
Senior Director, Regulatory and Technical Affairs

Cc: Jim Jones, OCSPP Assistant Administrator
Louise Wise, Deputy Assistant Administrator
Jeffery Morris, Deputy Director for Programs, OPPT
Tala Henry, Director, Risk Assessment Division, OPPT

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. More information about ACC is presented in the body of our comments.

American Chemistry Council
Initial Input to U.S. Environmental Protection Agency
In Regard to the Risk Evaluation Rule under the Lautenberg Chemical Safety Act

Table of Contents

I. Introduction and Executive Summary

The American Chemistry Council (ACC)[2] is pleased to provide the U.S. Environmental Protection Agency (EPA) this initial input on the Lautenberg Chemical Safety Act's (LCSA) requirement for the Agency to establish, by rule, the process for conducting risk evaluations. ACC appreciates EPA's early efforts to obtain input from stakeholders at its August 9, 2016, public meeting. We also appreciate EPA's solicitation of written comments to be entered into the docket, well in advance of publication of the proposed rule. Our comments both clarify, as well as supplement and expand upon, the oral comments we presented at the August 9 meeting.

ACC strongly supported Congress' efforts to update and reform the Toxic Substances Control Act (TSCA). We believe that high quality risk evaluation, using best available science and weight of the evidence (WoE), is at the very heart of the LCSA. Effective and efficient risk evaluations will help deliver the results intended by Congress.

Section 6(b)(4)(B) of the statute requires EPA to establish, by rule, "a process to conduct risk evaluations." This certainly should include a description of the sequence of events, timelines, opportunities for public comments and peer review. Both Sections 6 and 26 of the LCSA outline various substantive elements that apply to and inform risk evaluation. A risk evaluation must:

- Be conducted in a manner designed to determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment;" as set out in Section 6(b)(4)(A);
- Identify whether there exists "an unreasonable risk to a potentially exposed or susceptible subpopulation." EPA must identify potentially exposed or susceptible subpopulations relevant to the risk evaluation under conditions of use;
- Address the specific elements set out in Section 6(b)(4)(F); and
- Comply with the specific requirements of Section 26, including the best available science, weight of the evidence, and transparency requirements.

Because these elements are at the core of the risk evaluation process, and affect risk management measures, they are substantive and should be described in adequate detail in the regulation. In general, where risk evaluation elements are now required by statute, EPA should apply them uniformly and universally reflecting them in the body of the regulation.

The recommendations provided by ACC in these comments address screening and refined risk evaluations and are meant to apply to both human health and environmental risks. Specific tools, testing methods, databases, and the like may develop over time, or course, and can be updated as necessary in policies,

[2] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

procedures and guidance. Our comments strive to make these differentiations and explain where particular elements of risk evaluation should be included in the rule proper.

Specifically, our recommendations suggest definitions, and procedural steps and elements that will allow EPA to ensure that risk evaluations are consistent with the statutory requirements for EPA to use the best available science and WoE approaches. The recommendations also include definitions and procedural steps are not expected to change over time. ACC has referenced each of our suggestions to an existing EPA guidance, a National Academies (NAS) report, or another authoritative body or peer reviewed report. For instance, the recommendations in EPA's 2000 Risk Characterization Handbook still represent best practices today. Adding adequate definitions and explanation to the rule is particularly important to achieving incorporation of statutory requirements.

We also note that in addition to Section 6, Sections 26(h), 26(i), 26(j), and 26(k) of the LCSA each present legal requirements that are applicable to the risk evaluation. EPA will now need to provide a level of transparency regarding not only the inputs, but also the methods of the analysis, including clear descriptions of uncertainties and variability. EPA should leverage information from other jurisdictions where data and information is applicable and of sufficient quality to meet the science standards in the LCSA.

Incorporating these elements into the rulemaking creates a better platform for clear and consistent articulation of the Agency's understanding of statutory requirements, and will better support consistent and uniform application of the elements of risk evaluation.

It is critically important that EPA engage the public as EPA plans, scopes, and conducts risk evaluations. Industry scientists often have unique insight and experience with their companies' chemistries and collectively have a large body of knowledge of risk assessment processes globally, including an understanding of potential human health and environmental impacts. ACC encourages EPA to leverage this knowledge and engage early (well before draft risk evaluations are released) and frequently with industry throughout the risk evaluation process.

II. The Risk Evaluation Rulemaking Must Include both Procedural and Substantive Elements to Effect the Purposes of the Statute

Congress included a specific mandate to EPA to establish a risk evaluation rulemaking. There is little question that the rule must describe the process by which risk evaluations will be conducted.[3] However, to effect the purposes of the statute, the process described in the rule cannot merely set out timelines or the sequence of the risk evaluation. It must include a clear articulation of the substantive elements of risk evaluation, and more particularly, it must explain how it will apply the principles set out in Section 6(b)(4)(F), Section 26, and other parts of the statute. If Congress had intended the scientific standard of "best available science" or "weight of the scientific evidence" to be incorporated into guidance alone, it would have included them only in Section 26(l) on "policies, procedures and guidance."

[3] "[T]he Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A)…" Section 6(b)(4)(A).

The very purpose of the risk evaluation is to develop the evidentiary and scientific basis to enable EPA to complete the risk determination required by statute. That risk determination has substantive impact – it significantly affects conduct, activity or a substantive interest that is the subject of agency regulation. The determination following risk evaluation is a necessary prerequisite for a chemical to proceed to risk management, if warranted. The rule should thus include a clear description of how EPA will undertake risk evaluations in order to meet the new statutory requirements of the LCSA. This includes a description of the scoping process and requirements for a published scope as well as the elements of the risk evaluation itself and the mechanism for gauging adequacy as measured against statutory criteria.

III. The Proposed Rule Should Include a Tiered Approach to Risk Evaluation

We believe the statute contemplates a tiered approach to risk evaluation and recommend that EPA include a tiered approach in the rule. Under the LCSA, EPA must initiate the risk evaluation "upon designating" a chemical as a high-priority substance. The scope, however, is not required to be published "upon initiation" -- EPA has up to six months following the initiation of the risk evaluation to prepare and publish the scope. Congress intended this six month period to be used for a scoping exercise, where EPA identifies "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in the risk evaluation." This six month period is a "step" between the high priority designation and the publication of the scope.

In order for EPA to conduct risk evaluations consistent with the quality required by the LCSA and within the timeframes required, EPA should conduct a screening level evaluation during the scoping phase. During the scoping phase of risk evaluations, tools exist to allow EPA to conduct quantitative screening level analyses of multiple exposure scenarios, as appropriate for consumers, sensitive subpopulations, and the environment. This will allow EPA to have a more tailored focus on those populations and exposures of greatest concern during a refined risk evaluation process. Figure 1 below depicts ACC's recommended approach.

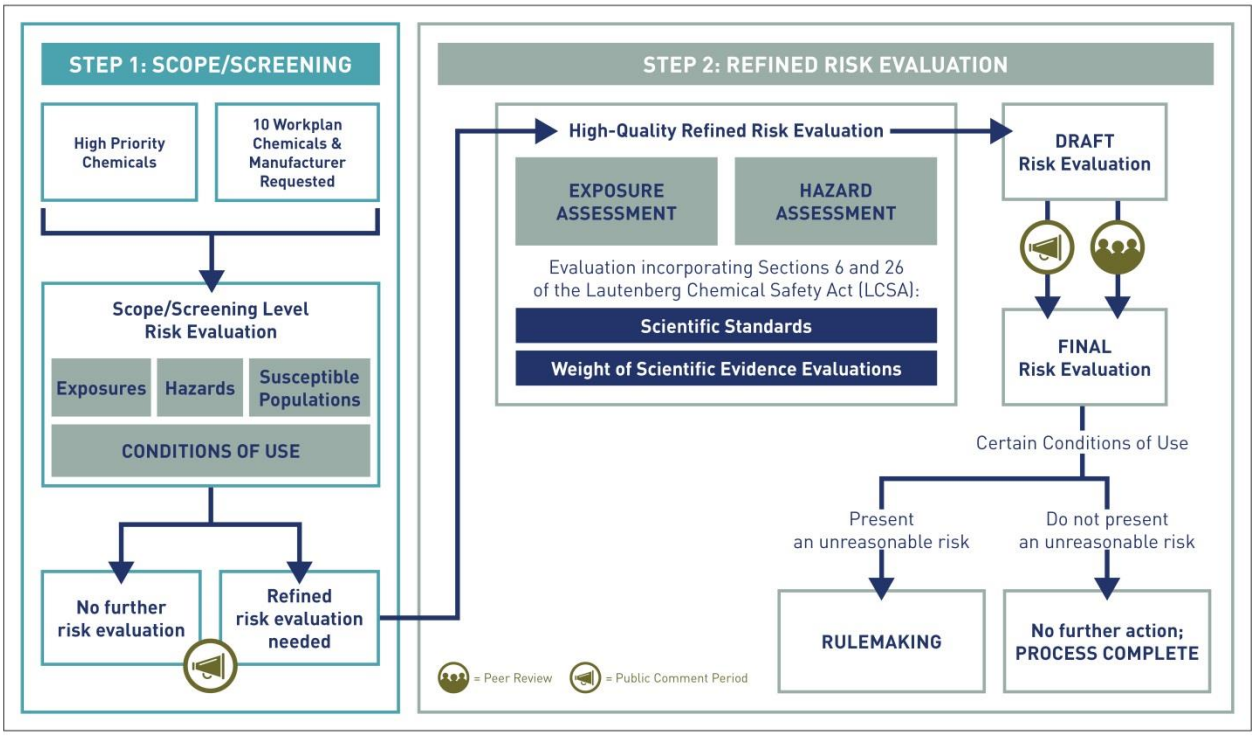


Figure 1. A Two-Step Process for Conducting Risk Evaluations
Note: This is a simplified version of the process.

A tiered approach, where EPA uses the scoping step (step 1) to conduct a quantitative screening level analysis, will allow EPA to focus its limited resources on more robust refined risk evaluations for only those conditions of use where unreasonable risks cannot be ruled out. Screening-level assessments require less data and information, and are typically deterministic and based on conservative, health protective assumptions and methods. When a screening assessment indicates low risk for a particular condition of use, the Agency should have a high degree of confidence that the potential risks are much lower than the calculation and, therefore, the actual risks are lower and/or perhaps non-existent. However, when a screening-level risk assessment indicates a potential concern for an adverse effect, this does not mean that the actual risks are significant and warrant action. Rather, it indicates the Agency should take a second step in the risk evaluation process to refine the evaluation to more accurately quantify potential risks.

The refined risk evaluation (step 2) will require realistic and representative data, higher tier modeling approaches, including probabilistic exposure modeling, and a more comprehensive consideration of human relevance and dose-response relationships. In a refined evaluation, EPA should also consider targeted exposure studies, as well as biomonitoring and environmental monitoring data, to the extent that this information is available and relevant. This approach is consistent with EPA's 2014 Framework for Human Health Risk Assessment to Inform Decision Making (HHRA Framework)[4], which also emphasizes the importance of a fit-for-purpose approach to risk evaluation. This approach is also consistent with EPA's exposure assessment guidelines and practices.[5] The concept of a tiered approach and a fit-for-purpose evaluation are woven throughout ACC's recommendations.

[4] See https://www.epa.gov/sites/production/files/2014-12/documents/hhra-framework-final-2014.pdf.
[5] See: https://www.epa.gov/expobox/exposure-assessment-tools-tiers-and-types-screening-level-and-refined.

The tiered approach ACC recommends is consistent with the approach EPA took in the problem formulation and initial assessment document for tetrabromobisphenol A (TBBPA).[6] In that document, EPA conducted an initial screening level evaluation to support its conceptual model and analysis plan. EPA appropriately used high-end exposure values coupled with the lowest toxicity values to evaluate uses and exposure pathways of potential concern. While EPA did not share the relevant risk evaluation calculations in its public document, the general approach is consistent with that of a screening level risk evaluation. ACC encourages EPA to continue with this approach and to transparently and clearly present quantitative screening level analyses for the conditions of use and exposure scenarios that are part of the conceptual model EPA develops as part of the scoping phase.

IV. The Rule Should Clarify the Process for Preparation and Contents of the Scope

As noted above, Congress allowed a six month period for preparation of the scope of the risk evaluation, contemplating that time and effort would be needed to move from prioritization to a published scope. The six month period is to enable EPA to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in the risk evaluation." Two things are evident from this language and the time frame afforded: 1) EPA should use this period to evaluate and decide which, if any, potentially exposed or susceptible subpopulations should be included in the risk evaluation (in other words, it need not include all such subpopulations, regardless of size, impact, or relevance); and 2) tEPA has flexibility to actually conduct a full risk evaluation of some or all the potential scenarios set out in the scope.

In short, EPA need not include every conceivable condition of use in a risk evaluation. This view is further buttressed by the definition of "conditions of use" in Section 3 of the LCSA, which points to the need for EPA to determine the relevant conditions of use: "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." (Emphasis added).

V. The Proposed Rule Should Include a Detailed Description of Substantive Elements of Risk Evaluation

The term, "risk evaluation" is not expressly defined in the LCSA. While the term "risk assessment" has been widely used in EPA programs and operationally has clear meaning derived from years of guidance, policies and practices, that term was not used in the statute. Therefore even though it may be reasonable to assume "risk evaluation" may fully equate with the term "risk assessment," given the context of its use (integrating hazard with exposure) in the LCSA, EPA is encouraged to explicitly define and operationalize this term as part of its rulemaking. The term will not have clear meaning until an interpretation is assigned by EPA. We believe the essential elements of a Section 6 and 26 risk evaluation must be articulated in a clear regulatory definition as we discuss below.

[6] EPA, Problem Formulation and Initial Assessment Tetrabromobisphenol A and Related Chemicals Cluster Flame Retardants, 2015, available at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-problem-formulation-and-2.

Section 6(b)(4)(B) of the statute requires EPA to establish, by rule, "a process to conduct risk evaluations." This process is itself required to meet a number of substantive elements described in the LCSA; a risk evaluation must:

- Be conducted in a manner designed to help the agency determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment;" as set out in Section 6(b)(4)(A).
- Include consideration of "an unreasonable risk to a potentially exposed or susceptible subpopulation." EPA must identify relevant potentially exposed or susceptible subpopulations relevant to the risk evaluation under conditions of use;
- Address the specific elements set out in Section 6(b)(4)(F); and
- Comply with the specific requirements of Section 26, including the best available science, weight of the evidence, and transparency requirements.

The very purpose of the risk evaluation is to develop the evidentiary and scientific basis to enable EPA to complete the risk determination required by statute. That risk determination has substantive impact – it significantly affects conduct, activity or a substantive interest that is the subject of agency regulation. The basis for the risk determination thus should be adequately described in the rule itself to offer sufficient notice to the regulated community. This is particularly important for decisions that inform safety and safety determinations.[7] Likewise, decisions that have broad reaching impact should be supported in regulations, not merely through guidance or agency policy.[8] While EPA cannot substitute policy or guidance for a regulatory description of what will constitute a complete and robust risk evaluation, we believe the necessary elements can be developed in this rulemaking in a timely manner.

VI. The Proposed Rule Should Ensure Consistency with Section 6(b)(4)(F)

As discussed below, Section 6(b)(4)(F) of the LCSA describes five requirements for risk evaluations that shall be considered by the Administrator and must be incorporated into the risk evaluation rulemaking.

[7] See, e.g., MST Express v. U.S. Department of Transportation, 108 F.3d 401 (D.C. Cir. 1997). DOT was directed under the Motor Carrier Safety Act (MCSA) to "prescribe regulations establishing a procedure to decide on the safety fitness of owners and operators of commercial motor vehicles." [Emphasis added]. The MCSA stated that implementing regulations would include "a means of deciding whether the owners, operators, and persons meet the safety fitness requirements." DOT promulgated regulations that set out a process for decision making but used guidance to articulate the tests by which the agency would determine whether vehicles met the safety fitness requirements. The court rejected DOT's reliance on guidance because it "failed to carry out its statutory obligation to establish by regulation a means of determining whether a carrier has complied with the safety fitness requirements."

[8] As a general matter, "…it seems to be established that 'regulations,' 'substantive rules' or 'legislative rules' are those which create law, usually implementary to an existing law." Gibson Wine Co. v. Snyder, 194 F.2d 329, 331 (D.C. Cir. 1952), cited by Brown Express, Inc. v. U.S., 607 F.2d 695, 700 (5th Cir. 1979). A "rule" is defined under Section 2 of the Administrative Procedure Act, in relevant part, as: "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." 5 U.S.C. § 551(4).

June 30, 2016

COMMENTS AT THE EPA PUBLIC SCIENCE MEETING ON TERT-BUTANOL

Nancy Beck, PhD, DABT
Senior Director, ACC

American® Chemistry Council

ACC

- Represents the leading companies engaged in the business of chemistry.
- ACC members are committed to improved environmental, health and safety performance through Responsible Care®.

Cross-cutting concerns

1) Use of outdated and problematic Preamble
2) Criteria for evaluating study quality
3) Benchmark dose modeling transparency
4) Quantification of the *Suggestive* cancer endpoint

Use of outdated and problematic Preamble

- Preamble was reviewed in 2015 by two Chemical Assessment Advisory Committees (Ammonia, Trimethylbenzenes). Reports sent to EPA in August and September 2015.
  - "The SAB recommends that the agency take measures to ensure that the Preamble in this and future assessments be structured so that it refers the reader to the appropriate guidance and cannot be construed to contradict policy by over summarizing existing guidance."
  - "Many of the components of such protocols are described in the Preamble of the ammonia assessment, but the extent and mechanisms for their application to the ammonia assessment are not sufficiently clear."
  - "Since the Preamble is a complex, "stand alone" document, at some future date (not for this ammonia assessment) it would be advisable to have it separately examined and reviewed in detail."

Recommendation:

- Preamble should be removed from this draft and all future assessments until a robust review is completed. In place of the preamble, within the t-butanol assessment, EPA should reference the specific relevant guidance (not general preamble discussion).
- For use under the Chemical Safety Act (2016), IRIS will need transparent methods describing best available science and weight of evidence approaches for each assessment.

Criteria for evaluating study quality (1)

- Clearer articulation of study quality criteria would be helpful.
  - Page LS-7: "With the exception of neurodevelopmental studies, these sources were conducted according to Organisation for Economic Co-operation and Development Good Laboratory Practice (GLP) guidelines, presented extensive histopathological data, or clearly presented their methodology; thus, these studies are considered high quality."
    - Not all studies followed OECD and GLP (eg NTP study)

Recommendations:

- Clearly state standards for high quality, relevance and reliability. Is the default GLP or OECD guideline compliant?
  - Klimisch "reliable without restriction": tests conducted according to internationally accepted test guidelines (i.e., relevance and reliability were determined in development of the test guidelines) ***and*** GLP compliant.
- All evidence tables should have a 3rd column noting study quality

Criteria for evaluating study quality (2)

- Improved clarity on the role of quality in evaluating neurodevelopmental studies
  - Page ES-1: "Neurodevelopmental effects also have been observed, but results were inconsistent."
  - Page ES-2: "There is inadequate information at this time to draw conclusions regarding neurodevelopmental toxicity, liver, and urinary bladder toxicity"
  - Page 1-55: "Each study evaluating neurodevelopmental effects, however, had limitations in study design, reporting, or both. In addition, results were not always consistent between studies or across dose. At this time, there is inadequate information to draw conclusions regarding neurodevelopmental toxicity."
    - Are the data inadequate due to study quality concerns? Or are the data simply inconsistent? Further clarity would be helpful.

Recommendation:

- EPA should provide clear criteria for study evaluation and should transparently benchmark each study against these criteria.

Criteria for evaluating study quality (3)

- The Chemical Safety Act (2016) will require a higher level of transparency, and clarity if IRIS is to be relied upon.
  - Weight of Evidence (Congressional Record June 7, 2016): “The term ‘‘weight of evidence’’ refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.”

Benchmark dose modeling transparency

- EPA BMD Technical Guidance (2012):
  - For reporting purposes, it is recommended that the BMD corresponding to 10% extra risk always be presented.

    Can serve as a comparison across chemicals and for hazard ranking
  - Is not a default, other values can be used based on statistical and biological considerations
- For absolute kidney weight endpoint, EPA presents *only* 10% relative deviation
  - Page 2-2 states: "A 10% relative change from control was used as a BMR for absolute kidney weight by analogy with a 10% change in body weight as an indicator of toxicity."
    - Analogy is not scientifically clear. Is a 10% change in absolute kidney weight known to be adverse? How would a 10% extra risk calculation compare?

Recommendations:

- Present extra risk and relative deviation findings
- Provide a clear justification of the modeling choice

Quantitation of the Suggestive Cancer Endpoint

- 2005 Cancer Guidelines (and page 2-18) state: "When there is suggestive evidence, the Agency generally would not attempt a dose-response assessment, as the nature of the data generally would not support one; however, when the evidence includes a well-conducted study, quantitative analyses may be useful for some purposes, for example, providing a sense of the magnitude and uncertainty of potential risks, ranking potential hazards, or setting research priorities."

- Tert-Butanol draft states (page ES-4): "Although tert-butanol was considered to have "suggestive evidence of carcinogenic potential," the NTP study was well conducted and quantitative analysis ***could be useful for providing a sense of the magnitude of potential carcinogenic risk*** (U.S. EPA, 2005a).(emphasis added)
  - Is this EPA's direction for how the value should be used?

Recommendation:

- Charge for peer reviewers should include a question asking for comment on the strength of the evidence and to recommend scientifically appropriate uses for any quantified cancer value.

View EO 12866 Meeting 2070-AK07

Title: N-Methylpyrrolidone (NMP) and Methylene Chloride; Rulemaking Under TSCA Section 6(a)

Agency/Subagency: 2070-EPA/OCSPP

Stage of Rulemaking: Proposed Rule Stage

Meeting Date/Time: 12/07/2016 03:00 PM

Requestor: W.M. Barr & Co.

Attendees:

List of Attendees	Participation
Danielle Jones - OMB/OIRA	In Person
Jim Kim - OMB/OIRA	In Person
Julie Park - OMB/OIRA	In Person
Jonah Richmond - EPA	In Person
Niva Kramek - EPA	In Person
Greg Louer - Arnold & Porter	In Person
Jim Laity - OMB/OIRA	In Person
Rebecca Drzal - W.M. Barr & Co.	In Person
Lisa Sloan - W.M. Barr & Co.	In Person
Larry Culleen - Arnold & Porter	In Person
Paul Winters - OMB	In Person
Anna Johnson - EPA	In Person
Sharon Cooperstein - EPA	In Person

Documents:

List of Documents
Handout

Methylene Chloride ($MeCl_2$ or DCM) TSCA Section 6(a) Proposal

RIN # 2070-AK07

Background on W.M. Barr

- 350 Employee-owners
- William Barr obtained the rights to methylene chloride paint removers from the Navy in 1946.
  - Developed by the Navy as an alternative to flammable removers in use at the time.
- Barr brands are the leading $MeCl_2$ formulations in consumer and commercial
- Barr and its many of it professional user/customers are small business enterprises and will be significantly impacted by any prohibition on retail sales of MeCl2 strippers

WM Barr Paint Removers

- WM Barr has 70 years experience with MeCl2 and Other types of Paint Removers for consumer and automotive use.
- We have constantly evaluated chemicals of potential use in paint removers.
- Our focus is to produce safe, effective paint removers which meet consumer needs and demands.
- We support efforts to ensure off-label uses, such as bathtub stripping, are prohibited.

Our Brands – Home Improvement

Our Brands - Automotive

Typical Retail Spaces

Paint Remover Products Come in Various Forms

- MeCl2 paint remover products
  - Liquid
  - Aerosol
  - Semi-paste
- Alternative paint remover products
  - Gel
  - Liquid
- Sizes – small sizes reduce storage and transfers risk, minimize disposal
  - Gallons
  - Quarts
  - 18oz Aerosol

Home Improvement Uses

- Customers
  - Hardware Stores
  - Mass Merchants
  - Home Improvement Centers
  - Paint Stores
- End Users
  - Do-it-Yourself (DIY) – 60-70%
  - Professionals

Customers - Automotive

- Customers
  - Professional Body Shops
  - Specialty Automotive Jobbers
  - Automotive Retail
- End Users
  - Professionals
  - A few DIYers
- Automotive Paint Removers
  - Barr brands supplies an estimated 70% of this market

Barr's Objectives

- Continue to be a leader in its field, both commercially and in establishing the bar for effective and safe use of its products
- To make OMB aware of its efforts to participate collaboratively through trade associations and with regulators
  - Participation in small business briefings with EPA
  - Consultations with CPSC
  - Meetings with state regulatory officials (e.g., Calif. DTSC)
  - Outreach to customers
  - Voluntary updates to its product labels
- Unfortunately, Barr's recent meeting with EPA took place after EPA had forwarded its proposed MeCl2 rule to OMB
- Ensure EPA's proposed rule meets the standards established by amended TSCA Sections 6 and 26 as well as E.O. 12866 and 13563

Section 26 of TSCA Requires EPA to

Although Section 26(l) permits EPA to propose regulations based on final risk assessments published before the 2016 amendments, such regulations nevertheless must comply with the requirements of Section 6. Nevertheless, Section 26 requires that EPA:

- Make decisions based on the best available science,
- Consider all of the scientific information reasonably available to the Agency, and
- Base its decisions on the weight of the scientific evidence.

Section 6 of TSCA Requires to Consider

- The benefits of such the chemical substance or mixture for various uses and the availability of substitutes for such uses
- The reasonably ascertainable economic consequences of the rule, after including consideration of—
  - the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
  - the costs and benefits of the proposed regulatory action and of one or more primary alternative regulatory actions considered; and
  - the cost effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions considered by the Administrator.
- When prohibiting or restricting in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use to be prohibited or restricted, will be reasonably available when the proposed prohibition or restriction takes effect.

Section 9 of TSCA Requires

- A determination of whether other federal agencies and other authorities available to EPA can sufficiently mitigate the risks being addressed under a Section 6 action under consideration.
- This should be done before issuing a proposed Section 6 rule.

Important considerations in light of TSCA's statutory standards

- Comments submitted by HSIA and Barr during small business consultation document errors and oversights in risk assessments
  - Certain data on exposures predate existing regulations
  - Data in EPA's records from NESHAPS submittals not consulted
- Economic assessment under estimates costs of alternatives
- Alternatives incorrectly assumed to be effective
- A careful comparative risk assessment of alternatives should be done
- Timely, risk-reducing voluntary labeling initiatives can be initiated now
- Restrictions on sales of small container sizes will act as a technical, if not a legal, prohibition on retail distribution, small business and consumer users

Current Federal Regulation of MeCl2

- OSHA has established and updated its workplace controls address inhalation exposure
- CPSC has provided guidance pursuant to the Federal Hazardous Substances Act and is considering petition to update and enhance its guidelines
- In 2008, EPA established NESHAP for paint stripping operations

Benefits of Methylene Chloride Paint Removers

- Methylene Chloride is a necessary component of paint removers used to strip chemically resistant coatings.
- No other solvent will strip the most resistant coatings.
- On many less resistant coatings the time frame for complete stripping is unacceptable for many commercial uses or DIY uses.
- Methylene Chloride offers a truly unique set of benefits and can be safely used as millions of uses each year shows.
- MeCl2 efficacy reduces exposure times and opportunities for adverse effects
- Poison Control Center Data indicate there has been a steady decline in reports of exposure-related adverse effects in recent years.

Methylene Chloride Performance Attributes

- Unmatched effectiveness
- Non-flammable
- Wax solubility allows slower evaporation
- Relatively low cost
- Very low ozone forming potential (VOC exempt)
- Not considered a stratospheric ozone depletor
- Low greenhouse gas potential

Composition of MeCl2 Removers

- Automotive Removers
  - High levels (70-85%) of MeCl2 combined with 2-5% Ammonium Hydroxide for removing two-component urethane and epoxy coatings.
  - Predominately Body Shop and Automotive Restoration users.
  - Well ventilated open shop and paint booth use. No reported serious injury.
  - While several alternative chemical paint removers have been introduced no other chemical combination has shown usefulness in these applications. The only viable alternative is sanding with the inherent risks of silica (100+ silicosis deaths per year) and exposure to other particulate toxins (lead, chrome, etc.)

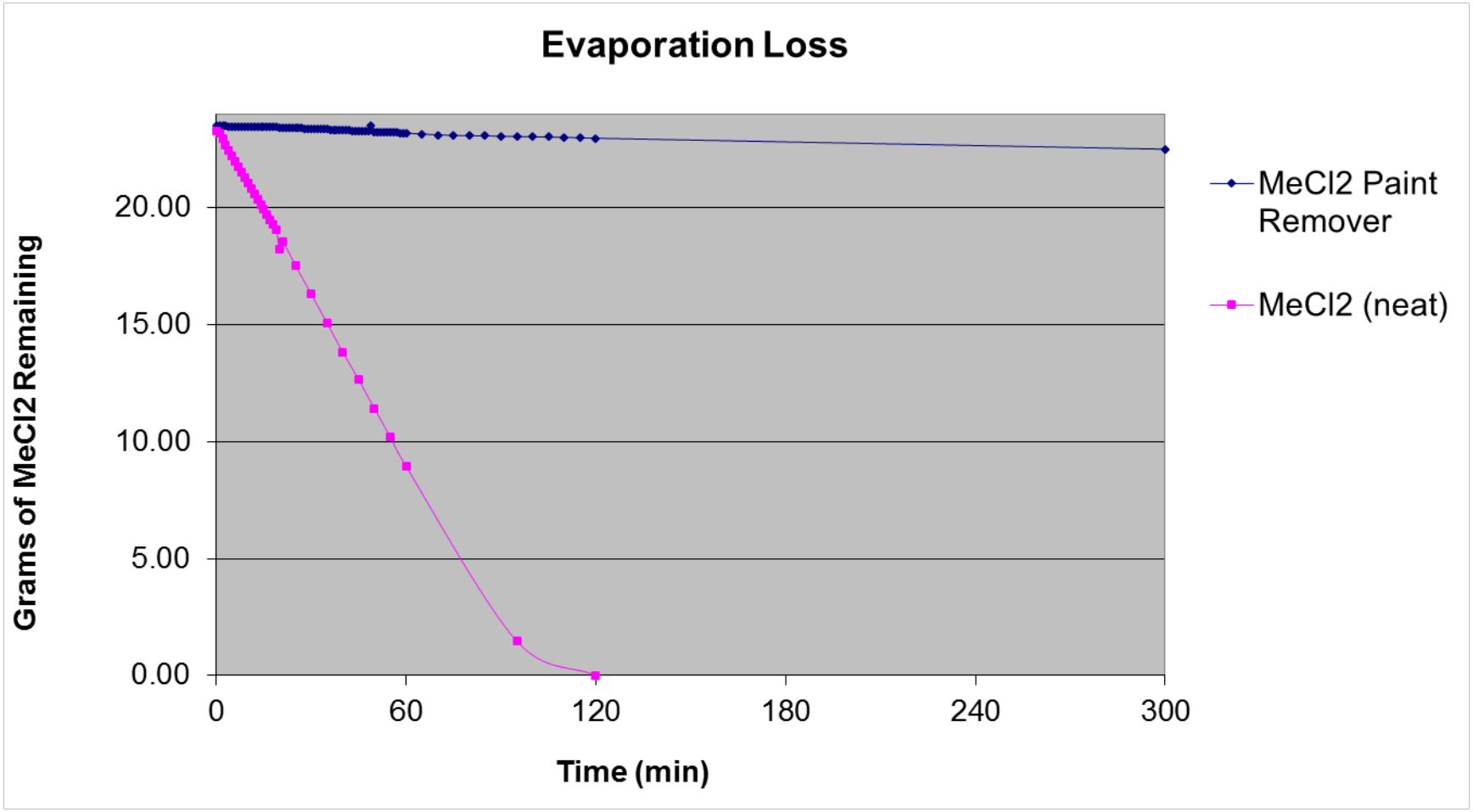
Composition of MeCl2 Removers

- Premium Home Improvement Removers
  - High (70-85%) levels of Methylene Chloride for removal of chemically resistant and multilayered coatings such as epoxies, OEM finishes, very old and crosslinked oil and alkyd based coatings.
  - Non-flammable.
  - No alternatives have proven to be as widely effective as these types of removers which have been in wide use for 70 years.
  - Combination of effectiveness, cost, environmental benefits, and safety does not exist in alternatives.
  - Excellent safety record for consumer use.

Specialty Removers

- These contain various levels of MeCl2, NMP, and other solvents specific to the intended use.
  - Furniture Strippers
  - Fiberglass Strippers
  - Stain Removers
  - Adhesion Removers
  - Others formulated to specific uses

MeCl2 Paint Removers formulated to retard evaporation and minimize airborne concentrations



2015 Barr Review Shows Alternatives Ineffective

Non-chemical alternatives: Sand blasting, abrasives, sanding, etc.

- Exposure and environmental release of heavy metals
- Exposure to respirable silica dust – 100 + deaths annually
- Not appropriate for many substrates - plastics, wood laminates, fiberglass, and other soft materials
- Many not appropriate for consumer use
- Some involve enormous capital investment

Chemical Alternatives to MeCl2 costly and ineffective too

- Benzyl Alcohol
  - Less effective – will not strip some chemically resistant coatings.
  - High cost- 450% cost increase vs. MeCl2
  - LVP status under evaluation
  - High Ozone Forming Potential – MIR = 4.89

Chemical Alternatives to MeCl2 (cont.)

- 1,3 Dioxalane
  - Less effective – will not strip some chemically resistant coatings.
  - High cost- 450% cost increase vs. MeCl2
  - Considered a VOC (max use 50%)
  - High Ozone Forming Potential – MIR = 5.47
  - Flammable – Flash Point 25F
  - Very volatile without ability to slow evaporation
  - Asphyxiation hazard

Chemical Alternatives to MeCl2

- Caustics
  - Poor removal for many applications
  - Extremely slow acting
  - Corrosive to skin and eyes

Acetone, Toluene, and Methanol

- Cost competitive to MeCl2
- Toluene and Methanol have reproductive effects
- Acceptable performance for light duty removal
- Poor performance on chemically resistant coatings
- Extremely flammable – Flash Points ~ 0^{F}
- Very volatile – Similar asphyxiation hazards to MeCl2

Unintended Consequences of Prohibition on Retail Sales of MeCl2

- Predominate removers will be Acetone, Toluene, and Methanol Removers – 'acceptable' performance on moderate chemically resistant coatings and cost.
  - Extremely flammable
  - Poison
  - Reproductive hazards
  - Possible carcinogen
  - High ozone emission potential
- Other low performing and more expensive removers will remain for consumer use market seeking "green label" claims
- Restricting sales to high-volume containers in direct sales to industrial users will create unnecessary storage, transfers and disposal risk, and encourage an market for illegal after market sales in small, unlabeled containers

$MeCl_2$ Risks Can Be Addressed with Labeling

- Barr has developed warning language that resonates with the consumers and other users
- Effectively communicates the acute hazards of off label use
- Two year effort, Barr partnered with
  - CPSC Agency Staff
  - CPSC Commissioners
  - Halogenated Solvent Industry Alliance
  - Formulators and chemical manufacturers
  - Shared interest in consumer safety
  - Conferred with state officials

Updated Labeling – More Timely and Cost Effective than Rulemaking

- Addresses acute hazards presented MeCl2 paint removers
- Prohibits use for stripping bath tubs
  - New hazard statements for the front and back panel
  - Heightened language around ventilation
  - Pictogram – customized safety lexicon
- PPE recommendations clear and easy to understand
  - Chemical resistant gloves
  - Chemical resistant splash goggles
  - Respirator

Additional Benefits of Updated Labeling

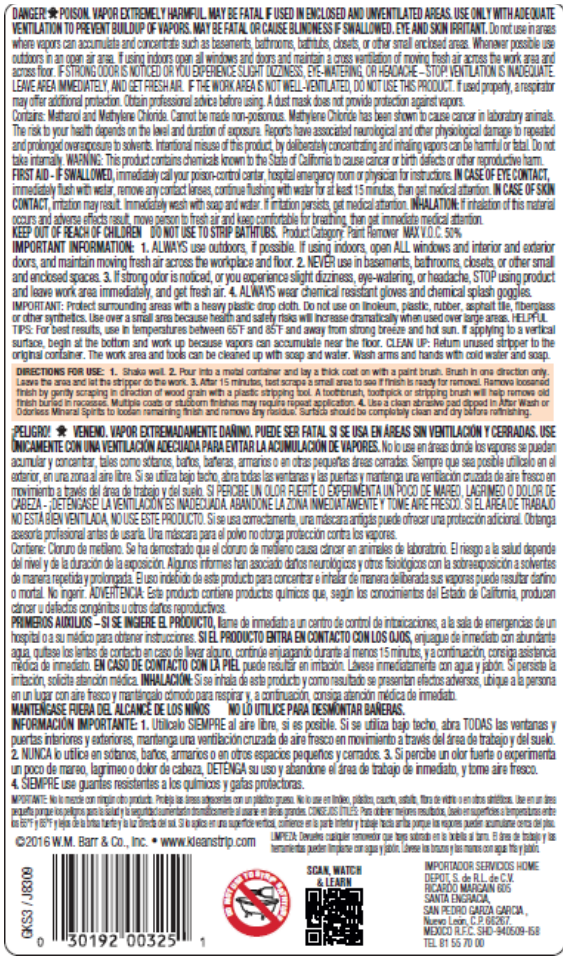
- Industry alignment
  - HSIA
  - American Coatings Association (ACA)
  - Consumer Specialty Product Association (CSPA)
  - American Chemistry Council (ACC)
- Barr products
  - New labels already in production
  - All products will reflect the new language year end
  - Website and customer outreach reinforce messages

Prohibition of Retail Sales of MeCl2 Strippers Unwarranted under TSCA

- Technical comments submitted by HSIA and Barr document several errors and oversights in current risk assessments
- Economic assessment overlooks and underestimates cost implications of alternatives
- Many alternatives erroneously assumed to be effective against all coating on all substrates
- A careful and comparative assessment of the safety and full environmental impacts of alternatives has not been made
- Impacts on small businesses dramatically underestimated in EPA's economic analysis at time of small business consultation
- Regulatory approaches short of a prohibition on retail uses (i.e., voluntary labeling initiatives) can be initiated now, captured in a Section 6(a) regulation to ensure all current and new market entrants comply

New Label


Klean Strip
AMERICA'S #1 STRIPPER BRAND
PREMIUM
Stripper
Strips paint, epoxy & polyurethane from wood, metal & masonry
Disuelve pintura, pegamento y poliuretano en madera, metal y mampostería
Fuerte • Adherencia
WORKS IN LESS THAN 15 MIN
STRONGEST
Removes Multiple Layers of Any Finish
PASTE
Thick Brushable Formula Clings to Surface
DANGER! ☠ POISON. MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOWED. EYE AND SKIN IRRITANT. VAPOR EXTREMELY HARMFUL. INHALATION OF VAPORS MAY CAUSE DEATH. Read entire label prior to use or storage.
ONE GALLON 3.785 LITERS
¡PELIGRO! ☠ VENENO. PUEDE SER LETAL O CAUSAR CEGUERA SI SE INGIERE. IRRITANTE DE LA PIEL Y LOS OJOS. VAPOR EXTREMADAMENTE DAÑINO. INHALAR LOS VAPORES PUEDE CAUSAR LA MUERTE.
Lea toda la etiqueta antes de usar o almacenar este producto.
J8071


DANGER! ☠ POISON. VAPOR EXTREMELY HARMFUL. MAY BE FATAL IF USED IN ENCLOSED AND UNVENTILATED AREAS. USE ONLY WITH ADEQUATE VENTILATION TO PREVENT BUILDUP OF VAPORS. MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOWED. EYE AND SKIN IRRITANT. Do not use in areas where vapors can accumulate and concentrate such as basements, bathrooms, bathtubs, closets, or other small enclosed areas. Whenever possible use outdoors in an open air area. If using indoors open all windows and doors and maintain a cross ventilation of moving fresh air across the work area and across floor. IF STRONG ODOR IS NOTICED OR YOU EXPERIENCE SLIGHT DIZZINESS, EYE-WATERING, OR HEADACHE - STOP VENTILATION IS INADEQUATE. LEAVE AREA IMMEDIATELY, AND GET FRESH AIR. IF THE WORK AREA IS NOT WELL-VENTILATED, DO NOT USE THIS PRODUCT. If used properly, a respirator may offer additional protection. Obtain professional advice before using. A dust mask does not provide protection against vapors.
Contains: Methanol and Methylene Chloride. Cannot be made non-poisonous. Methylene Chloride has been shown to cause cancer in laboratory animals. The risk to your health depends on the level and duration of exposure. Reports have associated neurological and other physiological damage to repeated and prolonged overexposure to solvents. Intentional misuse of this product, by deliberately concentrating and inhaling vapors can be harmful or fatal. Do not take internally. WARNING: This product contains chemicals known to the State of California to cause cancer or birth defects or other reproductive harm.
FIRST AID - IF SWALLOWED, immediately call your poison-control center, hospital emergency room or physician for instructions. IN CASE OF EYE CONTACT, immediately flush with water, remove any contact lenses, continue flushing with water for at least 15 minutes, then get medical attention. IN CASE OF SKIN CONTACT, irritation may result. Immediately wash with soap and water. If irritation persists, get medical attention. INHALATION: If inhalation of this material occurs and adverse effects result, move person to fresh air and keep comfortable for breathing, then get immediate medical attention.
KEEP OUT OF REACH OF CHILDREN DO NOT USE TO STRIP BATHTUBS. Product Category: Paint Remover MAX V.O.C. 50%
IMPORTANT INFORMATION: 1. ALWAYS use outdoors, if possible. If using indoors, open ALL windows and interior and exterior doors, and maintain moving fresh air across the workplace and floor. 2. NEVER use in basements, bathrooms, closets, or other small and enclosed spaces. 3. If strong odor is noticed, or you experience slight dizziness, eye-watering, or headache, STOP using product and leave work area immediately, and get fresh air. 4. ALWAYS wear chemical resistant gloves and chemical splash goggles.
IMPORTANT: Protect surrounding areas with a heavy plastic drop cloth. Do not use on linoleum, plastic, rubber, asphalt tile, fiberglass or other synthetics. Use over a small area because health and safety risks will increase dramatically when used over large areas. HELPFUL TIPS: For best results, use in temperatures between 65°F and 85°F and away from strong breeze and hot sun. If applying to a vertical surface, begin at the bottom and work up because vapors can accumulate near the floor. CLEAN UP: Return unused stripper to the original container. The work area and tools can be cleaned up with soap and water. Wash arms and hands with cold water and soap.
DIRECTIONS FOR USE: 1. Shake well. 2. Pour into a metal container and lay a thick coat on with a paint brush. Brush in one direction only. Leave the area and let the stripper do the work. 3. After 15 minutes, test scrape a small area to see if finish is ready for removal. Remove loosened finish by gently scraping in direction of wood grain with a plastic stripping tool. A toothbrush, toothpick or stripping brush will help remove old finish buried in recesses. Multiple coats or stubborn finishes may require repeat application. 4. Use a clean abrasive pad dipped in After Wash or Odorless Mineral Spirits to loosen remaining finish and remove any residue. Surface should be completely clean and dry before refinishing.
¡PELIGRO! ☠ VENENO. VAPOR EXTREMADAMENTE DAÑINO. PUEDE SER FATAL SI SE USA EN ÁREAS SIN VENTILACIÓN Y CERRADAS. USE ÚNICAMENTE CON UNA VENTILACIÓN ADECUADA PARA EVITAR LA ACUMULACIÓN DE VAPORES. No lo use en áreas donde los vapores se pueden acumular y concentrar, tales como sótanos, baños, bañeras, armarios o en otras pequeñas áreas cerradas. Siempre que sea posible utilícelo en el exterior, en una zona al aire libre. Si se utiliza bajo techo, abra todas las ventanas y las puertas y mantenga una ventilación cruzada de aire fresco en movimiento a través del área de trabajo y del suelo. SI PERCIBE UN OLOR FUERTE O EXPERIMENTA UN POCO DE MAREO, LAGRIMEO O DOLOR DE CABEZA - ¡DETÉNGASE! LA VENTILACIÓN ES INADECUADA. ABANDONE LA ZONA INMEDIATAMENTE Y TOME AIRE FRESCO. SI EL ÁREA DE TRABAJO NO ESTÁ BIEN VENTILADA, NO USE ESTE PRODUCTO. Si se usa correctamente, una máscara antigás puede ofrecer una protección adicional. Obtenga asesoría profesional antes de usarla. Una máscara para el polvo no otorga protección contra los vapores.
Contiene: Cloruro de metileno. Se ha demostrado que el cloruro de metileno causa cáncer en animales de laboratorio. El riesgo a la salud depende del nivel y de la duración de la exposición. Algunos informes han asociado daños neurológicos y otros fisiológicos con la sobreexposición a solventes de manera repetida y prolongada. El uso indebido de este producto para concentrar e inhalar de manera deliberada sus vapores puede resultar dañino o mortal. No ingerir. ADVERTENCIA: Este producto contiene productos químicos que, según los conocimientos del Estado de California, producen cáncer o defectos congénitos u otros daños reproductivos.
PRIMEROS AUXILIOS – SI SE INGIERE EL PRODUCTO, llame de inmediato a un centro de control de intoxicaciones, a la sala de emergencias de un hospital o a su médico para obtener instrucciones. SI EL PRODUCTO ENTRA EN CONTACTO CON LOS OJOS, enjuague de inmediato con abundante agua, quítese los lentes de contacto en caso de llevar alguno, continúe enjuagando durante al menos 15 minutos, y a continuación, consiga asistencia médica de inmediato. EN CASO DE CONTACTO CON LA PIEL puede resultar en irritación. Lávese inmediatamente con agua y jabón. Si persiste la irritación, solicite atención médica. INHALACIÓN: Si se inhala de este producto y como resultado se presentan efectos adversos, ubique a la persona en un lugar con aire fresco y manténgalo cómodo para respirar y, a continuación, consiga atención médica de inmediato.
MANTÉNGASE FUERA DEL ALCANCE DE LOS NIÑOS NO LO UTILICE PARA DESMONTAR BAÑERAS.
INFORMACIÓN IMPORTANTE: 1. Utilícelo SIEMPRE al aire libre, si es posible. Si se utiliza bajo techo, abra TODAS las ventanas y puertas interiores y exteriores, mantenga una ventilación cruzada de aire fresco en movimiento a través del área de trabajo y del suelo. 2. NUNCA lo utilice en sótanos, baños, armarios o en otros espacios pequeños y cerrados. 3. Si percibe un olor fuerte o experimenta un poco de mareo, lagrimeo o dolor de cabeza, DETÉNGA su uso y abandone el área de trabajo de inmediato, y tome aire fresco.
4. SIEMPRE use guantes resistentes a los químicos y gafas protectoras.
IMPORTANTE: No lo mezcle con ningún otro producto. Proteja las áreas adyacentes con un plástico grueso. No lo use en linóleo, plástico, caucho, asfalto, fibra de vidrio o en otros sintéticos. Úselo en un área pequeña porque los peligros para la salud y la seguridad aumentarán dramáticamente al usarlo en áreas grandes. CONSEJOS ÚTILES: Para obtener mejores resultados, úselo en superficies a temperaturas entre los 65°F y 85°F y lejos de la brisa fuerte y la luz directa del sol. Si lo aplica en una superficie vertical, comience en la parte inferior y trabaje hacia arriba porque los vapores pueden acumularse cerca del piso.
LIMPIEZA: Devuelva cualquier removedor que haya sobrado en la botella al tarro. El área de trabajo y las herramientas pueden limpiarse con agua y jabón. Lávese las manos y los brazos con agua fría y jabón.
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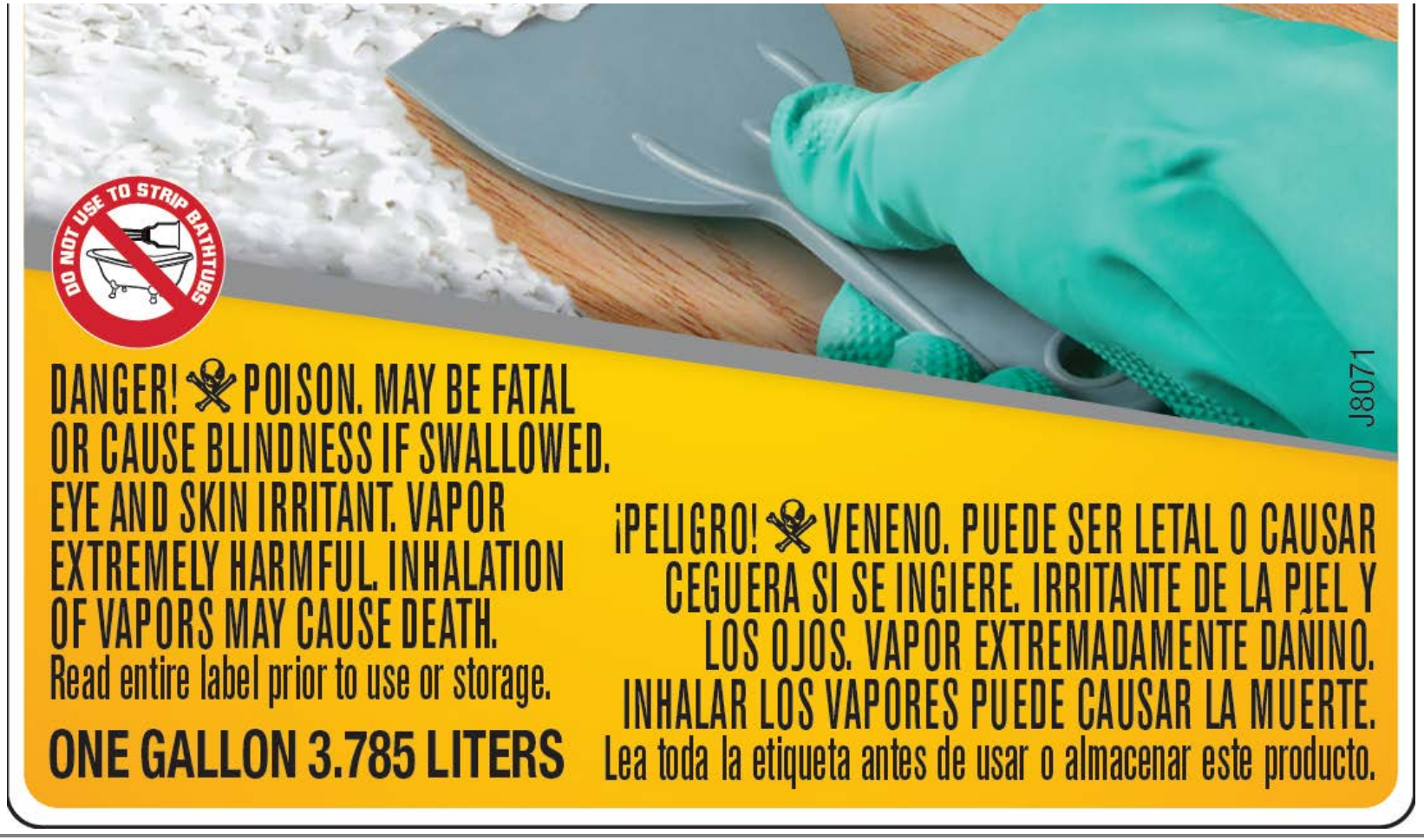
0 30192 00325 1
SCAN, WATCH & LEARN
IMPORTADOR SERVICIOS HOME DEPOT, S. de R.L. de C.V.
RICARDO MARGAIN 605
SANTA ENGRACIA,
SAN PEDRO GARZA GARCIA ,
Nuevo Leon, C.P. 66267,
MÉXICO R.F.C. SHD-940609-I58
TEL 81 55 70 00

New Label Up Close



New Label Up Close

DANGER! ☠ POISON. VAPOR EXTREMELY HARMFUL. MAY BE FATAL IF USED IN ENCLOSED AND UNVENTILATED AREAS. USE ONLY WITH ADEQUATE VENTILATION TO PREVENT BUILDUP OF VAPORS. MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOWED. EYE AND SKIN IRRITANT. Do not use in areas where vapors can accumulate and concentrate such as basements, bathrooms, bathtubs, closets, or other small enclosed areas. Whenever possible use outdoors in an open air area. If using indoors open all windows and doors and maintain a cross ventilation of moving fresh air across the work area and across floor. IF STRONG ODOR IS NOTICED OR YOU EXPERIENCE SLIGHT DIZZINESS, EYE-WATERING, OR HEADACHE – STOP! VENTILATION IS INADEQUATE. LEAVE AREA IMMEDIATELY, AND GET FRESH AIR. IF THE WORK AREA IS NOT WELL-VENTILATED, DO NOT USE THIS PRODUCT. If used properly, a respirator may offer additional protection. Obtain professional advice before using. A dust mask does not provide protection against vapors.
Contains: Methanol and Methylene Chloride. Cannot be made non-poisonous. Methylene Chloride has been shown to cause cancer in laboratory animals. The risk to your health depends on the level and duration of exposure. Reports have associated neurological and other physiological damage to repeated and prolonged overexposure to solvents. Intentional misuse of this product, by deliberately concentrating and inhaling vapors can be harmful or fatal. Do not take internally. WARNING: This product contains chemicals known to the State of California to cause cancer or birth defects or other reproductive harm.
FIRST AID - IF SWALLOWED, immediately call your poison-control center, hospital emergency room or physician for instructions. **IN CASE OF EYE CONTACT,** immediately flush with water, remove any contact lenses, continue flushing with water for at least 15 minutes, then get medical attention. **IN CASE OF SKIN CONTACT,** irritation may result. Immediately wash with soap and water. If irritation persists, get medical attention. **INHALATION:** If inhalation of this material occurs and adverse effects result, move person to fresh air and keep comfortable for breathing, then get immediate medical attention.
KEEP OUT OF REACH OF CHILDREN DO NOT USE TO STRIP BATHTUBS. Product Category: Paint Remover MAX V.O.C. 50%
IMPORTANT INFORMATION: 1. ALWAYS use outdoors, if possible. If using indoors, open ALL windows and interior and exterior doors, and maintain moving fresh air across the workplace and floor. **2.** NEVER use in basements, bathrooms, closets, or other small and enclosed spaces. **3.** If strong odor is noticed, or you experience slight dizziness, eye-watering, or headache, STOP using product and leave work area immediately, and get fresh air. **4.** ALWAYS wear chemical resistant gloves and chemical splash goggles.
IMPORTANT: Protect surrounding areas with a heavy plastic drop cloth. Do not use on linoleum, plastic, rubber, asphalt tile, fiberglass or other synthetics. Use over a small area because health and safety risks will increase dramatically when used over large areas. HELPFUL TIPS: For best results, use in temperatures between 65°F and 85°F and away from strong breeze and hot sun. If applying to a vertical surface, begin at the bottom and work up because vapors can accumulate near the floor. CLEAN UP: Return unused stripper to the original container. The work area and tools can be cleaned up with soap and water. Wash arms and hands with cold water and soap.

Educational Materials

Klean-Strip® & CitriStrip® REMOVER GUIDE

Strippers - America's # 1 Stripper Brand

Product	Premium Brushable	Premium Sprayable	Strip-X® Brushable	Adhesive Remover	CitriStrip® Gel
Chemical	Methylene Chloride	Methylene Chloride	Methylene Chloride	Methylene Chloride	NMP
Flammability	Non-Flammable	Non-Flammable	Flammable	Non-Flammable	Not Flammable
Ready to Strip	15 Minutes	15 Minutes	30 Minutes	30 Minutes	4 hours
Surface Type	Wood, Metal & Masonry	Wood & Metal & Masonry	Wood, Metal & Masonry	Wood, Metal, Concrete & Masonry	Wood, Metal & Masonry
Works Best on these Coatings	Oil /alkyd based paint, Polyurethane, Epoxy, Varnish & Shellac	Oil /alkyd based paint, Polyurethane, Epoxy, Varnish & Shellac	Oil /alkyd based paint, Polyurethane, Stain & Shellac	Adhesives & Mastics	Oil /alkyd based paint,Varnish, Lacquer & Shellac
Comments	• Fastest & most effective	• Sprayable stripper	• Great value priced remover that works well on stains and other coatings • Removes wood stains	• Strips all tough flooring adhesives, mastics, and cove based adhesives	• Safe and effective alternative to methylene chloride removers • Stays wet & active for up to 24 hours

Some states limit usage based on VOC regulations. See your state and local applicable rules.

091815

Educational Materials

Choose the Right Remover

Klean-Strip® Premium Stripper

- Works in 15 minutes or less
- Removes paint, epoxy, polyurethane, varnish & shellac from wood, metal and masonry
- Paste formula clings to vertical surfaces without runs or drips
- The most powerful stripper for the toughest jobs
- Fastest way to strip multiple layers of almost any finish from most surfaces

Klean-Strip® Premium Sprayable Stripper

- Works in 15 minutes or less
- Removes paint, epoxy, polyurethane, varnish & shellac from wood, metal and masonry
- Thin liquid formula with a convenient spray bottle for quick coverage
- All the strength of KS-3 Premium in a sprayable form to get into grooves & crevices

Klean-Strip® Strip-X Stripper

- Works in 30 minutes or less
- Removes stain from wood and removes shellac, varnish & paint from wood, metal & masonry
- Paste formula clings to vertical surfaces without runs or drips
- Good for quickly removing multiple layers of latex paint, or for getting back to the original wood by removing pigmented wood stains

Klean-Strip® Klean-Kutter Remover

- Works in 30 minutes or less
- Dissolves clear finishes such as varnish, lacquer, polyurethane & shellac from all types of wood
- Thin liquid formula brushes quickly & evenly or can be applied with a stripping pad
- Safe to use on antiques and fine furniture to refinish without harming the wood or damaging glue joints & veneers

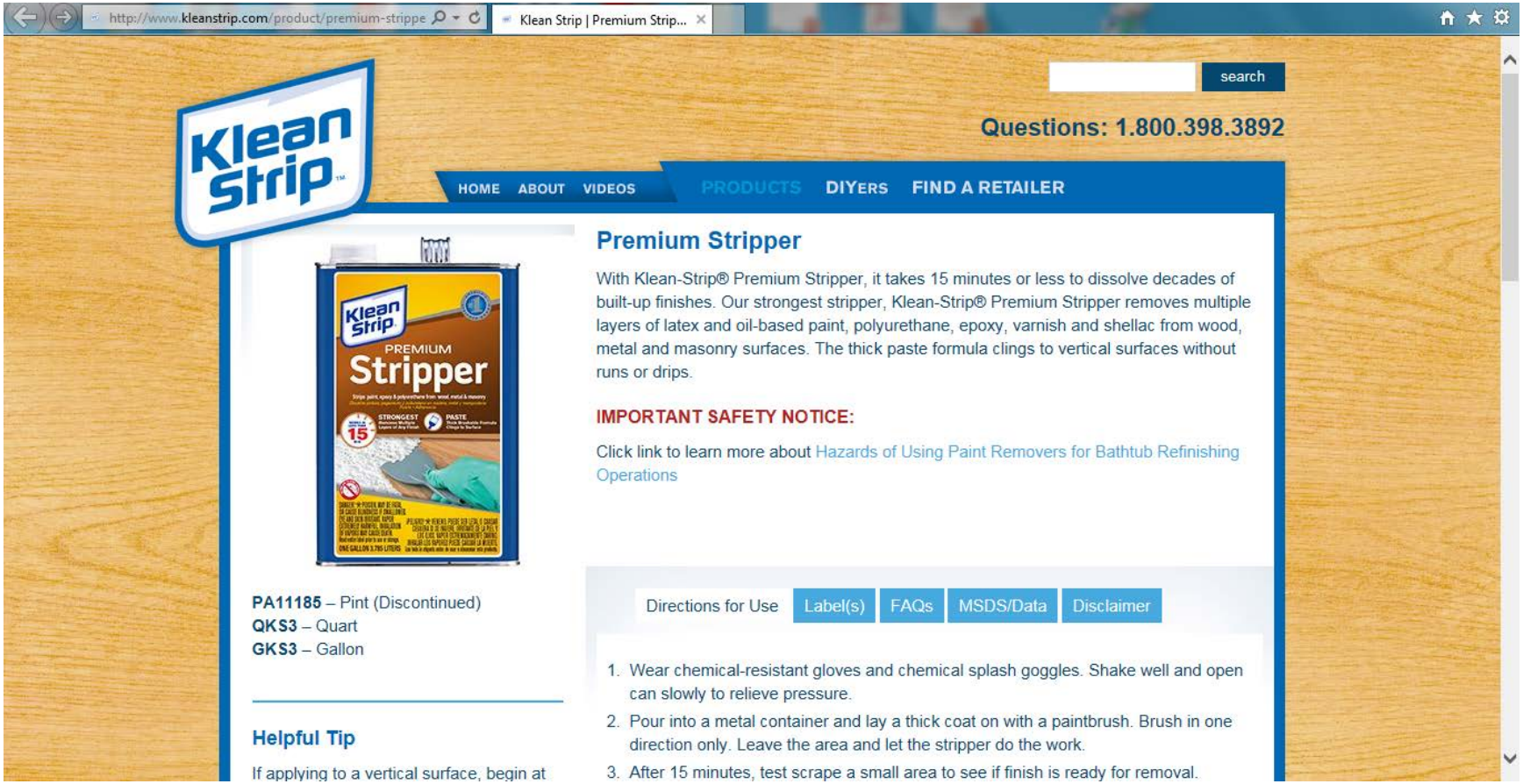
CitriStrip® Paint & Varnish Stripping Gel

- Works in 4 hours but stays wet and active for up to 24 hours
- Removes paint, varnish, polyurethane, lacquer & shellac from wood, metal and masonry
- Thick gel formula clings to vertical surfaces without runs or drips
- Safer formula with a pleasant orange scent -- Contains no methylene chloride
- Very easy to use formula for the novice -- Can leave on surface overnight to strip multiple layers

091815

(see other side for Solvent information)

Barr Website



Thank You

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Written Statement of
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Before the
U.S. Senate Committee on Homeland Security and Governmental Affairs
Subcommittee on Regulatory Affairs and Federal Management
Regarding a Hearing on the Agency Use of Science in the Rulemaking Process:
Proposals for Improving Transparency and Accountability

March 9, 2017

American Chemistry Council
700 2nd Street, N.E.
Washington, D.C. 20002

Summary

The American Chemistry Council (ACC)[1] appreciates this opportunity to provide testimony on Federal Agency use of science in the rulemaking process, and particularly on proposals for improving transparency and accountability.

The business of chemistry is a critical component for manufacturing safe, high quality products and ACC member companies rely on science to conduct the research necessary to discover new chemistries and identify new applications of existing chemistries. They also rely on science to develop new tools for assessing the potential hazards, exposures and risks of chemical substances. Similarly, they expect high quality, up to date science and relevant reliable assessment processes to underpin regulatory decisions by the Federal government.

Reliance on the highest quality, best available science is critical to ensuring public trust. Without it, consumers are at a severe disadvantage. Stakeholders can lose confidence in regulatory decision making, which in turn can lead to product de-selection that is not supported by science, unwarranted public alarm and unnecessary costs.

ACC supports actions to enhance the integration of the best available scientific knowledge and weight of the evidence methods as the foundation for regulatory decision making across Federal Agencies. We also support improving the technical quality and objectivity of Agency evaluations, particularly through enhancing the transparency of how the science is being considered, interpreted, and evaluated.

In 2002, Federal Agencies were directed to ensure the quality, objectivity, utility and integrity of information which they disseminated to the public.[2] In theory, this should have had a direct impact on improving the quality of scientific analyses that support regulatory decisions. Unfortunately, while most Agencies have committed to meeting these standards, we have seen that some of the scientific analyses that have come out of the EPA and other Federal Agencies fall short of meeting the objectivity and quality standards discussed in the government-wide Information Quality Guidelines.

[1] ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. It is also one of the nation's most heavily regulated industries. Chemistry companies are among the largest investors in research and development.

[2] Pursuant to what is commonly referred to as the Information Quality Act (Sec. 515 of the Treasury and General Government Appropriations Act for FY 2001, Pub. L. No. 106-554), the Office of Management and Budget (OMB) issued government-wide Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002) [hereinafter Information Quality Guidelines], available at: https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-24.pdf;

ACC's testimony today discusses some of the standards that already exist, discusses the new Lautenberg Chemical Safety Act scientific standards, and provides some suggestions for ensuring the quality of science that supports regulatory activities. We also share examples of where some Agencies' scientific evaluations continue to fall short.

I. The Need for Confidence in Science

As we are all aware from the news media, there is a large public perception that science may not inform Federal Agency decision making. Indeed even organizations like the American Association for the Advancement of Science (AAAS) have now become official partners in the planned April 22, 2017 March for Science. Dr. Rush Holt, the CEO of AAAS has stated "We see the activities collectively known as the March as a unique opportunity to communicate the importance, value and beauty of science."[3] Concerns about confidence in science, particularly to inform regulations, is not new and certainly did not begin with the 2016 elections.

In 2013, George Mason University conducted a survey to help capture the viewpoints of the scientific community on the state of regulatory risk assessment. The survey "Expert Opinion on Regulatory Risk Assessment" reached out to all members of the Society of Toxicology Risk Assessment Specialty Section, the Society for Risk Analysis Dose Response Section and the International Society for Regulatory Toxicology and Pharmacology.[4] The survey focused on how well and how frequently critical parts of a risk evaluation were conducted (e.g., was there a problem formulation, were standardized protocols used for data collection, was a weight of evidence approach used, was peer review sufficient). In general, the findings showed that there is widespread concern over the current application of these procedures and also showed concerns about the amount of attention given to scientific factors in risk management.[5]

In July 2016, almost 200 toxicologists signed "an appeal for the integrity of science in public policy."[6] This appeal urges legislators to embed the "rules of evidence" of the scientific method in statutes governing administrative policy and regulations. These scientists are concerned that precautionary regulations and policies are being presented as objective science, when in reality they are not. In another recent article, Dr. Andrew Rosenberg of the Union of Concerned Scientists stated, "When science is sidelined from policy decisions, we all lose."[7] ACC shares the concerns and recommendations of this diverse set of scientists. Too often we see scientific assessments, or even policies, that are driven by default assumptions rather than actual scientific evidence.[8]

ACC has consistently called upon the EPA to improve the design and conduct of its chemical assessments. In 2014, ACC released Principles for Improving Chemical Hazard and Risk

[3] See Science Magazine, Feb 28, 2017 article available at: http://www.sciencemag.org/news/2017/02/will-they-or-won-t-they-what-science-groups-are-saying-about-joining-march-science.
[4] The Survey and results can be found at: https://cmpa.gmu.edu/wp-content/uploads/2013/12/GMU-Study-Report.pdf.
[5] Ibid at page 2.
[6] See article available at: http://www.sciencedirect.com/science/article/pii/S0300483X16301123.
[7] See Science Magazine, Feb 17, 2017 article available at: http://science.sciencemag.org/content/355/6326/696/tab-pdf.
[8] See NIOSH Carcinogen Policy example provided in Appendix 1 of this testimony.

Assessments.[9] ACC did not invent these principles. For years, authoritative bodies, like the National Academy of Sciences (NAS), have provided similar constructive input to the EPA.[10] Appendix 1 of this testimony provides some specific examples of cases where Federal Agency evaluations have not met scientific standards.

II. Tools and Standards Exist to Improve Agency Science

Improving Federal Agency science should not be as challenging as it has been. Significant governmental and non-governmental guidance already exists. As noted below, often this guidance is not followed.

a. Information Quality Guidelines

In 2002, the Office of Management and Budget (OMB) released the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (Information Quality Guidelines).[11] The guidelines were then adopted by Federal Agencies and the OMB's principles were to be reflected in the agency-specific guidelines.

With regard to the analysis of risks to human health, safety and the environment, Agencies have adopted or adapted the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act (SDWA) Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)). In these amendments, Congress emphasized that EPA must use the best available scientific evidence for risk information. Since the Information Quality Guidelines directed all Agencies to adopt this standard, Agencies were directed, "to the degree that an Agency action is based on science," to use:

> (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

Additionally, the 1996 SDWA amendments directed EPA "to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable." The Information Quality Guidelines adopted this language and directed all Agencies:

> [I]n a document made available to the public in support of a regulation [to] specify, to the extent practicable:[12]

[9] See ACC principles available at: https://www.americanchemistry.com/Chemical-Hazard-and-Risk-Assessments-Principles/ and further details at: https://www.americanchemistry.com/Policy/Chemical-Safety/Chemical-Assessments/Principles.pdf.

[10] See for instance chapter 7 in the 2011 NAS Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde available at: https://www.nap.edu/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde.

[11] The Information Quality Guidelines are available at: https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-24.pdf.

[12] Bracketed language reflects changes to text for clarity.

(i) each population addressed by any estimate [of applicable risk effects];
(ii) the expected risk or central estimate of risk for the specific populations [affected];
(iii) each appropriate upper-bound or lower-bound estimate of risk;
(iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and
(v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data.

b. Memorandum on Updated Principles for Risk Analysis

In 2007, OMB and the Office of Science and Technology Policy (OSTP) issued a joint memorandum to Executive Departments and Agencies on Updated Principles for Risk Analysis (Principles for Risk Analysis).[13] This memorandum was intended to reinforce the principles developed in 1995. While the focus was on actions directed at improving public health, safety, and the environment, it was noted that many of the principles were relevant to other fields, such as financial or information technology risk analyses.

The Principles for Risk Analysis reiterated the requirements for best available science as they were articulated in the Information Quality Guidelines and presented further important information regarding the use of and presentation of assumptions, judgments, and uncertainties in risk analyses. For instance, among other requirements, the Principles for Risk Analysis require that:

> Judgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgments and their influence on the risk assessment should be articulated.[14]
>
> Results based on different effects and/or different studies should be presented to convey how the choice of effect and/or study influences the analysis. The presentation of information regarding different scientifically plausible endpoints should allow for a robust discussion of the available data, associated uncertainties, and underlying science.[15]
>
> Due to the inherent uncertainties associated with estimates of risk, presentation of a single estimate may be misleading and provide a false sense of precision. Expert panels agree that when a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided.[16]

[13] See: https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-24.pdf.
[14] Ibid, at page 8.
[15] Ibid, at page 8.
[16] Ibid, at page 6.

c. Non-Governmental Reports on Improving Science in Regulations

Improving Peer Review:

In addition to government guidance, other consensus groups have spoken to the needs for ensuring high quality science. For instance, in 2009 the Bipartisan Policy Center put out a report entitled "Improving the Use of Science in Regulatory Policy."[17] Important recommendations in this report included:

> The Administration needs to promulgate guidelines (through executive orders or other instruments) to ensure that when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.[18]
>
> The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest.[19]

In 2012, the Keystone Center released a report entitled "Improving the Use of Science in Regulatory Decision-Making."[20] This report stressed the importance of consistency and transparency in selecting peer review panels and also noted that the regulatory process is better when there is a consistent, transparent and systematic review and evaluation of the scientific literature.

The importance of a robust peer review process cannot be underestimated. Peer review is essential in the evaluation of scientific information to ensure the development of scientifically defensible assessments. It allows for the review of the underlying assumptions, methodology, criteria, and conclusions reached in the evaluation. Federal Agencies have several mechanisms available to them to conduct peer review of scientific information; however, these peer review processes and approaches are inconsistently applied, including the selection of peer review panel members and the consideration given to public and peer review comments.

For example, during some EPA peer review meetings, the peer reviewers have appeared to be overly deferential to EPA and reluctant to be seen as criticizing EPA staff. We have also seen situations where peer reviewers have suggested discounting a study solely based on the funding source, without any consideration of the quality of the study. Also, EPA staff often comment throughout peer review meetings, essentially participating as peers, while stakeholders, including industry experts, are typically excluded from the

[17] See: http://cdn.bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf.
[18] Ibid, at page 4.
[19] Ibid, at page 45.
[20] See: https://www.keystone.org/wp-content/uploads/2015/08/091812-Research-Integrity-Roundtable-Report.pdf.

dialogue. This practice undermines the integrity of the reviewers' role as independent and external to the assessment itself.

Additionally, a critical element of peer review is the consideration of public comments. The public plays an important role in the review process by helping identify key scientific information and potential concerns with the assessment being evaluated. Unfortunately, within some Agencies, there is no robust consideration of public comments in the peer review process. For example, reviewers on the EPA Science Advisory Board (SAB) are not given clear advice regarding what it means to "consider" public comments. In fact we have seen SAB chairs ignore public input because they are not required to address it. When this has occurred, SAB staff have not clarified to the peer reviewers that they can and should respond to public input.

Improving Systematic Review:

The importance of systematic review in risk evaluation was mentioned in the 2012 Keystone Center report, and emphasized in a 2014 NAS report of its Review of EPA's Integrated Risk Information System (IRIS) Process.[21] This NAS panel noted that the use of systematic review approaches would "substantially strengthen" the IRIS process at EPA. Unfortunately, we have yet to see the IRIS program release an assessment that is consistent with these NAS recommendations.

Data Access and the Protection of Confidential Business Information:

Both the Bipartisan Policy Center report and the Keystone Center report discuss the need to protect proprietary business information. The legitimate need for protection must be balanced against public interest in the disclosure of relevant studies and data for the purposes of reproducibility.[22] The OMB Information Quality Guidelines recognize this tension and note that

> Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard.

When it comes to environmental, health and safety information about chemicals, the Toxic Substances Control Act (TSCA) requires that EPA have access to that information. ACC member companies' current practice is to share summary results of industry studies with EPA or to provide raw data underlying health, safety and environmental studies with EPA upon request. Thus the Agency has the information it needs to ensure the safe regulation of chemicals, and EPA can rely on this information in its regulatory decisions. While any proprietary information must be protected, there are processes that exist to make robust study summary information available to the public in a manner that is sufficient to ensure public understanding of the data and address transparency demands. When it comes to full disclosure to the public, decisions to share raw data with non-regulatory bodies are made on a case by case basis. Companies weigh factors such as the

[21] See: http://dels.nas.edu/Report/Review-Integrated-Risk/18764.
[22] See the Keystone Center report at page 20.

potential health/environmental impact of the product, the commercial value of the data, the age of the data, and other administrative, ethical, financial, legal, technical, and public health considerations.

III. Science Standards in the 2016 Lautenberg Chemical Safety Act

When the Lautenberg Chemical Safety for the 21st Century Act (LCSA)[23] was passed in 2016, it was the first time Congress directed a Federal Agency to consider not only the best available science but also the weight of the scientific evidence (WoE). These scientific standards, added to TSCA in Section 26 of the LCSA, have a prominent role in ensuring the Act achieves the fundamental objective of improving public confidence in the federal regulatory system. EPA now has a mandate to apply high quality, reliable and relevant scientific information.

To date, EPA appears to be interpreting these scientific standards as implying that "business as usual" is consistent with the standards. EPA is reluctant to explicitly incorporate the best available science and WoE standards into the framework rules that it is developing to implement the LCSA. Instead, the Agency has suggested that simple reliance on existing guidelines and current practices are sufficient to meet the standards in Section 26.[24] This is of great concern to ACC.

For example, Section 26(i) of the LCSA requires that EPA make decisions using a WoE approach. While a definition of WoE is not provided in the statute, the June 7 Congressional Record provides a definition that was entered into the record by Senator Boxer, the ranking minority member on the committee:

> Weight of the evidence means a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.[25]

This definition is also consistent with the June 2015 House Report language.[26]

Importantly, the definition refers to using a systematic review approach, as has been recommended by the Keystone Center report and the NAS in 2014. It also suggests that evidence be judged on its quality.

Notably, EPA's proposed risk evaluation rule does not incorporate this definition. EPA has asked, however, for comment on this approach.

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[23] P.L. 114-182, 130 Stat. 448 (June 22, 2016).
[24] EPA's draft framework rules for prioritization and risk evaluation can be found at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-5.
[25] See Senate Congressional Record, June 7, 2016 at page S3518, available at: https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf.
[26] See House Report at page 33, available at: https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.

A recent example demonstrates that EPA apparently does not interpret WoE in the same way Congress did in the LCSA. In the draft risk assessment of 1-bromopropane (released prior to enactment of LCSA), EPA did not conduct a systematic review, and the draft assessment did not provide information regarding the quality of the individual studies.[27,28] Although the assessment identified some quality considerations, EPA did not provide any information regarding its own findings from its quality review of the individual studies.[29,30] Additionally, EPA did not describe how considerations were applied and what constitutes a study of "high quality" or "good quality." While EPA staff orally noted that they followed a WoE approach,[31] EPA simply chose the value that provided the lowest point of departure and thus would be most health protective.

The 1-bromopropane draft risk assessment is not consistent with the best available science or the WoE approach envisioned under the LCSA. If EPA chooses to simply follow current practices, the Agency will embark on a process that is not consistent with the new Section 26 science standards.

Section 26 requires EPA to develop, within two years of enactment, any new policies, procedures and guidance that are necessary to ensure compliance with the LCSA. In addition, within five years of enactment and then once every five years, EPA is required to review these policies, procedures and guidance. This approach will ensure that EPA is consistently relying upon scientific approaches that are consistent with the state of the science.

IV. Potential Solutions to Improving Agency Science

ACC provides the following four recommendations to improve the science supporting regulatory decision making.

a. Improve and Clarify Scientific Definitions

ACC believes that the intent of Congress in drafting the scientific standards in the LCSA is clear. It is also clear that EPA's proposed interpretation diverges from Congressional intent in important respects. Clarifying that the intent of scientific standards is to improve existing Agency practices would be useful. In addition, providing clear and specific definitions for terms like best available science and WoE would be beneficial to the consistency, reliability and credibility of EPA's regulatory decisions. These definitions should address not only what Agencies should consider when evaluating scientific information, but also what information

[27] See Comments of the American Chemistry Council on the TSCA Work Plan Chemical Draft Risk Assessment of 1-Bromopropane , Docket No. EPA-HQ-OPPT-2015-0084, May 9, 2016.
[28] See peer review report/meeting minutes available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0805-0028, at page 41 which states: "While the Agency indicates that the literature was thoroughly reviewed for robustness, adequacy, etc., the Committee found that it is not clear what exact methodology was used to systematically rate, rank, and select studies to inform sections of the risk assessment. For example, was a quantitative ranking system developed for study quality?"
[29] Ibid.
[30] See draft available at: https://www.epa.gov/sites/production/files/2016-03/documents/1-bp_report_and_appendices_final.pdf, at Appendix M.
[31] See Chemical Safety Advisory Committee Meeting Transcript available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0805-0027; at page 130.

Agencies should present in evaluations. Requiring the Agencies to "show their work" and present their thought process in a transparent and clear manner would be have tremendous value. For example, adopting the language from the SDWA Amendments, we suggest the following definition of best available science:

> *Best available science* means information that has been evaluated based on its strengths, limitations and relevance and that the Agency is relying on the highest quality information. In evaluating best available science, the Agency will also consider the peer review of the science, whether the study was conducted in accordance with sound and objective practices, and if the data were collected by accepted methods or best available methods. To ensure transparency regarding best available science the Agency will describe and document any assumptions and methods used, and address variability, uncertainty, the degree of independent verification and peer review.

Defining WoE clearly would also be advantageous. As noted previously, we suggest the definition articulated in the Senate debate on LCSA on June 7, 2016. When using this definition, it will also be important to clearly define the term "systematic review" as there may not be a uniform interpretation of that term among stakeholders.

A particular concern in applying the best available science and weight-of-the-evidence is the tendency of federal agencies to use default assumptions, even when data are available.

Despite more than 30 years of extensive mechanistic toxicological research by academia, research institutions and the private sector, some regulatory programs in EPA continue to rely on default approaches for hazard characterizations and risk assessments that date back to the 1970s. Even though frameworks for integrating mechanistic information and mode of action have been developed by authoritative bodies and incorporated into the EPA cancer risk guidelines,[32] at the present time, there is uneven use within EPA of such approaches in hazard characterizations and risk assessments. EPA's Office of Pesticide Programs has often determined, based on WoE evaluations that include consideration of mode of action and human relevance, that carcinogenic effects in animal studies are not relevant to humans or the carcinogenic effects are secondary to target organ toxicity, and thus no carcinogenic risks are posed to humans at doses below those which produce such toxicities. However, the IRIS program continues to rely on the 1970s default linear approach for cancer risk assessment. The IRIS program steadfast reliance on default linear approaches has significant consequences for many chemicals and can create tremendous costs to address "phantom risks" in site cleanups.[33] This outdated manner in which the EPA IRIS program deals with mode of action knowledge does not comport with use of best available science.

Therefore, in implementing the definitions of best available science and WoE for the evaluation of the potential carcinogenic effects of substances, when supported by the scientific data, EPA should present non-linear modeling approaches consistent with the available data and scientific understanding of endogenous exposures and mode of action, in lieu of, or at a minimum in addition to, a linear default. Further, such assessments should include, in addition to upper

[32] See EPA 2005 Guidelines for Carcinogen Risk Assessment
[33] See George M. Gray and Joshua T. Cohen Nature 489, 27–28, 06 September 2012.

bound calculations, the distribution of estimated hazards or risks, including central tendency values, and clear criteria for when defaults are justified, including criteria for the application of uncertainty factors.

b. Improve Oversight and Develop Quality Checklists

Considering the guidance that already exists from OMB, other consensus bodies, and within the Agencies, stronger oversight to ensure that Agencies are following existing guidance could be highly effective. This oversight could come from independent offices within Agencies, Congress, or OMB or OSTP within the Executive Office of the President. One tool that may be effective is to develop a checklist to ensure that quality standards are met in scientific evaluations that support regulations. For instance, a recent publication from former EPA scientists has suggested that to promote transparency and consistency, risk evaluations could be compared to a guide or checklist which depicts all the important elements of a high quality assessment.[34] Drs. Dellarco and Fenner-Crisp suggest that this guide "could be used by authors, sponsors, risk assessors, peer reviewers, and other interested stakeholders to determine if an assessment meets the current best scientific practices."[35]

c. Improve Peer Review Practices

As noted earlier, the importance of a robust peer review process cannot be underestimated. Ensuring that peer review panels are composed of a diverse group of experts that have the breadth and depth of experience necessary to review scientific analyses in a transparent and comprehensive manner would be beneficial. It is also important to ensure that peer reviewers are fully independent from the program office issuing the assessment and conflicts of interest are fully evaluated and disclosed. More details on improving peer review can be found in the OMB Information Quality Bulletin for Peer Review,[36] as well as in reports from other consensus bodies, as discussed in Section II.

d. Change Publication Incentives and Standards for Scientific Grants and Funding

Much has been written about the lack of reproducibility of research findings published in peer reviewed journals.[37] The trend towards "publish or perish" puts immense pressure on researchers to publish findings, and in particular to publish predominantly positive findings.[38]

Publication bias is common to published academic literature. This leads to bodies of literature in which the majority of publications support a given hypothesis. Publication bias stems from the fact there are many fewer incentives for publishing negative information or information that does

[34] See publication available at: https://ehp.niehs.nih.gov/15-10483/.
[35] Ibid
[36] See: https://www.gpo.gov/fdsys/pkg/FR-2005-01-14/pdf/05-769.pdf.
[37] See for example: http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124, or http://www.nature.com/news/reproducibility-1.17552.
[38] See for example: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3999612/.

not support a hypothesis. Promotions and job security in academia, as well as having grants funded by Federal Agencies, are often tied to an author's publication record.

Government Agencies can play an important role by 1) changing the incentives for grant funding such that decisions to fund research do not depend so heavily upon finding positive results and 2) putting in place standards to ensure that research studies are designed in a manner that will make them useable for regulatory decision making. Standards for funding could ensure that research studies follow best scientific practices and are designed with regulatory use in mind. For instance, for chemical risk assessment, studies should be designed to test more than three doses such that a dose-response analysis can be conducted. Unfortunately we have seen too many examples of government funded research where only one high dose is tested. While this information may have some value, it is then difficult to use these data to determine what impact the same chemical may have at more environmentally relevant lower dose ranges. If the government demanded a more robust study design when approving the research projects, the data obtained would likely be much more useful.

V. Conclusion

Ensuring that Federal decision making is firmly based on the use of high quality science is critical to helping the government meet its obligation to protect human health and the environment. This can be achieved through common sense reforms that will lead to more efficient and effective regulatory decisions. ACC looks forward to working with members of the Committee to enhance approaches to ensure that high quality science is the foundation to regulatory decision making.

Appendix 1: Examples of Scientific Concerns with Federal Science Evaluations

Below ACC provides a few specific examples where Federal Agencies have fallen short when it comes to using the best available science.

a. Case 1: OSHA Crystalline Silica PEL

Background
OSHA finalized its workplace Permissible Exposure Limit (PEL) for crystalline silica in March, 2016. The final PEL reduced the standard from 100 $\mu g/m^3$ to 50 $\mu g/m^3$.

Crystalline silica (commonly encountered as beach sand) is the second most abundant mineral in the Earth's crust. It is ubiquitous in rocks, gravel, sand and soils; plays a crucial role in construction and transportation; and is essential for many manufacturing processes and countless products. For example, it is a critical material for foundries and steel making, and is a key component of abrasives, paints, high-tech equipment, glass and ceramics.

OSHA contended that the PEL of 100 $\mu g/m^3$ was not sufficiently protective. In fact, however, the data clearly shows that the incidence and rate of silicosis mortality have declined dramatically since adoption of the 100 $\mu g/m^3$ PEL in 1971, and the remaining cases can be attributed to higher silica exposures that were prevalent decades ago (allowing for latency) and to exceedances of the 100 $\mu g/m^3$ PEL. Moreover, the best evidence indicates that for silicosis and other potential pulmonary diseases, including lung cancer, there is a concentration-based threshold for silica exposure that exceeds 100 $\mu g/m^3$.

Importance
The new PEL is not economically feasible across multiple sectors of general industry and therefore will cause significant economic disruption throughout the economy. OSHA estimated that the annualized costs for all of general industry to comply with the revised standard would be $359 million. That estimate of compliance costs is deeply flawed and vastly understates the true costs of compliance, which are likely to be more than an order of magnitude higher. It would be far more cost-efficient and effective to bring all general industry employers into compliance with the longstanding PEL of 100 $\mu g/m^3$ rather than mandating that they attempt to comply with the new PEL of 50 $\mu g/m^3$.

Scientific Concerns
Because of its long latency period, silicosis cases seen today are attributable largely to exposures that occurred decades ago – in most cases, to exposures that began before OSHA's long-standing PEL of 100 $\mu g/m^3$ was even adopted. OSHA's argument that silicosis cases are underreported does not alter the fact that silicosis cases have dropped dramatically in the previous 40+ years, as silicosis cases have been underreported relatively consistently through that same time period. There are fundamental shortcomings and limitations in OSHA's risk assessment for all of OSHA's identified endpoints of concern:

- Important statistical errors in modeling and inference, including in particular a failure to adequately control for biases, which can lead to false positive results.

- A failure to properly model exposure measurement errors, which are common in the silica worker cohort studies in particular.
- Generally, uncertainties are not well characterized in the preliminary quantitative risk assessment.
- A failure by OSHA to carry out any causal modeling or analysis that would allow it to conclude that a reduction in the PEL would actually reduce adverse health effects.

The alleged association between silica exposure *per se* and lung cancer remains controversial in the scientific community. OSHA did not properly weigh and consider the totality of the epidemiological evidence, discounting the significance of negative studies while choosing to highlight those studies that would confirm OSHA's position. Furthermore, as noted above, the best evidence points to an exposure concentration threshold for potential silica-related lung cancer that exceeds the PEL of 100 $\mu g/m^3$ that applied in general industry before the new rule was adopted in 2016.

b. Case 2: EPA IRIS Assessment of Trimethylbenzenes (TMB)

Background
On September 9, 2016, EPA issued its final report on the IRIS assessment of Trimethylbenzenes (TMBs), which addresses the potential non-cancer and cancer human health effects from long-term exposure to TMBs. Humans are not exposed to individual TMB compounds, but to complex mixtures. According to EPA, the primary uses for TMBs are as a blending agent in gasoline formulations (C9 aromatic fraction); solvents; and as a paint thinner.

In its review of TMBs, the EPA fell far short in meeting its obligations to improve its IRIS processes and assessment reports. Without explanation, EPA failed to respond to public comments on the draft TMBs assessment, even though the IRIS process for developing assessments explicitly includes a response to comments element.

Importance
As a final report, the IRIS assessment on TMBs will inform risk management decisions on TMBs by EPA's program and regional offices.

Scientific Concerns
The IRIS assessment of TMBs does not accurately represent the health effects associated with exposure to TMBs because EPA failed to utilize a consistent and transparent data evaluation procedure for evaluating and weighing the full body of evidence.

In particular, EPA failed to rely on available guideline studies on commercial complex C9 aromatic mixtures that industry conducted under EPA's TSCA program. The entire commercial C9 aromatic blend, which contains a high percentage of TMBs, has similar toxicological properties and health effects as the individual isomers of TMB. Thus, guideline studies on the commercial complex of aromatic mixtures are highly relevant to assessing the toxicology of TMBs.

EPA's Office of Pesticide Programs (OPP) has also reviewed the toxicology of TMBs and determined that the health effects of TMBs can be efficiently assessed by relying on C9 aromatic

mixture studies. OPP reached different scientific conclusions, including different quantitative health effect numbers, than that of EPA's IRIS Program. EPA, however, did not resolve these differences during the IRIS assessment of TMBs.

c. Case 3: NIOSH Cancer Policy

Background

In the NIOSH Carcinogen Policy, released in December 2016, NIOSH states that underlying this entire policy is the "recognition that there is no known safe level of exposure to a carcinogen."[39] ACC believes this statement is based on a default assumption and not clear scientific evidence, as certain carcinogens have thresholds or doses below which no adverse effects are identified.[40,41] Assuming that every chemical is toxic at high exposures and linear at low exposures does not comport with modern-day scientific knowledge of biology and there is no compelling evidence-based justification for a general low-exposure linearity. Instead, case-specific mechanistic arguments are needed.[42]

d. Case 4: EPA IRIS Assessment of Ethylene Oxide (EO)

Background

EPA posted the final IRIS Assessment of EO in December 2016. EPA, using unsupportable, conservative, risk assessment modeling, concluded that the one-in-a-million lifetime cancer risk associated with exposure to EO is far below EO background levels currently in the environment and EO levels naturally converted from ethylene in humans through breathing.

This conclusion is not plausible, and not scientifically supportable. It is based on an inadequate evaluation of a body of evidence from human studies that include historical exposure levels to

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[39] See NIOSH Carcinogen Policy available at: https://www.cdc.gov/niosh/docs/2017-100/default.html.

[40] See, for example Olden K, Vulimiri SV. 2014. Laboratory to community: chemoprevention is the answer. Cancer Prev Res (Phila). 7(7):648-52. http://cancerpreventionresearch.aacrjournals.org/content/canprevres/7/7/648.full.pdf at 650; which states: "Our understanding of toxicologic mechanisms has advanced considerably since the linear non-threshold model was adapted for cancer risk assessment. Knowledge of mechanism of action is critical for informing dose–response relationship below the experimental observable range. Johnson and colleagues (1) have used new technologies in analytical chemistry and molecular biology to characterize downstream biologic events in the exposure disease continuum. They showed that AFB1 is a classic genotoxic substance in that it binds covalently to DNA and induces mutations. In fact, DNA adduct formation exhibits a characteristic linear dose–response curve over a wide range. But, further analysis demonstrated a threshold mode of action, with respect to internal dose of active metabolite and hepatocarcinogenesis. That is, there was substantial adduct formation and DNA damage without having any affect [sic] on development of hepatocellular carcinoma."

[41] See, for example: United States Environmental Protection Agency (EPA). 2015. Chemicals evaluated for carcinogenic potential office of pesticide programs, annual cancer report. Washington, DC. http://npic.orst.edu/chemicals_evaluated.pdf. EPA has determined that a number of substances that produce cancer at high doses are not likely to be carcinogenic to humans at low doses.

[42] Rhomberg LR, Goodman JE, Haber LT, Dourson M, Andersen ME, Klaunig JE, Meek B, Price PS, McClellan RO, Cohen SM. 2011. Linear low-dose extrapolation for noncancer health effects is the exception, not the rule. Crit Rev Toxicol. 41(1):1-19. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038594/pdf/btxc12-001.pdf and Bogen, KT. 2016. Linear-No-Threshold Default Assumptions for Noncancer and Nongenotoxic Cancer Risks: A Mathematical and Biological Critique. Risk Analysis Risk Analysis, Vol. 36, No. 3. http://onlinelibrary.wiley.com/doi/10.1111/risa.12460/pdf. .

EO that are far higher than current occupational exposure limits. Other, more accurate, data sources are available, and alternative scientific risk assessment modeling approaches could have been used, but EPA made no serious, systematic attempt to integrate all of the evidence.

Importance

A determination by EPA that EO, with a myriad of important applications including the sterilization of medical equipment for surgery, can cause cancer at less than one part-per-trillion[43] exposure will needlessly cause alarm and confusion, not only among workers, but also in the general population and in the public health and medical communities. These numbers are not reliably measurable, and are orders of magnitude below current endogenous and exogenous levels of EO.

Scientific Concerns

EPA did not adequately consider study quality into the IRIS review. Industry cohorts were not considered with the other epidemiology data sets even though this cohort was stronger than foreign cohorts used that contained occupational exposure interferences.

EPA did not fully utilize linear and non-linear modeling approaches (as allowed within the cancer assessment guidance) to estimate cancer risk from current EO exposure levels and expected DNA repair mechanisms.

EPA did not consider realistic exposure scenarios and fully delineate endogenous vs. exogenous EO and associated health impacts.

In 2007, EPA's SAB identified problems with the linear regression modeling and low dose extrapolation for determining cancer risk. The SAB concluded that substantial revisions were needed in the IRIS assessment including:

- Acquiring and using individual data for modeling rather than grouping populations for modeling that currently results in overly conservative estimated cancer risks;
- Given the distribution of and questionable association with certain cancer types, considering using both linear and non-linear approaches to estimate cancer risk;
- Providing more transparency and correcting flaws associated with inappropriately grouping lymphohematopoietic (LH) cancers and combining genders for the dose-response analysis.

In 2015, a specially selected SAB Committee reviewed a revised draft EO IRIS assessment. The committee, however, did not conduct an independent, unbiased review. Problems included:

- Inaccurate public statements by several SAB members indicating industry produced scientific studies should be disqualified due to potential industry influence, and the acceptance by SAB and IRIS staff of such a position; no evidence of biased data sponsored by industry was ever presented, and it is clear that those members advocating this position should have been disqualified due to these clear biased positions.

[43] 1 part per trillion is roughly equivalent to 1 second in 320 centuries or 1 inch in 16,000,000 miles

- Lack of understanding by SAB members of new evidence-based medicine concepts regarding mutagenicity of cancer cells and the contribution of naturally occurring EO in DNA repair mechanisms;
- Recommendation of epidemiology data sets with questionable or scientifically unsound characteristics to estimate cancer risk and rejection of alternative data sets that are as or more robust than those selected;
- EPA still did not use individual data for modeling as recommended in 2007, and did not seriously explore alternatives to the linear low dose modeling approach.

Even though the SAB made extensive recommendations in its 2015 report and public comments were submitted on the IRIS draft reviewed by the SAB, EPA still did not respond fully to all comments submitted or implement all the changes recommended by the SAB.

e. Case 5: National Ambient Air Quality Standard for Ground-Level Ozone

Background

In 2015, EPA lowered the National Ambient Air Quality Standard (NAAQS) for Ground-Level Ozone from 75 ppb to 70 ppb. Ozone, which is one of six criteria pollutants regulated under Section 109 of the Clean Air Act, is formed from a reaction between nitrogen oxide (NOx), volatile organic compounds (VOCs), and sunlight. Exposure to relatively high concentrations of ozone can cause adverse respiratory effects and interfere with plants' ability to produce and store food.

In 2008, the ozone NAAQS was set at 75 ppb. Areas were not designated as complying or failing to comply with this standard until May 2012 due to unnecessary delays following the Obama Administration's premature reconsideration of the standard in 2010. This resulted in areas across the country not being allowed sufficient time to begin implementing the 2008 standard before EPA changed the standard again, which the Agency justified as being necessary to protect public health and welfare. However, a closer look at EPA's work during this most recent review process questions the need to revise down the standard.

Scientific Concerns

EPA relied on ecological epidemiology studies, also known as time-series analyses and clinical studies, as the basis to lower the ozone NAAQS to 70 ppb in 2015. However, EPA failed to adequately characterize the uncertainties associated with adverse health effects reported in these studies. Ecological epidemiology studies are not scientifically rigorous enough and are not designed to determine if ozone was responsible for the demonstrated the health effects. Clinical studies are limited by the small sample sizes and because they do not adequately consider the normal variation in the lung function.

For example, in the 2015 standard, EPA relied on two new studies, Schelegle *et al.* (2009)[44] and Kim *et al.* (2011).[45] These studies both used a small sample which, while not unusual for a

[44] Schelegle, ES; Morales, CA; Walby, WF; Marion, S; Allen, RP. 2009. 6.6-Hour inhalation of ozone concentrations from 60 to 87 parts per billion in healthy humans. Am. J. Respir. Crit. Care Med. 180(3):265-272.
[45] Kim, CS; Alexis, NE; Rappold, AG; Kehrl, H; Hazucha, MJ; Lay, JC; Schmitt, MT; Case, M; Devlin, RB; Peden, DB; Diaz-Sanchez, D. 2011. Lung function and inflammatory responses in healthy young adults exposed to 0.06 ppm ozone for 6.6 hours. Am. J. Respir. Crit. Care Med. 183:1215-1221.

controlled human exposure study, proves difficult as a basis for drawing broader conclusions with regard to the protection of public health. EPA identified lung function decrements of only 2.8% to be adverse effects when the variation of lung function in normal subjects can vary by over 5% (Pellegrino *et al*. 2005)[46] to 17.6% (Medarov *et al*. 2008).[47] EPA must rely on biological, not just statistical, significance in identifying an adverse health and provide clear guidance on how to define adverse effects.

Ultimately, these studies did not actually support health effects below the 75 ppb standard, and EPA primarily justified the regulation impacting 300 million people on study results from just a few individuals.

[46] Pelligrino, R; Viegi, G; Brusasco, V; Crapo, RO; Burgos, F; Casaburi, R; Coates, A; van der Grinten, CPM; Gustafsson, P; Hankinson, J; Jensen, R; Johnson, DC; MacIntyre, N; McKay, R; Miller, MR; Navajas, D; Pedersen, OF; Wanger, J. 2005. Interpretive strategies for lung function tests. Eur. Respir J. 26: 948-968.
[47] Medarov BI, Pavlov VA, Rossoff L. 2008. Diurnal variations in human pulmonary function. Int J Clin Exp Med. 1(3):267-273.

March 20, 2017

Docket Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW Washington, DC 20460-0001

Sent electronically to www.regulations.gov Docket ID# EPA-HQ-OPPT-2016-0636

Re: ACC Comments on EPA's Proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act as amended by the Lautenberg Chemical Safety Act

Dear Sir/Madam:

The American Chemistry Council (ACC)[1] appreciates the opportunity to provide written comments to the Office of Chemical Safety and Pollution Prevention to inform the Agency's development of a prioritization process rule under the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Chemical Safety Act (LCSA). ACC is committed to being a constructive stakeholder in the effective implementation of the LCSA and we provide these comments to assist the Agency in its development of a chemical evaluation and management program that is efficient, science-based, and consistent with the legal requirements of the LCSA.

Prioritization is the first step in the LCSA's framework for evaluating active chemicals in commerce and the prioritization process rule must establish a risk-based screening process and criteria to identify high and low priority substances for risk evaluations under the LCSA. If you have any questions, please contact me at: 202-249-6403 or Sarah_Brozena@americanchemistry.com.

Sincerely,

Sarah H. Brozena

Sarah Brozena
Senior Director, Regulatory & Technical Affairs

Cc: Jeffrey Morris, Director, OPPT
Wendy Cleland Hamnett, OCSPP
Ryan Schmit, OCSPP

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 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. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

American Chemistry Council
Comments on EPA's Proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act as amended by the Lautenberg Chemical Safety Act

Docket ID# EPA-HQ-OPPT-2016-0636

March 20, 2017

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EXECUTIVE SUMMARY

EPA has suggested four steps in its proposed rule to implement the prioritization requirements of Section 6(b) of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act:

- "Pre-prioritization" to narrow the pool of potential candidate substances
- Initiation of the prioritization process by identifying candidate substances and soliciting public comment
- Proposed priority designation, including an opportunity for public comment
- Priority designation

The American Chemistry Council (ACC) has three major concerns with EPA's proposed prioritization process rule. Our concerns relate to the proposed pre-prioritization step, the treatment of low priority designations, and EPA's failure to address the LCSA Section 26 science standards in the rule. ACC's comments include specific recommendations to address these concerns.

EPA's proposed prioritization process hinges on the "pre-prioritization" step. EPA does not fully and clearly describe this step, its statutory authority or limitations. Pre-prioritization is not mentioned in TSCA section 6(b) as amended. EPA asserts that the statute leaves it "broad discretion" to choose which chemicals on the TSCA Inventory to put into the prioritization process. However, EPA must exercise its discretion in a reasonable manner and is required to describe the statutory authorities for its exercise of discretion. EPA has not done so here.

EPA intends the pre-prioritization step to inform prioritization decisions and the risk evaluation process, without regard to other relevant provisions of the statute. Because EPA asserts that it may need additional time to gather or develop information for risk evaluations, it has proposed to use the pre-prioritization step to gather information on substances with "insufficient information" for risk evaluation. ACC acknowledges that the statute imposes time constraints on the Agency once the prioritization process is triggered, but we believe that EPA has other tools available to address information needs in both the prioritization and risk evaluation stages in a timely, efficient manner.

For example, in its pre-prioritization step EPA does not address the important relevant testing requirements of Section 4(a)(2)(A) or (B), the statement of need requirements of Section 4(a)(3) or the tiered testing requirements of Section 4(a)(4). As proposed, the pre-prioritization step conflates the prioritization and risk evaluation processes in ways that are confusing to the regulated community. Importantly, the pre-prioritization step appears contrary to congressional intent.

In prioritization, it is very important that all substances be treated consistently, by the same transparent criteria, and that the process is replicable. Other than noting the statutory obligation to designate as high priorities the Work Plan chemicals that meet certain "preference" criteria, the proposed rule does not define the criteria or tools by which EPA will choose Work Plan and other chemicals from the active TSCA Inventory for the pre-prioritization or candidate "pool." EPA did not seek any stakeholder input on this question. EPA has not explained how many chemicals it proposes to include in the pre-prioritization or prioritization pool, or whether and how it will

"batch" chemicals to move them forward into the "initiation of prioritization" step. Although EPA has identified the nine criteria by which it proposes to narrow the pool into a list of candidates for prioritization, EPA does not define the criteria and or discuss the methodology by which these criteria will be applied. EPA proposes no timeframe for the pre-prioritization step, and provides little guidance on the status of chemicals included in pre-prioritization but excluded from prioritization.

EPA's treatment of low priority chemicals raises significant concerns. EPA's proposal to require that low priority designations be based upon "all" conditions of use is a gross misinterpretation of the statute. This flawed interpretation of EPA's authority will cause the Agency to designate most chemicals in commerce as high priorities, and the Agency states as much in the preamble to the proposed rule. Congress did not intend this result. Low priority designations were seen as one mechanism to enhance public confidence in the safety of a chemical substance under its conditions of use, short of a full risk assessment. EPA has continuing authority to revise priority designations at any time based on new information.

EPA has failed to include the LCSA Section 26 science standards in the prioritization process rule itself. EPA continues to assert that, while relevant to prioritization, EPA is not obliged to include these standards in the rule. ACC respectfully but strongly disagrees with EPA's reasoning.

ACC's comments include a series of recommendations to address the shortcomings of the proposed prioritization process rule. Our recommendations describe:

- A transparent process for pooling and batching active chemicals in commerce for prioritization screening.
- A process to gather available information needed to reach a decision.
- A "bridging" step to permit EPA to assess the sufficiency of information for anticipated priority designations of candidate chemicals, which will inform the risk evaluation scoping process (should it be necessary).
- Revisions that recognize EPA's discretion to designate a low priority substance based on one, some or all conditions of use
- Identification of science-based criteria, tools and standards that apply in the prioritization process.

American Chemistry Council
Comments to U.S. Environmental Protection Agency on
Its Proposed Procedures for Prioritization of Chemicals for
Risk Evaluation under the Toxic Substances Control Act

INTRODUCTION

The American Chemistry Council (ACC) is pleased to provide the U.S. Environmental Protection Agency (EPA) these comments on the Agency's proposed procedures for prioritization of chemicals for risk evaluation under the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Chemical Safety Act (LCSA). The LCSA requires EPA to establish, by rule, a risk-based screening process to identify high and low priority substances for risk evaluations under the LCSA.

ACC strongly supported Congress's efforts to update and reform TSCA. One of ACC's principles for modernizing TSCA called on EPA to systematically prioritize chemicals for purposes of risk evaluations. Without a scientifically based prioritization process, EPA would not be able to meet efficiently the other requirements of the LCSA and achieve the objectives of TSCA reform that Congress intended. As discussed in more detail below, EPA's proposed prioritization process falls short.

Congress designed the LCSA to allow chemicals to be systematically prioritized and then to evaluate those substances presenting the greatest potential risk. This design is apparent in every part of the LCSA. It begins with a reclassification of the full catalog of chemistries in U.S. commerce, the TSCA Inventory. The LCSA requires that the TSCA Inventory be sorted, so that chemicals that are currently active in commerce are separated from those no longer manufactured, imported or used; only chemicals that are active in commerce are subject to the prioritization and risk evaluation. This enables EPA to focus resources for its multi-year, time-and-resource intensive risk evaluations on chemicals that are actually in current use. EPA must next undertake a prioritization process, to inform the sequence of chemicals that will undergo risk evaluation. EPA must then undertake a formal scoping process, to define the conditions of use (and potentially exposed sub-populations relevant to the use) that will be included in the scope of the risk evaluation of the chemical.

Prioritization of chemicals for various purposes is not new to the Agency. In 2011, EPA held a Stakeholder Dialogue on Prioritization and established a Discussion Blog for additional input on the topic. In our comments to that discussion blog, ACC identified several general principles for prioritization (Attachment A). We believe these principles are reflected in the LCSA requirements, in particular the LCSA's recognition that prioritization is a risk based screening process that integrates information on both hazard and exposure potential. In 2011, ACC developed a two-step quantitative and qualitative tool to "proof test" our prioritization principles (Attachment B). We presented our principles and our prioritization tool to EPA in 2011, as well as to other industry and NGO stakeholders at the time. In 2012, EPA published its methodology to identify chemicals for its TSCA Work

Plan for Chemical Assessment (TSCA Work Plan) program.

I. ACC's Vision for a TSCA Prioritization Process Consistent with the LCSA

The LCSA requires EPA, by rule, to establish a risk-based screening process to designate chemicals as high or low priorities for risk evaluations. The LCSA includes criteria and considerations by which EPA must make these priority designations. To ensure EPA consistently has risk evaluations underway, the LCSA requires EPA to identify at least one new high priority for every risk evaluation that is completed.[2] EPA's ability to designate additional priorities for evaluation is limited only by the Agency's ability to complete risk evaluations in accordance with the deadlines established by Congress.[3] Thus, Congress requires EPA to carefully choreograph the identification of high priority substances for risk evaluations, in order to ensure that appropriate resources are available to complete the evaluations with the established deadlines. This implies a framework that efficiently coordinates EPA's prioritization process with EPA's risk evaluation process.

ACC's vision for the prioritization process is one that enables EPA to meet all the requirements of the LCSA and congressional intent. Prioritization must be a risk based screening process in which EPA integrates hazard, use and exposure information to designate chemicals or categories of chemicals as either high or low priority for risk evaluations based on the criteria in Section 6. Information used to make prioritization decisions must be reasonably available; new information should be required through Section 4 tools only if EPA makes a determination pursuant to Section 4(a)(2)(B) that new information is necessary for prioritization. Prioritization designations must be based upon the science standards of LCSA Section 26, particularly best available science and weight of the scientific evidence. The basis for prioritization designations must be transparent and EPA's decisions must be communicated objectively and in neutral terms.

ACC's vision of a prioritization process that meets these requirements includes six steps (see discussion below and the flowchart illustrating these steps on the next page and in Attachment C). ACC recommends that EPA clarify the needed timelines, criteria, tools, approaches and processes for these six steps, publish them for comment and include them in the final rule. Alternatively, EPA should propose these clarifications in a supplemental rule prior to the Agency's first application of the prioritization process. ACC's recommended six steps for the prioritization process are as follows:

1. **Pool and Batch:** EPA must "pool" active chemicals in commerce as candidates for designation as high or low priority for risk evaluation, based on transparent criteria/methods/approaches/tools and processes. EPA should then "batch" these candidates for information gathering. As EPA acknowledges in the "re-population" discussion of the preamble to the proposed rule[4], the pace of EPA's completion of risk evaluations factors into the finalization of EPA's prioritization decisions. As a result, ACC expects that the number of candidates per "batch" for information gathering should be relatively small, at least in the early years of LCSA implementation. EPA's development of pools and batches should be subject to

[2] 15 U.S.C.2605(b)(3)(C)
[3] 15 U.S.C. 2605 (b)(2)(C)
[4] 82 Fed.Reg. 4825, 4833 (January 17, 2017).

estimated timeframes.

2. **Information Gathering:** Because Congress intended prioritization decisions to be based on reasonably available information, EPA should take a sequenced approach to information gathering on chemicals that EPA "batches" for prioritization. The sequenced steps should begin with EPA gathering reasonably available information about potential hazards, uses and potential exposure by relying upon sources such as read across/Quantitative Structure Activity Relationship (QSAR) information; Chemical Data Reporting (CDR) reports; EPA's CompTox Dashboard; High Production Volume (HPV) Challenge program; exposure information/models; EPA's Chemical Assessment and Management program (ChAMP); EPA's Voluntary Children's Chemical Evaluation Program (VCCEP); Canada's Chemical Management Program (CMP); OECD's eChemPortal; and robust study summaries developed under the EU's Registration, Evaluation, and Assessment of Chemicals (REACH). If this information is insufficient to designate the priority of a batched chemical, EPA should issue a notice in the Federal Register for voluntary call-ins of the type of information needed for prioritization and request discussions with manufacturers and processors of the chemicals. If voluntary information is still inadequate to prioritize, EPA should consider issuing TSCA Section 8(a) or 8(d) rules to require manufacturers/processors to collect existing information needed to prioritize. Finally, if EPA makes a determination subject to Section 4 requirements that new information is necessary to prioritize (and explaining why), EPA may issue Section 4 rules, orders or consent agreements. EPA should also be held accountable to using that information. The testing/exposure information EPA requires to be developed through Section 4 must be tiered. Finally, throughout the information gathering step, EPA should be asking whether it needs to "iterate" the information gathering process for prioritization, i.e., ask itself whether additional information should be gathered to designate a chemical as a high or low priority and if so to obtain it through the information gathering step process.

3. **Sufficient Information to Designate:** If EPA concludes it has sufficient information to designate the priority of a substance it can move that substance to the "Initiation of prioritization" step. If EPA concludes it has sufficient information to designate a substance as a high priority chemical, it should conduct a "pre-screening" review to identify potential data/information needs for scoping the risk evaluation (a bridging step between prioritization and scoping). If information on the chemical is deemed sufficient for scoping, the high priority chemical can then be put into the queue for "initiation" of the prioritization process at the appropriate time. If information is determined not sufficient for scoping, EPA should begin to collect/develop necessary information to scope the risk evaluation. This information screening "bridge" step should help EPA meet the 6-month statutory deadline for scoping a risk evaluation. However, this step would not replace either scoping itself or the anticipated need for EPA to collect other information during scoping. Further, it is not anticipated that this

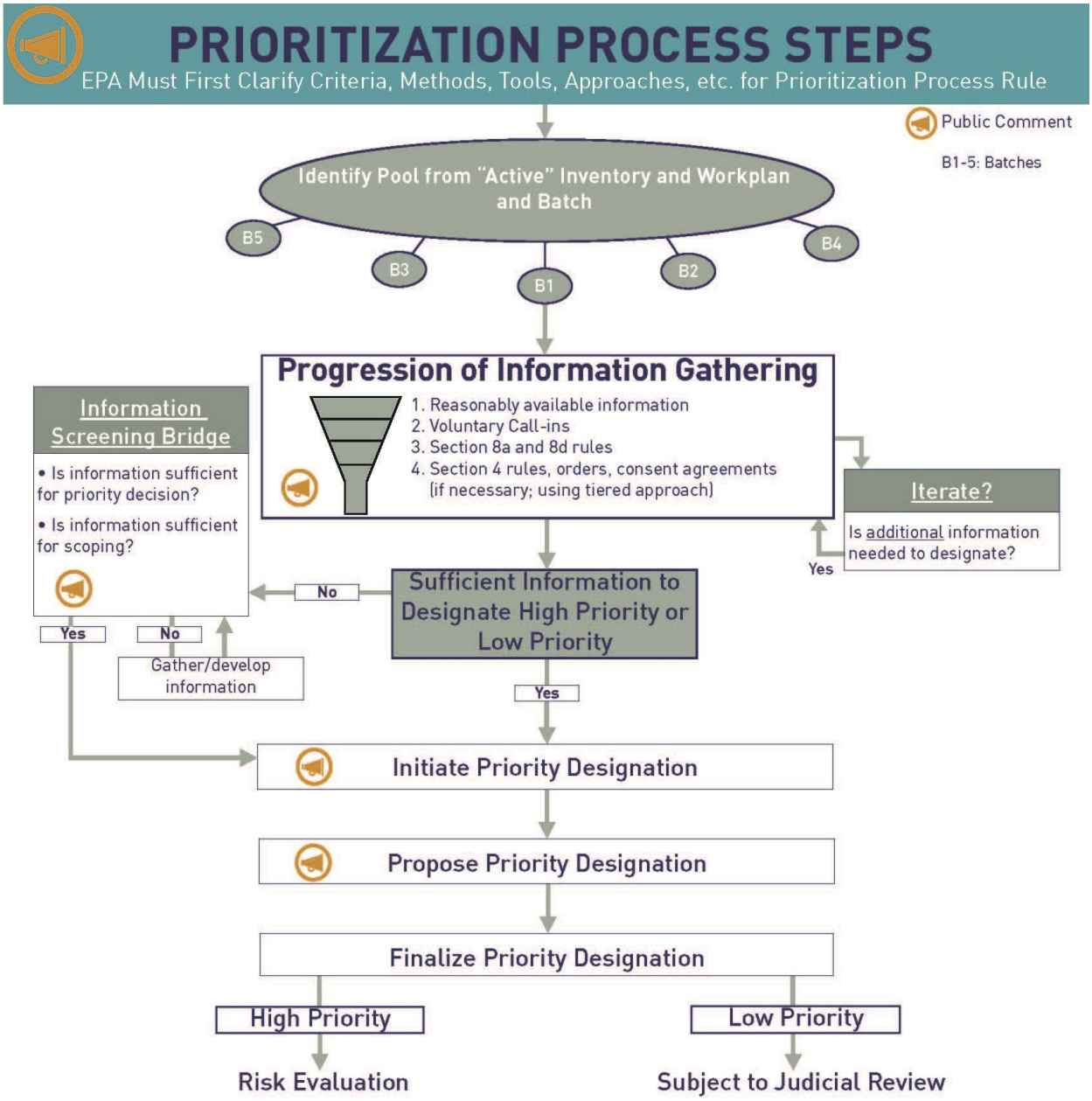
step will develop all the information it will need for risk evaluation. EPA will not necessarily know what information it may need for risk evaluation until it actually conducts it.

4. **Initiate the Priority Designation:** EPA must announce a candidate for prioritization and request "relevant information" about that chemical and provide 90 days for persons to submit that information to EPA. The LCSA deadlines for priority setting (no less than 9 months; no more than 12 months) begin at this step. EPA will "pace" its priority designations to be ready when risk evaluations are near completion and ready to be replaced with a new priority.

5. **Propose Priority Designation:** EPA must propose a designation of a chemical as a high or low priority, including the basis for its proposal, and provide a 90 day public comment period.

6. **Finalize the Designation of High Priority or Low Priority Chemical:** EPA must finalize its designation of the chemical as either a high or low priority within the statutory deadlines (no less than 9 months; no more than 12 months). Low priority chemical designations are final agency action, subject to judicial review. EPA must communicate final designations of high priority chemicals very carefully to prevent the creation of "red-lists" of chemicals and other mis-interpretations by states or the marketplace.

   To help EPA understand ACC's vision of the prioritization process, we have attempted to capture a simplified version of it in the flowchart below. (See comments' text for more details.)


PRIORITIZATION PROCESS STEPS
EPA Must First Clarify Criteria, Methods, Tools, Approaches, etc. for Prioritization Process Rule
Public Comment
B1-5: Batches
Identify Pool from "Active" Inventory and Workplan and Batch
B5
B3
B1
B2
B4
Progression of Information Gathering
1. Reasonably available information
2. Voluntary Call-ins
3. Section 8a and 8d rules
4. Section 4 rules, orders, consent agreements (if necessary; using tiered approach)
Iterate?
Is additional information needed to designate?
Yes
Information Screening Bridge
• Is information sufficient for priority decision?
• Is information sufficient for scoping?
No
Sufficient Information to Designate High Priority or Low Priority
Yes
No
Gather/develop information
Yes
Initiate Priority Designation
Propose Priority Designation
Finalize Priority Designation
High Priority
Low Priority
Risk Evaluation
Subject to Judicial Review

II. Overview of LCSA Prioritization Process Requirements

Sections 6(b)(1) and (2) of the LCSA address EPA's prioritization of chemical substances for risk evaluations. Section 6(b)(1) directs EPA to establish – by rule – a "risk based screening process," including criteria for designating substances as high or low priority for risk evaluations. The language at Section 6(b)(1)(A) specifies what EPA must "consider" in this process and it lays out criteria by which substances will be designated as high priority or low priority. These include "consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed."

Section 6(b)(1) prescribes: a timeframe (between 9-12 months) within which final prioritization designations must be made once EPA initiates the process; a requirement that EPA request interested persons submit "relevant information"; a time period (90 days from initiation of the prioritization process) for persons to submit information to EPA; a requirement that EPA propose its priority designation "along with an identification of the information, analysis, and basis" used to make the designation; and a 90 day public comment period on the proposed designation. There is also an opportunity to extend the deadline for submitting information to EPA if that information is required under Section 4, subject to certain limitations.

Section 6(b)(2)(A) makes clear that the prioritization process rule does not apply to EPA's identification of the first 10 high priority substances. Section 6(b)(2)(D), requires EPA to give "preference" to TSCA Work Plan chemicals that meet specific persistence and bioaccumulation criteria, are known human carcinogens and have high acute and chronic toxicity.

EPA's proposed prioritization process rule establishes four steps or phases in prioritization: 1) "pre- prioritization" during which EPA would narrow a pool of potential candidates for high or low priority designation, loosely based on application of nine criteria EPA used to identify the 90 Work Plan chemicals, and subject them to information gathering; 2) "initiation" of the prioritization process in which EPA would announce candidates as high or low priority and provide a 90 day public comment period; 3) EPA's "proposed" designation of chemicals as high or low priority (with EPA's basis) with another 90 day public comment period; and 4) EPA's "finalization" of the priority designations.

Three of EPA's proposed process steps for prioritization (initiation, proposal and finalization) are largely recitations of the statute. The first step, pre-prioritization, in contrast, represents EPA's attempt to create a pragmatic solution to the statute's tight timeframes that do not allow much time to collect or develop information needed for prioritization. However, EPA's proposed pre-prioritization step is opaque, leaving many questions unanswered about how it would work and whether it is in fact authorized by the LCSA.

III. EPA Should Clarify Pre-Prioritization Step in Final Rule or Alternatively in Supplemental Rule

EPA asserts that "TSCA does not limit how EPA must ultimately select a candidate chemical substance to put into the prioritization process"[5] and that it has "broad discretion"[6] to choose what chemicals to put into the prioritization process. Therefore, EPA proposes to select candidates from the TSCA Inventory based on both the policy objectives in preamble section III A (identifying high priorities with greatest hazard and exposure potential first; designating low priorities to "conserve resources for the chemical substances with the greatest potential risks"[7] and giving the public notice of substances for which potential risks are low or non-existent) and the pre-prioritization considerations in preamble section III F (the preferences for Work Plan Chemical designations, the high and low priority criteria in the LCSA Section 6(b), and the nine Work Plan criteria).[8]

This is as much detail as EPA has provided to explain the criteria that will underpin EPA's selection of candidates to go into the "pools" of candidates in the pre-prioritization step in the first instance. The regulated community needs more detail and clarity around this step since EPA suggests it will narrow its focus on chemical substances from the entire TSCA Inventory using these criteria.[9] The general public needs more detail to have confidence that EPA is using a transparent, credible prioritization process. Greater specificity is required regarding how EPA will select chemicals that go into the candidate "pools," how often EPA expects to identify new "pools" of candidates; how many chemicals will be in each "pool"; whether all candidate chemicals in a candidate pool move to initiation and if so, whether there are any timelines for EPA to move chemicals from the pool to the initiation step, etc. This information is important so the regulated community can plan to gather available information about the candidates and potentially budget to develop new information that may be needed for prioritization. Whether through this rulemaking or in a supplemental rulemaking, EPA should provide opportunity for public comment on the criteria and methods by which it will identify the pools of candidates for possible prioritization.

It is also essential that EPA provide greater clarity about the pre-prioritization step to ensure it is consistent with the LCSA requirements and congressional intent for a prioritization process screening rule. Pre-prioritization is not even mentioned in the LCSA. EPA describes pre-prioritization as the first step in the prioritization process, but later implies that it is in fact outside of the prioritization process for designating chemicals as high or low priority for risk evaluations.[10] EPA asks for public comment on whether and how EPA should solicit additional input at this pre-prioritization stage, but that is difficult to respond to in detail since it is not clear exactly how this pre-prioritization stage will function. There is no discussion of key steps in the pre-prioritization process other than EPA's discussion of narrowing the candidates through criteria, and gathering or developing information about these candidates.

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[5] 82 Fed. Reg. at 4831.
[6] Id. at 4830.
[7] Id. at 4829.
[8] Id. at 4830.
[9] EPA must correct this statement in the final rule because Congress intended EPA to identify substances from those classified as active in commerce during the Inventory Reset, not from the whole TSCA Inventory.
[10] 82 Fed. Reg. at 4831.

EPA must accurately communicate the purpose of the resulting list of "narrowed" candidates to prevent mis-interpretation of the significance of the listing. As EPA has made clear, prioritization is not a risk evaluation. Therefore, ACC suggests that EPA develop a neutral name to describe such a list of candidates for potential prioritization. One suggestion is to call it "Candidate Chemicals for Potential Information Gathering"

RECOMMENDATION: ***For all the reasons discussed above, ACC strongly urges EPA to publish a notice on these needed clarifications to the prioritization process, amending its original proposal and seek public comment on these before finalizing this rule. In the alternative, EPA should propose and finalize a supplemental rule containing detailed clarifications, definitions, criteria, methods, etc. before its first application of the prioritization process.***

A. EPA Should Update Its TSCA Work Plan Criteria Before Using Them in Pre-Prioritization of Non-Work Plan Chemicals and Should Begin Planning to Integrate 21st Century Tools

Although EPA distinguishes the TSCA Work Plan chemicals program from the LCSA's requirements, EPA has proposed using nine of the criteria it used in its 2012 TSCA Work Plan methodology (to identify Work Plan chemicals) as "considerations" it will use in pre-prioritization to initially narrow the pool of potential candidate chemicals that move into prioritization. EPA's proposal to use these qualitative list-based criteria for this purpose is not appropriate, since some of them do not fulfill the best available science standard required by Section 26 of the LCSA. For example, the persistence and bioaccumulation criteria that EPA used in its Work Plan methodology are out of date.[11] [12] [13]Another example is the criteria on detection in human and/or ecological biomonitoring programs. ACC recognizes the utility of biomonitoring data to understand potential for exposure, but mere detection in biomonitoring samples does not indicate that a risk is present; rather the information only suggests it must be considered in conjunction with hazard data to establish the relative priority of a substance for further assessment. Indeed, as future analytical capabilities continue to expand and detection limits are driven increasingly lower, using biomonitoring data in a meaningful way will be even more important to an efficient, thoughtful process that effectively directs resources to assessing chemicals of greatest priority.

Biomonitoring data is not only an important tool to verify exposures occurring among humans, it also can serve as a robust and irrefutable exposure metric that can be used quantitatively to calculate risks using Biomonitoring Equivalents[14] For example, Health Canada has utilized Biomonitoring Equivalents (BEs) as a tool for prioritization as part of their Chemicals Management Plan (CMP)[15] Likewise, Aylward et al. (2013)[16] have analyzed US based biomonitoring data from NHANES in the context of US EPA risk assessment (cancer and non-cancer) values using the

[11] SETAC Pellston Workshop on Science-Based Guidance and Framework for the Evaluation and Identification of PBTs and POPs.

[12] The Origin and Evolution of Assessment Criteria for Persistent, Bioaccumulative and Toxic (PBT) chemicals and Persistent Organic Pollutants (POPs), M. Matthies et al., Environ.Sci.: Processes Impacts, 2016, DOI 10.1039/C6EM00311G.

[13] Comparing Laboratory and Field Measured Bioaccumulation Endpoints, Burkhard et al, IEAM, Vol 8, Number 1, 2011.

[14] Becker RA, Hays SM, Robinson S, Aylward LL., 2012. Development of screening tools for the interpretation of chemical biomonitoring data. J Toxicol.; Article ID: 941082. doi: 10.1155/2012/941082.

[15] St-Amand, A., K. Werry, L.L. Aylward, S.M. Hays, A. Nong. 2014. Screening of population level biomonitoring data from the Canadian Health Measures Survey in a risk-based context. Toxicol. Letters. 231(2):126-34.

[16] Aylward LL, Kirman CR, Schoeny R, Portier CJ, Hays SM. 2013. Evaluation of biomonitoring data from the CDC National Exposure Report in a risk assessment context: perspectives across chemicals. Environ Health Perspect. 121(3):287-94.

corresponding BEs. Since data from NHANES is largely considered indicative of general population exposures, this approach can be a useful tool to determine whether general population exposures exceed EPA's reference concentrations (RfCs), reference doses (RfDs), or unit cancer risks. Although biomonitoring results can be an important component of prioritization, when BEs are available for substances under consideration by the Agency, they should be used to place biomonitoring concentrations into a health risk context. Such use is consistent with the LCSA mandate for EPA to employ best available science in a risk-based framework for priority setting under TSCA.

EPA should establish a criteria-based approach to narrowing the pools of candidate chemicals for prioritization that is representative of the current state of knowledge with the opportunity to update this approach to reflect new science developments. Nowhere in EPA's proposal does it reference any of the 21st Century hazard and exposure based tools that EPA might use to identify either the pools for the prioritization process or to narrow the candidates in the prioritization pool. Tools developed by EPA's Office of Research and Development – such as ToxCast, ExpoCast, SHEDs-HT,etc. – hold particular promise in the near term for prioritization screening activities. Further, EPA should make certain that the databases underpinning some of its qualitative criteria are current, e.g. the Household Products Database as a source of information about presence of chemicals in consumer products. Finally, EPA should consider and review the details of risk assessment developed for other regulatory regions, such as Canada and the EU as source for designating high and low priority chemicals.

RECOMMENDATION: EPA should update and fine-tune its current TSCA Work Plan criteria (e.g. persistence and bioaccumulation; biomonitoring) and databases before implementing its prioritization process. In addition, EPA should consider the applying 21st Century tools and begin the planning needed for OCSPP to integrate these into the prioritization process when they are ready to be used for these purposes. EPA should also consider the risk assessments developed for other regulatory regions such as Canada and the EU as sources for designating high and low priority chemicals.

B. EPA's Proposed Use of the Pre-Prioritization Step to Gather Information for Risk Evaluations Needs to Be Better Supported and Articulated

One of the most surprising elements of EPA's proposed prioritization process rule was the discussion of its plans to use a pre-prioritization step to gather information for risk evaluations on substances with "insufficient information" for risk evaluation.[17] EPA has authority under Section 8 of TSCA to gather existing information about chemicals and under Section 4 to develop new information when needed for risk evaluations. EPA's plan to address risk evaluation information needs, even before a chemical is prioritized, raises several significant concerns, however. First, the proposal has the potential to create "fishing expeditions" for data. Second, it is an unrealistic expectation for EPA to think it could know at the pre- prioritization stage what information it might need to begin gathering/requiring for risk evaluation – well before it has even designated the chemical as a high priority. Finally, EPA has failed to discuss the limitations in Section 4 on EPA's authority to require industry to develop new information for risk evaluations (e.g. EPA must issue statements of need). ACC's concerns are exacerbated by the fact that EPA's discussion of this proposed activity during the pre-prioritization step is vague.

[17] "For chemicals with insufficient information to conduct a risk evaluation, EPA generally expects to pursue a significant amount of data gathering before initiating prioritization." 82 Fed. Reg. at 4828.

ACC is well aware that information about potential hazards and potential uses and exposures of a chemical is critical to sound decision-making by EPA – for both prioritization and risk evaluation decisions. ACC is also well aware of the aggressive timeframes within which both prioritization and risk evaluations must be conducted. ACC strongly believes that both prioritization and risk evaluation processes are more efficient if they use iterative and tiered processes and that these processes help ensure science-based decision-making. ACC recommends therefore that EPA clearly distinguish in the prioritization process rule those elements that are specific to gathering of reasonably available information and those elements relating to the development of existing or new information through TSCA Sections 8 and 4.

For example, information gathering about candidate chemicals for high and low priority designations should be clearly sequential and iterative. EPA should first gather reasonably available information about potential hazards, uses and potential exposures of a candidate chemical and integrate that information. Sources of such information could include: QSAR and read-across information; information from the Chemical Data Reporting (CDR) and from EPA's Dashboard; information from the TSCA Work Plan Chemicals program as well as from other EPA efforts to develop and assess chemicals such as EPA's High Production Volume (HPV) Challenge Program, its Voluntary Children's Chemical Evaluation Program (VCCEP) and its Chemical Assessment and Management Program (ChAMP); exposure scenario information –both actual or estimated from exposure models; information from Canada's Chemical Management Program (CMP) and from the European Chemical Agency's (ECHA) robust study summaries developed for REACH; and REACH use scenarios (though EPA must be cognizant of potential differences in EU and U.S. use scenarios and address these through U.S.-centric use mapping).

As EPA is gathering reasonably available information, it could also request voluntary submission of information about a candidate chemical's potential hazards, uses and exposure from manufacturers, processors, distributors and users of candidate chemicals. It should invite discussions with manufacturers, processors, distributors and downstream users of a candidate chemical.

If EPA concludes after it has implemented those initial information gathering steps that it still needs more information to prioritize, it should then turn to its Section 8(a) and 8(d) rule authority to seek additional existing information. Only if after using its Section 8 authority EPA determines that new information is necessary to prioritize should EPA then consider using its Section 4 test rule/order or consent agreement authorities to develop that information. Section 4 imposes limitations on when EPA can develop new information for prioritization. Congress generally expected EPA to base prioritization decisions on reasonably available information. EPA should acknowledge these limitations in the final rule – both in the preamble and the rule itself.

Once EPA can make a preliminary determination that it has sufficient, integrated hazard, use and exposure information to designate a candidate chemical as a low or high priority, EPA should use a "bridging" step for chemicals being considered as high priority candidates before prioritization is actually initiated. At this "bridging" step, the Agency could consider whether it has sufficient information to "scope" a risk evaluation of the chemical. In this step, EPA might conduct a screening review of the candidate chemical to ascertain what additional hazard, use and exposure information might be needed to scope a risk evaluation of a high priority candidate. If information is identified as needed, and could be gathered/developed at this stage, the Agency could seek to obtain it. EPA's expectation that it can obtain all the information it needs to conduct a risk evaluation at the "pre-prioritization" stage, however, is unrealistic. EPA will have to consider other approaches to efficiently meet the risk evaluation process's statutory deadlines.

To address preliminary "insufficient" information findings, an additional "iterative" step might also be useful. Such a step might allow the Agency time to pursue different avenues for information before automatically defaulting to a high priority designation based on a finding of "insufficient" information to designate a candidate as a low priority. EPA's preamble discussion of the sufficiency or insufficiency of information to designate high or low priorities for risk evaluations is conclusory at best.[18] EPA provides little indication how it will decide whether the available information it has or can gather is sufficient or not; and what it will take to be considered "sufficient." EPA must provide greater clarity here, as well as for purposes of EPA's determination of the need for new information and its use of Section 4 in priority setting. ACC's comments on the proposed risk evaluation rule provide a definition of "sufficiency of information" that might be adaptable to the prioritization context.[19] ACC urges EPA to better explain the application of this concept more fully in the prioritization process rule.

Finally, the Section 4 "statement of needs" requirement must be met if EPA concludes it can't prioritize without the development of new information. Overall, information gathering and information development at any stage in the prioritization process should use tiered and iterative processes for greater efficiencies, for meeting animal welfare requirements, and for meeting statutory deadlines. Integration of hazard, use and exposure information in a risk-based screen is also essential to prioritization which Congress intended would be a risk-based screening process, not a risk evaluation.

RECOMMENDATION: ***EPA should use tiered, iterative approaches to information gathering/development in the prioritization process rule. EPA should also carefully delineate the requirements imposed on EPA to make determinations of need for new information in prioritization and statements of need for risk evaluations, as required by Section 4 of TSCA. EPA must also integrate hazard, use and exposure information in its prioritization risk based screening process.***

C. The Importance of Transparency in Prioritization Cannot Be Over-Emphasized

As discussed above, there are many questions that the Agency must answer in its final rule concerning the specific steps of the prioritization process. Many of these steps also raise transparency issues. One of the most fundamental transparency issues that the Agency needs to address in the prioritization process is adequate notice to manufacturers and processors at critical points in the process.

While it may be obvious that EPA would provide notice and request for comment/input once a chemical is in a "pool" or narrowed to be included in a "batch" to be prioritized, the Agency should also provide earlier notice about what groups of active chemicals in commerce from which it plans to identify potential candidates for prioritization. The Agency should also explain the methodology it will use to narrow and refine the pool of candidates. With each pool of candidates, the Agency should explain how it applied its methodology to narrow that pool and how it plans to "batch" them for efficient prioritization screening. The Agency should be clear about the number of chemicals it will address in each "batch" and how much time it will provide to gather information about a chemical in a batch.

[18] Id. at 4830 and 4831.

[19] Sufficiency of information means that, taking into account the importance of the determination, the Agency has appropriately relied on the best available science, considering the weight of the scientific evidence to make a reasoned and transparent fit-for-purpose determination.

Transparency in the prioritization process is critical to enable the regulated community to understand the Agency's methodologies, criteria and processes and to better plan how they should prepare in advance. In addition, transparency is critical to instill public trust and confidence in the determinations ultimately made by EPA. Much of the pre-prioritization process is opaque as proposed. Without more transparency, the rule establishing the prioritization process risks being unduly vague and EPA's actions under it both arbitrary and capricious.

RECOMMENDATION: ***Greater transparency is a central tenet of the LCSA. EPA must provide as much early notice as possible in the prioritization process, including about the methodology, criteria and processes it will use to select a "pool" of candidates for potential prioritization, to narrow and "batch" these pools, and its anticipated timing for announcing pools and narrowing batches, and about requiring information to be gathered, etc.***

IV. EPA's Interpretation of Its Authority to Designate Low Priority Substances Is Short-Sighted, Contrary to Congressional Intent, Inconsistent with Best Available Science and Must Be Revised

A. EPA's Interpretation of Conditions of Use in the Prioritization Context Is a Strained Reading of the Statute and Contrary to Congressional Intent and Policy Objectives.

Under the LCSA, EPA must designate chemicals as high or low priority for risk evaluations. The key criteria by which EPA must determine whether a chemical is a high or low priority, however, are its hazard potential and exposure potential **under its conditions of use** and significant changes in the conditions of use. EPA's proposed prioritization process rule allows high priority chemicals to be designated as such based on a single condition of use, but requires all low priority designations to be based on "**all** conditions of use." This requirement for low priority designations is not mandated by the LCSA and was not intended by Congress. EPA concludes that the standard for a low priority chemical "effectively requires EPA to determine that under no conditions of use does the chemical meet the high priority substance standard."[20] This proposed standard for designating low priority chemicals is such a high hurdle even EPA admits "it will be more difficult to support such designations."[21]

EPA bases its reasoning for its proposed approach to low priority designations on a cramped reading of the LCSA Sections 6(b)(1)(B)(i) and (ii) provisions on identification of high priority and low-priority substances and on its broad interpretation of the term "conditions of use" throughout its proposed implementation of the LCSA to mean "all" conditions of use. ACC discusses this same EPA interpretation of "conditions of use" in depth in ACC's comments on EPA's proposed risk evaluation process rule.[22]

In the preamble to the proposed prioritization process rule, EPA first emphasizes that Section 6(b)(1)(B)(ii)'s provision for designating a substance as a low priority must have "information sufficient" to establish that a substance does not meet the (B)(i) standard for designating a chemical as a high priority chemical. EPA discusses its rationale for concluding it can designate high priority

[20] 82 Fed. Reg. at 4830.
[21] Id.
[22] American Chemistry Council Comments on the Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (RIN 2070-AK20).

chemicals under "a single condition of use, provided the hazard and exposure potential associated with that single use support such a designation."[23] But EPA then creates a "converse" construct of the high priority designation standard to support its position on low priority designations. EPA concludes that since it can designate a chemical as a high priority because of the Section 6(b)(1)(B)(i) language, "***a*** potential hazard and ***a*** potential route of exposure under ***the*** conditions of use,"[24] that low priorities can be so designated only if they don't meet this high priority standard under ***all*** conditions of use. This argument in the "converse" coupled with EPA's interpretation of "the" conditions of use to mean "all" conditions of use is strained and counter to Congressional intent.

A better interpretation is that a chemical could be designated low priority if it **does not** meet the "may present an unreasonable risk" high priority standard for "a" potential hazard or "a" potential route of exposure ***under a, some, or all conditions of use.*** EPA has flexibility here that it needs to apply, given the 6(b)(1) requirement for EPA to designate chemicals as low priority and the important policy objectives for low priority designations.[25] EPA's strained reading of the phrase "conditions of use" in designating low priority chemicals is wholly at odds with congressional intent to help the Agency focus its risk evaluation resources on high priority chemicals and conditions of use that raise the greatest potential for risk. [26] Further, EPA's reference to its Safer Chemicals Ingredients List (SCIL)[27] as a starting point for identifying low priority chemicals is disingenuous since the SCIL list does not represent all conditions of use of those chemicals.

A chemical under certain conditions of use may warrant a risk evaluation while that same chemical under other conditions of use may not warrant a risk evaluation at all. EPA should not have to scope a risk evaluation or conduct risk evaluations on most chemicals under all conditions of use before it can conclude that a certain use is not likely to present an unreasonable risk. EPA should be able to set aside chemicals for certain conditions of use through low priority designations where EPA concludes that the chemical does not meet the "may" present standard for those conditions of use. Designating low priorities for risk evaluations based on less than "all" conditions of use will help EPA meet its deadlines for scoping risk evaluations, will conserve resources, and will enable EPA to focus its risk evaluation efforts on chemicals that meet the high priority criteria under certain conditions of use. EPA has authority to determine that certain conditions of use of a chemical are likely to have low potential for risk and can be designated as "low priority" for risk evaluation. EPA should use this authority to help it focus its risk evaluations on chemicals designated as high priority under certain conditions of use.

B. EPA's Abuse of Discretion Argument

EPA provides as its rationale for addressing all conditions of use in the low priority designation process that EPA "considers that it would be an abuse of that discretion to simply disregard known,

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[23] 82 Fed. Reg.at 4830.

[24] 15 U.S.C. 2605(b)(1)(B)(i) (emphasis added).

[25] 82 Fed. Reg. at 4829, Section IIIA notes "conserving resources" and giving "the public notice of chemical substances for which potential risks are likely low or nonexistent," as important policy objectives.

[26] See Senate Congressional Record, June 7, 2016, at page 3519, in which Senator Vitter states: "The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical. This assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's deadlines. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency's job would be more difficult." https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf

[27] 82 Fed. Reg. at 4830.

intended or reasonably foreseen uses in its analyses."[28] This rationale is specious. In addition to the points raised in ACC's comments on EPA's proposed risk evaluation process rule concerning "reasonably foreseen" uses, Congress anticipated that the prioritization process would be an iterative process, not a "one and done" process as EPA wishes to construct (except when it does not, as in its discussion of revisions to priority designations).

EPA has the authority to designate chemicals as low or high priority based on reasonably available information. The Agency can rely on new information where necessary, and should seek "sufficient" information, but EPA does not need "perfect" or "complete" information on "all" known, intended or reasonably foreseen conditions of use at the prioritization stage. EPA can return to a chemical later in time and designate it as a high priority for a condition of use not addressed in the original priority designation. EPA has the authority to focus its priority designations and its risk evaluations on certain conditions of use.

Rather than an abuse of discretion, it would be a proper exercise of EPA's discretion -- given the many conditions of use of some chemicals, the aggressive deadlines which Congress established in the LCSA, and the limitations on EPA resources – for EPA to focus on even a single condition of use when designating the priority of a chemical for a risk evaluation. In fact, it might be an abuse of discretion if EPA insists on assessing "all" conditions of use and that decision jeopardizes the intended purpose of the LCSA to focus the Agency's risk evaluation efforts on a chemical's risks under its conditions of use in order to produce timely, high quality risk based decisions on chemicals. In its proposed rule's treatment of low priority designations, EPA has chosen an interpretation that violates other sections of the LCSA such as the statutory deadlines for the prioritization process as a whole.

C. EPA's Default to High Priority Designations Is Flawed Due to EPA's All Conditions of Use Interpretation.

If the Agency concludes it has insufficient information to designate a chemical as a low priority, EPA proposes that the chemical automatically default to a high priority designation.[29] While there is a sound policy basis for this principle – to create incentives for the timely development of hazard, use and exposure information for prioritization purposes – the application of this policy will undermine the ability of the Agency to make low priority designations. Further, the fact that EPA would make this default determination at the proposed "pre-prioritization" step implies that EPA will seldom initiate low priority designations during the official prioritization process, as Congress envisioned. EPA's ability to focus its risk evaluation resources will be seriously challenged.

To avoid this result, EPA should amend its inflexible "all" conditions of use requirement and consider creative solutions to improve the Agency's ability to make low priority designations, consistent with the statute. Here are some suggestions for EPA's consideration:

- Add an iterative step to allow another opportunity for development of sufficient information to support low priority designations.
- Develop criteria to allow for low priority designations under certain conditions of use, e.g., uses of low concern polymers; conditions of use of a chemical already regulated under other statutes, e.g., disposal under RCRA; etc.

[28] Id. at 4829.
[29] 82 Fed. Reg. at 4827.

- Make revision of high priority designations to low priority more efficient. Low priority designations can be triggered for potential revision to high priority designation (within the confines of the prioritization process) purely on the basis of new information. But high priority designations can only be revised to be a low priority after going through a complete risk evaluation. In light of the value of low priority designations to conserving EPA's resources, EPA should consider whether there are faster, more efficient ways in which EPA could revise a high priority designation to low priority, e.g. after the information screening "bridge" step before scoping the risk evaluation, discussed above.

D. Congress Authorized Ongoing Designations of Low Priority Chemicals

In the preamble to the proposed rule, EPA discusses the LCSA's requirement that it continue to designate high priority substances. The Agency then asserts that there is no "comparable requirement to continue designating additional Low-Priority Substances" after three and one half years from enactment.[30] This conclusion is flawed.

A better reading of LCSA Section 6(b)(2)(C) is that ongoing designations are expected of both high and low priority substances. The section does not distinguish between high and low priorities but instead says, "The Administrator shall continue to designate ***priority substances*** …" Even under the EPA's apparent reading of this provision, nothing in the LCSA prevents EPA from continuing to designate low priorities, and it is manifestly in EPA's best interests to do so. Congressional intent for continuing designations of low priorities is also clear.[31]

While EPA contends that "the statute does not require EPA to designate more than twenty Low-Priority Substances," it also admits that "doing so ensures that chemicals substances with clearly low hazard and exposure potential are taken out of consideration for further assessment, thereby conserving resources for the chemical substances with the greatest potential risks. There is also value in identifying Low- Priority Substances as part of this process, as it gives the public notice of chemical substances for which potential risks are likely low or nonexistent, and industry some insight into which chemical substances are likely not be regulated under TSCA."[32] The more low priority designations EPA can make, the better focused will be EPA's risk evaluations of high priority chemicals. EPA should specifically acknowledge its continuing designations of both high and low priority substances in the rule itself.

E. Best Available Risk-Based Scientific Procedures Enable EPA to Designate Low Priority Chemicals

Risk-based prioritization approaches, using fit-for-purpose science-based procedures to integrate toxicity information with exposure information have been employed successfully by Canada to prioritize the 23,000 substances on the Canadian Domestic Substances List (similar to U.S. TSCA Inventory). Of these 23,000 substances, Canada determined that less than 20% required further assessment, resulting in setting aside approximately 19,000 as low priority. If EPA used similar best available scientific risk-based procedures to prioritize chemicals, the Agency should be

[30] 82 Fed. Reg. at 4827.

[31] Senate Committee on Environment and Public Works Report 114-67 to accompany S. 697, at pages 11-12. https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf

[32] 82 Fed.Reg. at 4829.

able to differentiate low priority from high priority substances efficiently and effectively. As noted above, differentiating and designating Low-Priority Substances—chemicals with clearly low hazard and exposure potential—enables the Agency to communicate to the public and the commercial sector those chemical substances for which potential risks are likely low or nonexistent. The scientific methods and procedures are available, or will soon be available in the case of 21st Century Tools, for EPA to conduct risk based prioritization, and the Agency should make use of these best available scientific tools for prioritization.

RECOMMENDATION: ***For all the reasons discussed above, EPA should revise its proposed rule to make clear that the Agency has broad and flexible authority to designate chemicals as low priorities for risk evaluations based on a, some or all conditions of use.***

V. Scientific Standards Must Be Referenced in the Prioritization Process Rule

A. Prioritization Decisions Must Be Based on Section 26 Standards for Best Available Science, Weight of the Scientific Evidence, and Transparency

Pursuant to Section 26 of the LCSA, EPA must ensure that its high and low priority designations under Section 6(b) are based on the best available science and the weight of the scientific evidence and that it make the basis of its decisions available to the public. Because these are prioritization decisions, however, it is ACC's expectation that EPA's application of these standards would be "fit for the purpose" of prioritization as opposed to risk evaluation. For example, greater uncertainty and more conservatism in the "best available science" information that is used for prioritization purposes may be anticipated. Prioritization decisions might be made on the basis of estimated information from an exposure model while a risk evaluation decision might require actual exposure information in some cases.

ACC urges EPA to reference the Section 26 science standards in the prioritization process rule in order to hold itself accountable to meet these standards within its Section 6 decisions designating high and low priority substances for risk evaluations. The Sections 26 (h), (i) and (j) provisions are legally mandated requirements of the LCSA and are equally applicable to the prioritization process and risk evaluation "rule" requirements. Including references to these sections in the rule itself would aid understanding and application of these requirements by EPA, the regulated community and stakeholders. This in turn would better ensure consistency in EPA's prioritization decisions over time, and ultimately enhance the credibility of these decisions. Importantly, because EPA's low priority designations are subject to judicial review, clarity on the application of EPA's science standards is necessary.

If Congress had intended the scientific standards of "best available science" or "weight of the scientific evidence" to be incorporated into guidance alone, it would have included them only in Section 26(l) on "policies, procedures and guidance." In addition to including these standards in the prioritization rule, EPA can certainly also describe some of the details of its prioritization methodology and decision making process in later-developed guidance.

Inclusion in the rule of specific references to Sections 26(h), (i) and (j) requirements about the scientific information, methods, models, characterization of uncertainty of information to prioritize, and use of weight of the scientific evidence to make decisions, puts the regulated community on notice about the quality of the information needed for EPA to support sound prioritization decisions. If EPA only includes references to these standards in guidance, it implies that EPA could ignore

these requirements if it chooses to do so. This is not the case.

B. EPA Should Address Other LCSA Science-Based Requirements in the Rule (Such As Tiered Testing and Animal Welfare Requirements). EPA Should Also Include a "Reserved" Placeholder in the Prioritization Rule for Incorporation of 21st Century Methods for Prioritization.

Section 4(a)(4) of the LCSA requires EPA to use tiered testing and assessment approaches when EPA needs to develop new information under this section. EPA should include this requirement in its prioritization process rule at the appropriate steps.

Similarly, Section 4(h) requires the Agency to promote the development and incorporation of new scientifically valid test methods that are alternatives to testing of vertebrate animals. These types of methods may be of particular early importance to EPA during the prioritization process and therefore should be referenced in the rule. The Senate Environment and Public Works Committee's Report clearly articulated the importance of the animal welfare provisions in its report on the Senate approved legislation, S. 697, that preceded the development of the House and Senate compromise in the LCSA:

"[The Act] includes extensive provisions by which EPA is to minimize the use of animals in testing under TSCA. EPA is to consider integrated testing strategies, greater efficiencies in testing through category approaches and formation of consortia, tiered testing and assessment strategies, and alternative testing methods, among others. Importantly, EPA is to develop a strategic plan to promote the development and implementation of reliable test methods to reduce, refine, or replace the use of laboratory animals.[33]

Finally, EPA's Office of Research and Development has been working on 21st Century methods (high throughput hazard and exposure tools like ToxCast and ExpoCast) that scientists believe will be of great value to EPA's prioritization efforts under the LCSA in the near future. EPA should include a "reserved" section in the prioritization process rule to allow the Agency the opportunity to include references to these tools.

VI. Responses to EPA's Questions

A. Animal welfare requirements and scientific standards

EPA requests comment on pros and cons of codifying Section 4 animal welfare requirements and Section 26 scientific standards and definitions in the prioritization procedural rule. ***Response:*** These are legal requirements of the LCSA and so should be incorporated into the rule rather than solely in non-binding guidance. Putting these into guidance alone suggests that EPA views these requirements as not being mandatory, which is not correct. ACC sees no downside to codifying these requirements into the rule. EPA's rationales for not doing so – these requirements are applicable without inclusion in a rule; EPA is not directed to implement these requirements by rule; and these requirements can be addressed in guidance – miss the point. The upsides are many:

- Codifying them in the rule will provide the regulated community, the

[33] Senate Committee on Environment and Public Works Report 114-67 to accompany S. 697, at page 10. See also Congressional Record S3520 (June 7, 2016) (Statement of Senator Inhofe on section 4 during the Senate debate on LCSA). https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf

broader stakeholder community and EPA itself greater certainty about what EPA must rely upon in making prioritization designations

- Codifying these requirements in the rule will assure consistency in EPA's prioritization decisions
- All of the above will enhance the credibility of EPA's prioritization decisions.

B. EPA requests comments on its proposed process for prioritization overall.

Response: First, EPA relies heavily upon the "pre-prioritization" step in the process rule, but provides very little detail about how it would function. As recommended above, EPA must clarify this step and should publish a notice with more details and seek public comments on it before finalizing this rule. Alternatively, EPA should propose and finalize a supplemental rule to provide the necessary level of detail before EPA's first application of the prioritization process.

Second, EPA's process for prioritization overall seems resigned to codifying a "slow road" to prioritization by a) ignoring the value of low priority designations; and b) lining up high priority chemicals to wait for what EPA envisions as a slow risk evaluation throughput. EPA's prioritization process, in other words, lacks vision for the potential future throughput of the program. The role of 21st century tools will help the Agency both prioritize chemicals and evaluate the risks of high priority chemicals, consistent with Congress's intent that the Agency make timely decisions.

C. Public input at pre-prioritization step

EPA requests comment on whether and how EPA should solicit additional input at the pre-prioritization phase." ***Response:*** It is not only appropriate, but well advised for EPA to solicit public input at each stage of the prioritization process. From a "data quality" perspective it is important for the public to have the opportunity to comment on the data/information that EPA believes is relevant to prioritization of chemicals for risk evaluation. As discussed in our comments above, ACC believes EPA must take a sequenced, step-wise approach to gathering available information and/or developing new information in the pre- prioritization stage. It makes sense for EPA to first gather reasonably available information, then solicit public input to identify additional data/information from stakeholders, on a voluntary basis. Then EPA should use reporting tools under Section 8 for additional existing information if needed. Only after using these approaches should the Agency consider ordering the development of new information for prioritization purposes, subject to the requirements of LCSA Section 4.

D. Consideration of substitutes in pre-prioritization

EPA asks "whether and how information on the availability of chemical substitutes should be taken into account during this phase [pre-prioritization] of the prioritization process". ***Response:*** Substitutes are not relevant to and should not be considered in the prioritization process. Both the LCSA and EPA's proposed prioritization process rule (at 702.11(b)) make clear that EPA cannot consider "non-risk factors" as part of prioritization. The availability of "substitutes" is a "non-risk factor." Alternatives can certainly be taken into account in the risk management stage, after the risk evaluation, but do not have a role in the prioritization process.

VII. Additional Specific Comments

A. Category of Chemical Substances

LCSA Section 6(b)(1)(A) specifically authorizes EPA to prioritize a category of chemical substances in its prioritization process and EPA's proposed rule at Section 702.1(c) makes clear that nothing in the prioritization procedures should be interpreted as a limitation on EPA's existing TSCA Section 26(c) authority for EPA to take actions on categories of chemicals. The term "category of chemical substances" was already defined in TSCA Section 26(c).

Therefore, it will underpin any prioritization of categories that EPA might undertake.[34] EPA's proposed prioritization process rule does not otherwise address the category issue, but ACC urges EPA to take note that in the prioritization (and risk evaluation) contexts, chemicals in a category may not all have the same hazards, applications or conditions of use, so there will be questions about how EPA would address the hazard and use profiles in the prioritization context. It will be critical for EPA to ensure that any category approach taken is science based. Further, it is very important that EPA be transparent when it contemplates category approaches to prioritization so that stakeholders can fully understand all the factors leading to EPA's consideration of a category of chemicals for prioritizing for risk evaluations.

B. Inactive chemicals and new chemicals

EPA makes clear in the preamble that "all chemical substances listed on the TSCA Inventory are subject to prioritization"[35] and that it has authority to prioritize both new chemicals and inactive chemicals for risk evaluations under Section 6.[36] The Agency also notes, however, that EPA does not expect new chemicals to be high priority candidates because EPA will be making risk determinations about new chemicals under Section 5.

The Agency also notes that the Inventory Reset rulemaking will distinguish active from inactive chemicals in commerce, which will "inform EPA's exposure judgments during the prioritization process."[37] ACC interprets EPA's discussion to suggest that prioritization of inactive chemicals is anticipated to occur only in exceptional cases. Inactive chemicals, under the Inventory Reset definition, will not have been in commerce for the past 10 years, so prioritization of these will likely be reserved for "legacy" chemical issues, e.g., those whose disposal conditions may at some later point in time suggest the need for an updated TSCA risk evaluation to derive a risk management clean-up standard.

It is ACC's view, however, that the broader directive to EPA in the LCSA is to focus its prioritization process on the designation of high and low priority chemicals that are active in commerce; and that the scope of the risk evaluation should focus on chemicals under those conditions of use that present the greatest or lowest potential for both toxicity and exposure.

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[34] TSCA 26(c) (15 U.S.C 2625(c)) defines "category of chemical substances" as a "group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances."

[35] 82 Fed.Reg. at 4830.

[36] Id.

[37] 82 Fed. Reg. at 4830.

C. Waivers

EPA has proposed that all comments that could be raised on issues in a proposed low priority designation be presented during the comment period, and that any issues not raised then be considered to have been waived. Waived issues could not form the basis of an objection or challenge in any subsequent administrative or judicial proceeding on the designation of the substance as a low priority substance (which is subject to judicial review). EPA points to the statutory deadlines in the prioritization process as the policy justification for this proposal.[38]

ACC urges EPA to remove this waiver requirement from the prioritization rule. First, it is inconsistent with Congress's intent that the prioritization process be iterative and science-based. Low priority designations should be able to be modified – expanded or contracted – based on new information that is brought to the Agency's attention after the designation. This new information might not have been known during the public comment period on the low priority designation. It would be bad public policy to consider new information waived because that could discourage stakeholders from gathering or developing relevant information about a chemical. Second, participation in the notice and comment rulemaking process of prioritization is governed by statute – through the Administrative Procedures Act (APA) and the judicial review provisions of Section 19 of TSCA. There are no issue exhaustion provisions in TSCA. EPA cannot by regulation, impose an issue exhaustion requirement that trumps the statutory rights and obligations of stakeholders under the APA and TSCA Section 19.[39]

D. Definitions

As an addendum to ACC's recommendations for EPA to reference the Section 26 science standards in the prioritization process rule, ACC offers the following definitions for EPA's consideration:

- **Best available science** means information that has been evaluated based on its strengths, limitations and relevance and the Agency is relying on the highest quality information. In evaluating best available science the Agency will also consider the peer review of the science, whether the study was conducted in accordance with sound and objective practices, and if the data were collected by accepted methods or best available methods. To ensure transparency regarding best available science the Agency will describe and document any assumptions and methods used, and address variability, uncertainty, the degree of independent verification and peer review.
- **Weight of the evidence** means a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

[38] Id. at 4833.

[39] See ACC Comments on EPA's Proposed Rule: Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (RIN 2070-AK20) for additional discussion of the waiver/lock down/issue exhaustion issue.

E. Repopulation of High Priority Substances

EPA's preamble discussion of the "repopulation" of high priority substances[40] presents a reasonable approach by which the Agency could meet the LCSA obligation to finalize the designation of one new high priority substance upon completion of a risk evaluation for another substance. The one-for-one approach makes sense as this program gets underway.

ACC suggests, however, that EPA consider a placeholder in its rule to anticipate changes in the rate at which EPA might be able to conduct risk evaluations over time (based on use of 21st Century tools and methods) and hence potentially change the rate at which EPA may need to designate high priorities for risk evaluation.

VIII. Summary of ACC's Recommendations:

Throughout these comments, ACC has included many specific recommendations for EPA to consider as it develops its final prioritization process rule to address ACC's concerns about the proposed rule. These recommendations urge EPA to direct its authority on what it is mandated to do under the LCSA – designate high priority and low priority chemicals for risk evaluations in accordance with both the criteria in LCSA Section 6 and the LCSA Section 26 science based standards. To help the regulated community provide EPA the information the Agency will need to prioritize chemicals for risk evaluations, EPA must clarify the prioritization process as a whole and develop an efficient and focused prioritization process rule that meets the LCSA mandate and Congressional intent.

ACC strongly urges EPA to amend its proposal to include these suggested recommendations and seek public comment before finalizing the prioritization process rule. Alternatively, EPA should propose a supplemental rule providing more detail and clarifications on the prioritization process steps involved and finalize it prior to the Agency's first application of the prioritization process . To help foster the submission of information needed to prioritize chemicals for risk evaluations, EPA must ultimately develop an efficient and focused prioritization process rule that clearly lays out the major steps for meeting its mandate.

[40] 82 Fed. Reg. at 4833.

ACC's General Principles on Prioritization

(Developed for EPA Dialogue 7-2011)

- EPA should **systematically prioritize** chemicals for purposes of safe use determinations.
- As a general matter, prioritization should be based on **existing hazard and exposure data and information (including models, read across, QSAR, etc.)** and **industry should be responsible** for providing EPA with this data and information.
- Chemicals **lacking adequate hazard and exposure** information should be considered **a higher priority** (until relevant information is provided that suggests otherwise).
- Industry should be provided an **opportunity to provide EPA additional data/information.** (Timing is an issue, however. And the format in which the information is provided to EPA must be useable/digestible by EPA, e.g. robust summaries.)
- **Hazard, use and exposure based criteria should be integrated** to form the basis for EPA's prioritization decisions. Prioritization should not be based on either hazard-only or exposure- only information.
- The prioritization process and science based criteria that EPA uses to prioritize chemicals must be **transparent.**
- Prioritization should be a **dynamic, iterative process**. Re-examination of priorities should occur as new information becomes available and as new chemicals are approved for manufacturing.
- For prioritization to be successful, it must include three critical elements: **reliable and up-to- date chemical data and information; evaluation criteria that consider both hazard and exposure information together; and established cutoffs to make priority decisions.**
- **EPA's communication about priority chemicals must be clear about what the list is and what it is not, to avoid unintended consequences of product de-selection** purely on the basis of listing.
- **Transparency; consistent, scientific criteria; intersection of both hazard and exposure information; dynamic process** so new information can be incorporated as it is made available and so if priorities are initially "wrong" they can be corrected.

Attachment B

ACC Prioritization Screening Approach

I. Introduction

This document provides background on ACC's approach to chemical prioritization screening. The approach is based on the following general principles:

- The purpose of this approach is to identify substances as priority to receive more detailed evaluation and assessment which, when conducted, could possibly lead to risk management measures.
- Apply a science- and risk-based approach, considering both the degree of hazard and extent of exposure potential in setting priorities.
- Include criteria applicable to the range of chemicals being screened. Apply this principle through a two-step process rather than just those information elements available only for subsets of chemicals.
- Leverage available data and existing hazard classification frameworks already in use across industry and agreed by regulators.
- Incorporate relevant science advances where there is broad acceptance in the scientific community, e.g. improvements in how persistence and bioaccumulation considerations are addressed.
- Allow for the incorporation of significant new information to ensure prioritization decisions remain current.
- Adopt a simple, transparent screening method.
- Include opportunity for public review and comment to ensure the best available data and information is used in prioritization decisions.
- Allow professional judgment to be applied where appropriate, e.g. in hazard classification and second-tier ranking.

II. Applying Initial Screening Step in ACC's Prioritization Approach

The first step in applying ACC's prioritization approach is to apply criteria on human health and environmental toxicity potential to chemical substances.

A. Hazard Potential

The U.N. Globally Harmonized System of Classification and Labeling (GHS) was developed and internationally agreed to by many governments to provide criteria and a consistent approach for hazard classification of chemicals. It can also provide a recognized and generally accepted method for sorting chemicals in a prioritization process. The GHS framework has been used by international bodies, such as the OECD and WHO, and was endorsed by EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to support prioritization.

The GHS system applies to both human health and ecological endpoints. It includes criteria for both human and ecological health. For human health, criteria are available for both acute and chronic classifications, as well as CMR categorization. For ecological

endpoints, criteria are similarly available for both acute and chronic classification. The use of one common system allows for appropriate assessment of all substances. GHS classification information is readily available for all substances, as U.S. manufacturers have developed GHS classifications for their products to meet international requirements.

ACC's support of the GHS criteria for purposes of this prioritization tool is not a categorical endorsement of the GHS criteria for any other purpose. ACC has been an active participant in the development of GHS and supports the system in principle. The GHS has not been broadly implemented to date in the U.S., although the Occupational Safety and Health Administration (OSHA) has indicated an intent to publish a regulation applying GHS in the workplace. ACC's December 29, 2009, comments on OSHA's proposed rule to modify the existing Hazard Communication Standard (HCS) to reflect the GHS urged that implementation of the GHS adhere to certain principles (e.g., continued application of the "Building Block Approach" of the Purple Book). ACC made specific recommendations concerning details of the Hazard Classification definitions, cut-off values, among others. ACC stands behind those comments. In ACC's view, the use of GHS criteria in a screening-level prioritization of chemicals can materially assist in determining which chemicals receive additional evaluation by the Environmental Protection Agency, but does not necessarily preclude the use of other appropriate, applicable criteria developed under other systems.

To classify a chemical in a hazard based priority ranking where there is not direct data on the chemical, EPA can employ the full range of approaches, such as QSAR, SAR, read- across and other modeling tools in which EPA has confidence based on molecular structure. In those situations where there still remains insufficient information on either environmental or human health hazards, the chemical would be classified as "high" for its environmental or health ranking.

1. ***Environmental Ranking***

Table 1 provides a summary of how GHS criteria could be logically used for chemical management prioritization.

Table 1. Environmental Safety - Hazard Ranking

GHS Classification - Environmental	**Ranking**	**Environmental Rank Score**
Acute I or Chronic I or Insufficient Information to Classify	High	4
Acute II or Chronic II	Medium High	3
Acute III or Chronic III/IV or none	Medium	2
Not classified	Low	1

2. ***Human Health Ranking***

Table 2. Human Health - Hazard Ranking

GHS Classification - Human Health	Ranking	Health Rank Score
GHS CMR Cat 1a, 1b; OR Repeat Dose </= 10 mg/kg/day (oral); </= 20 mg/kg/day (dermal); </= 50 ppm/6hr/day (gas inhalation); </= 0.2 mg/l/6h/day (vapour inhalation); </= 0.02 mg/l/6h/day (dust mist fume inhal). OR insufficient information to classify	High	4
GHS CMR Cat 2; OR Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	Medium High	3
Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	Medium	2
Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	Low	1

It is important to note that specific concerns about children's health (specifically potential hazards and adverse effects on the nervous system) and those caused by endocrine disruption mechanisms are addressed in this prioritization process:

- The GHS CMR "R" classification includes specific evaluation of effects on development in utero and upon growth, maturation and reproduction. ("R" stands for reproductive toxicity and includes adverse effects on sexual function and fertility, as well as developmental toxicity in offspring).
- Endocrine activity is not a distinct toxicological hazard per se, but rather a measure of a compound's ability to interact with components of the endocrine system. The prioritization process evaluates data and information on relevant apical tests, including tests for reproduction and developmental toxicity (potential endocrine pathways). Thus, even if specific

screening for potential endocrine activity has not yet been conducted on certain compounds, hazard identification based on observable outcomes from apical toxicity tests (e.g., outcomes such as pathologic states indicative of disease conditions) covers all modes of action, including endocrine pathways.

- The toxicity information evaluated (CMR and repeat dose toxicity) is directly relevant to evaluating potential hazards to all individuals, including children. Such data typically includes: 1) identification and definition of possible hazards upon all major organ systems from both acute and repeated exposures, including the nervous system; 2) detection of potential hazards arising from in utero exposures, including possible effects on the nervous system; 3) evaluation of potential of a substance to affect reproduction; and 4) evaluation of the potential of a substance to damage DNA.

Integration of Hazard Elements:

Each of the environmental and human health classifications is assigned a numeric value based upon its ranking, with 1 being the lowest value and 4 the highest. The greatest ranking (highest hazard potential score) of either Environmental or Human Health is used in a substance-specific priority ranking. The numeric value does not imply relative weighting, but rather a numerical order of priority.

B. Exposure Potential Ranking

The screening method allows for an initial indication of the extent of exposure potential by considering:

1. The chemical's uses and use pattern(s).
2. Production volume as a first pass indicator of relative emission/release potential since magnitude and route (i.e. air, water, soil) of emissions is not available for all substances.
3. Persistence and bioaccumulation characteristics of the substance.

Together the 3 elements are used to rank exposure potential.

1. Use Patterns

The proposed approach applies the most current 2006 TSCA Inventory Update Reporting rule (IUR, now called the Chemical Data Reporting rule (CDR) data. To keep the initial prioritization simple and transparent, the approach "bins" different use patterns to align with general exposure potential – intermediates, industrial use, commercial use and consumer use. These patterns are the same as those reported in the IUR and are consistent with REACH exposure categories (intermediates, worker, professional, consumer). Chemicals with consumer product use are likely to have widespread potential for general population exposures and are given high priority ranking within the approach. For the initial prioritization approach, child specific products are captured under general consumer products and all consumer products are weighted equally (see additional discussion below under Second Tier Considerations). Intermediates will have low general population exposures, since these substances are consumed, by definition, within the workplace. Therefore, they are given the lowest priority ranking within the approach. In the context of the proposed approach, the intermediates category includes both intermediates and non-isolated intermediates. A chemical used in multiple use patterns is

assigned the priority of the highest use, e.g., a chemical in both industrial and commercial uses would be assigned the commercial Medium-High rank.

Table 3. Use Patterns - Exposure Ranking

Use Pattern	Ranking	Use Pattern Score
Consumer	High	4
Commercial	Medium-High	3
Industrial	Medium	2
Intermediates	Low	1

The IUR Definitions of these terms are (40 CFR 710.3, 710.43):

- "consumer use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of article) when sold to or made available to consumers for their use.
- "commercial use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "industrial use" means use at a site at which one or more chemical substances or mixtures are manufactured (including imported).
- "intermediate" means any chemical substance:
    - which is intentionally removed from the equipment in which it is manufactured, and
    - which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s)
- "non-isolated intermediate" means any intermediate that is not intentionally removed from the equipment in which is it manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

2. Production Volume

Recognizing that detailed exposure information will not be available for all substances to be screened, the proposed approach uses production volume as an indicator of exposure, which is widely used in many prioritization schemes. As production volume is just a rough surrogate of emissions, ACC suggests only very broad categories, covering about two orders of magnitude each. It may be useful to consider how additional exposure estimates may be applied in the second tier assessment.

Table 4. Production Volume as Emission Surrogate - Exposure Ranking

Production Volume as Emission Surrogate	Ranking	Volume Score
>= 100,000,000 lbs national aggregate	High	4
1,000,000 lbs to < 100,000,000 lbs national aggregate	Medium – High	3

>= 25,000 lbs to < 1,000,000 lbs national aggregate	Medium	2
< 25,000 lbs (below IUR site reporting limit)	Low	1

3. Persistence and Bioaccumulation

Persistence and bioaccumulation are viewed as indicators of exposure, and therefore are considered under the exposure axis of the approach. A persistent substance that is emitted to the environment at the same rate as a non-persistent substance with similar partitioning properties will result in higher exposure to humans and the environment. In fact, multimedia modeling clearly indicates that environmental persistence in the compartment to which a substance partitions is a good indicator of human exposure potential (MacLeod & McKone et al. 2004). Similarly, substances that are not subject to biotransformation by higher organisms will exhibit a high bioaccumulation potential that results in higher exposures via the food chain (Arnot et al. 2010). Therefore, it is recommended to apply the proposed persistence and bioaccumulation criteria in assessment of exposure potential as described below.

The persistent and bioaccumulative (P&B) criteria of the proposed approach are targeted toward organic chemicals. Separate assessment criteria are likely needed for P&B evaluation for inorganics/metals, as in the approach taken by Canada's Chemical Management Program (CMP).

For assessing persistence, based upon recent expert consensus (Boethling et al., 2009) it is recommended to distinguish persistent from non-persistent chemicals using the following criteria:

- Volatile chemicals can be defined using a vapor pressure cut-off (i.e., > 1000 Pa)
    - For volatile chemicals, persistent versus non-persistent chemicals are differentiated using a half-life cut-off in air (e.g., a substance is not persistent if air half life is < 2 days).
    - For non-volatile chemicals, non-persistent substances can be defined as substances that are deemed:
        - readily or inherently biodegradable using standard biodegradation tests (OECD 301, 302, 306 test guidelines) or SAR or read across from measured data on a related substance,
        - show an equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111),
        - evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g. OECD 308/309) have half lives below 180 days, OR
        - if data are lacking, evaluation via BIOWIN model (EPIWEB 4)
    - Non-volatile substances that are not biodegradable or subject to abiotic losses based on the above criteria would be considered persistent.

For assessing bioaccumulation, the key question for screening is the potential for biomagnification based on recent expert consensus (Gobas et al. 2009). To determine if a substance has the potential to biomagnify the following metrics have been agreed:

- Trophic Magnification Factor (TMF)>1, fish Biomagnification Factor (BMF)>1, fish Bioaccumulation Factor (BAF)/Bioconcentration Factor (BCF) > 5000. These metrics can be

derived using lab or field measurements (where available) or recently improved computational models that are included in EPA's EPIWEB model that can be freely downloaded at www.epa.gov/oppt/exposure/pubs/episuite.htm.

This approach allows all organics to be addressed and is a scientifically updated version of the approach used in Canada's CMP.

Based on the above recommendations, substances can be grouped with regard to persistence and bioaccumulation as follows:

Table 5. Persistence and Bioaccumulation - Exposure Ranking

Persistence and Bioaccumulation	**P&B Ranking**	**P&B Score**
Persistent and Bioaccumulative	High	5
Persistent and Not Bioaccumulative OR Not Persistent and Bioaccumulative	Medium	3
Not Persistent and Not Bioaccumulative	Low	1

Integration of Exposure Elements:

As demonstrated in the tables, each factor (use pattern, P&B, and production volume) would be assigned a numeric score based upon its ranking. All 3 factors are added to arrive at an overall value. These values are then separated into categories from low to high exposure potential. A proposed "banding" approach is illustrated in Table 6.

Table 6. Integration of Exposure Rankings

Combined Score – All 3 elements	**Exposure Rank**	**Exposure Ranking Score**
11 – 13	High	5
9 – 10	Medium High	4
7 – 8	Medium	3
5 – 6	Medium Low	2
3 – 4	Low	1

Overall Priority Grouping:

In the overall approach, both hazard and exposure elements are considered when placing a substance in a risk-based prioritization ranking. The overall prioritization score for priority grouping and risk evaluation is based on the combined consideration of the hazard and exposure rankings. Priority Groups 7, 8, and 9 are deemed High Priority; Priority Groups 4, 5, and 6 are Medium Priority; and Priority Groups 2 and 3 are Low Priority.

Review and Comment:

It is important that screening be done in an open and transparent way and that the best available information be used. When screening for thousands of chemicals, EPA may not have access to all available information. The process should provide an opportunity for review and comment on initial rankings and an opportunity to submit additional relevant data and information to update proposed rankings with improved information.

III. Second Tier Considerations:

After the initial screening, some substances within individual priority groupings may require further rank ordering, particularly where a large number of chemicals are in the same priority group. Listed below are the types of information that will be useful to consider in this Second Tier rank ordering:

Biomonitoring/Environmental Monitoring Data:

Mere detection of chemicals in humans or the environment, i.e.,"found in biomonitoring (CDC), found in water (NCOD), and found in air", while providing an indication of exposure, does not provide a useful criterion for exposure potential because almost any industrial or commercial chemical could be detected at trace levels, given increasingly sensitive analytical methods. Therefore, detection alone primarily reflects only the fact that a specific chemical was included in a measurement program. This criterion will also tend to bias the prioritization of chemicals for which well-established analytical methods are available. Consequently, this criterion is not used in the initial prioritization scheme. However, within a particular priority grouping, reliable monitoring information should be considered for Second Tier rank ordering within a quantitative process that assesses if the data is above a level of concern (i.e., places it in a risk context).

Use in Children's Products:

Protection of childrens' health is a top priority and, in the initial ranking, child-specific products are captured under general consumer products and all consumer products are weighted equally. The specific IUR reporting of information on chemical use in products intended for children would be considered further within a particular priority grouping for Second Tier rank ordering, noting the following points:

- the IUR definition is based upon use in a child specific product rather than child specific exposure potential[1] (see below). Without knowing a specific product type, it is difficult to understand if

[1] IUR definition (Federal Register Volume 75, Number 156, Friday August 30, 2010, p. 49686): Intended for use by children means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers "yes" to at least on of the following questions for the product into which the submitter's chemical substance or mixture is incorporated:

(1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?

(2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger?

(3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

potential child exposure is greater than for a non-child specific product. For example, how does child exposure to a general use cleaner compare to exposure from use in a child's raincoat. In the VCCEP assessments, there are examples for inhalation exposures where estimates of passive child exposure during adult product use exceeded conservative estimates of child exposure during active use of a child-specific product (such as a hobby product) – differences were related to the amount of product used and substance concentration within the product (MEK VCCEP Submission).

- the IUR definition targets children age 14 and younger. Younger children may be exposed to a variety of non-child specific products that are in general household use. Older children may be exposed to a variety of additional products.
- the IUR information request is targeted to manufacturers, which may not have direct knowledge of all uses, particularly the presence in products for specific subpopulations, such as children. Therefore, it is not clear that the information requested for the IUR information would be consistently available across all substances being screened. Ideally, this information should be requested from formulators of child-specific products.

Therefore, for the initial prioritization approach, which represents a broad, unrefined categorization, child specific products are captured under general consumer products and all consumer products are weighted equally. The IUR information on child specific use would be utilized within a particular priority grouping for Second Tier rank ordering. If the IUR information is utilized, it is important that the limitations above be considered in its application.

Emissions Data:

Production volume, which is readily available for substances, is used in this proposed approach, but only serves as a surrogate for environmental emissions. For further prioritization, data or estimates of environmental emissions can be used to refine prioritization. Estimates of environmental emissions will be available for some substances (e.g., TRI data). When TRI data are utilized it should be recognized that it addresses only emissions that result from industrial and not wide dispersive uses. In other cases, emissions estimates can be developed as a percentage of production volume based upon consideration of use categories. Within a particular priority grouping, available emissions information can be considered for Second Tier rank ordering, with the understanding that emissions information is not an indicator of actual exposure.

Similarly, non-isolated system intermediates, by definition, would have de minimis exposure potential. Therefore, this IUR information could be considered within a particular priority grouping for Second Tier rank ordering.

International Risk Management Actions:

An initial screening approach for chemical prioritization should be based upon consistent application of specific hazard and exposure science elements that define risk potential.

The hazard and exposure elements should be applicable across all substances being evaluated. For initial screening, existence of international risk management action plans should not be a factor that determines priority grouping. Risk management plans may be based upon many factors, including political drivers. It is unclear how factors, their relative weighting, and the rigor of the evaluation may vary across agencies and substances. For initial screening

purposes, the same science-based criteria should be used to rank all substances. Consideration of existing international risk management plans could be utilized to check the functioning of the approach and could be considered within a particular priority grouping for Second Tier rank ordering with the possible effect of moving a chemical up in a grouping if actions are being taken internationally.

IV. Summary

ACC's prioritization approach is an example of a risk-based screening prioritization process that implements the general principles outlined at the outset of this document. It is based upon widely available information that can be utilized to understand the relative priority of chemicals for further evaluation from a risk perspective, i.e., integrating both hazard and exposure elements. Implementation of the screening framework will be most effective when utilizing the best available information. When conducting screening for thousands of chemicals, EPA may not have access to all available information. An open and iterative process that includes an opportunity for review and comment on initial rankings, together with the information that led to the result, and an opportunity to update the ranking with improved information will create a transparent and scientifically sound process.

V. References

Arnot, J.A., D. Mackay, T. F. Parkerton, R. T. Zaleski, C. S. Warren (2010), Multimedia modeling of human exposure to chemical substances: The roles of food web biomagnification and biotransformation, Environmental Toxicology and Chemistry 29(1):45–55.

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MacLeod, M., T. E. McKone (2004). Multimedia persistence as an indicator of potential for population-level intake of environmental contaminants, Environmental Toxicology and Chemistry 23(10):2465–2472.

van Wijk,D., R. Chénier, T. Henry, M. D Hernando, C. Schulte (2009). Integrated Approach to PBT and POP Prioritization and Risk Assessment' Integrated Environmental Assessment and Management, 5(4):697–711.

Proposed Prioritization Approach

DRAFT May 6, 2011

Exposure Elements				
Use Pattern	intermediate	industrial - not intermediate	commercial	consumer
Use Score	1	2	3	4
Persistence / Bioaccumulation (PB)	not P, not B		P & not B OR B & not P	P&B
PB Score	1		3	5
Tonnage	<25,000 lbs (below IUR site reporting limit)	25,000 - <1MM lbs IUR aggregate	1MM- <100MM lbs IUR aggregate	≥ 100MM lbs IUR aggregate
Tonnage Score	1	2	3	4
SUM (Use + PB + Tonnage Scores)	range 3 -13			

PRIORITY GROUPING = Hazard + Exposure Rankings				Exposure Ranking = Based on Sum (Use + PB + Tonnage Scores)				
				3-4	5-6	7-8	9-10	11-13
				low	med-low	medium	med-high	high
Hazard Ranking = Higher Score from Environmental and Human Health Hazards				1	2	3	4	5
		Environmental Hazard	Human Health Hazard					
1	low	not classified	Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	2	3	4	5	6
2	medium	Acute III OR Chronic III/IV ; [not acutely toxic and no chronic data]	Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	3	4	5	6	7
3	med-high	Acute II or Chronic II	GHS CMR Cat 2; OR GHS Repeat Dose Cat 2: Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	4	5	6	7	8
4	high	Acute I OR Chronic I OR insufficient information to classify	GHS CMR Cat 1a, 1b; OR GHS Repeat Dose Cat 1: Repeat Dose </= 10 mg/kg/day (oral); </= 20 mg/kg/day (dermal); </= 50 ppm/6hr/day (gas inhalation); </= 0.2 mg/l/6h/day (vapour inhalation); </= 0.02 mg/l/6h/day (dust mist fume inhal). OR insufficient information to classify	5	6	7	8	9

Hazard and Exposure Criteria for Prioritization Approach

HAZARD

Environment and Human Health Classifications based upon GHS

Environmental:

From GHS classification guidance document:

Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment

Classification categories			
Acute hazard (*Note 1*)	**Long-term hazard** (*Note 2*)		
	Adequate chronic toxicity data available		**Adequate chronic toxicity data not available** (*Note 1*)
	Non-rapidly degradable substances (*Note 3*)	**Rapidly degradable substances** (*Note 3*)	
Category: Acute 1 $L(E)C_{50} \leq 1.00$	**Category: Chronic 1** NOEC or $EC_x \leq 0.1$	**Category: Chronic 1** NOEC or $EC_x \leq 0.01$	**Category: Chronic 1** $L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 2 $1.00 < L(E)C_{50} \leq 10.0$	**Category: Chronic 2** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 2** $0.01 <$ NOEC or $EC_x \leq 0.1$	**Category: Chronic 2** $1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 3 $10.0 < L(E)C_{50} \leq 100$		**Category: Chronic 3** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 3** $10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
	Category: Chronic 4 (*Note 4*) Example: (*Note 5*) No acute toxicity and lack of rapid degradability and BCF $\geq$ 500 or, if absent log Kow $\geq$ 4, unless NOECs > 1 mg/l		

Human Health:

As above, based upon GHS

EXPOSURE

Use Elements - based upon IUR

Intermediate consumed during industrial processing
industrial (not intermediate) - used in an industrial setting
commercial occupational use in nonindustrial setting
consumer general population residential use

Persistence:

Volatile substance (VP > 1000 Pa): Not Persistent if air half life < 2 days
Nonvolatile (VP < 1000 Pa): Not Persistent if:
a) ready biodegradability (OECD 301)
b) inherent biodegradability (OECD 301, 302, 306)
c) read across from measured data on a related substance.
d) equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111)

OR, a substance is Not Persistent if:
e) evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g., OECD 308/309) have half lives below 180 days.

OR, if data are lacking:
f) evaluation via BIOWIN model (EPIWEB 4)

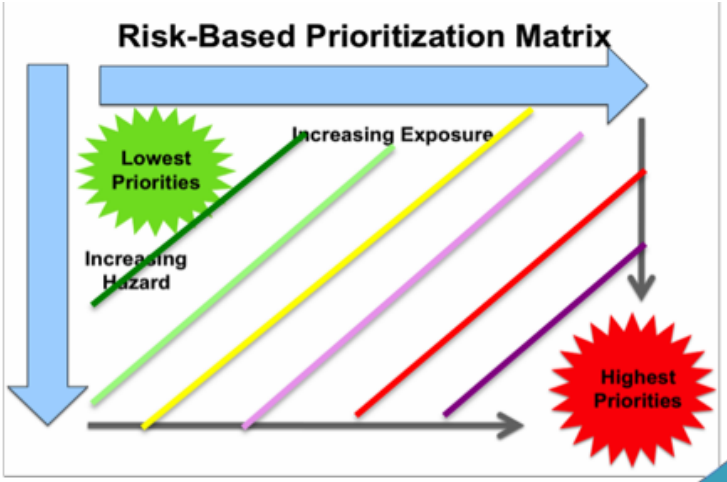
Bioaccumulation:

A substance is not bioaccumulative if:
a) measured TMF < 1 (field study)
b) measured fish BMF < 1 (lab study)
c) measured fish BCF < 5000 (lab study)
d) predicted BCF < 5000 using the BCFBAF model included in EPIWIN 4 The above order reflects the preference for use in decision-making

NOTE -- P&B CRITERIA ARE FOR ORGANICS

Tonnage - based upon IUR reporting ranges

< 25,000 lbs (below IUR site reporting limit)
25,000 - <1 MM lbs national aggregate
1MM - <100 MM lbs national aggregate
≥100 MM lbs national aggregate

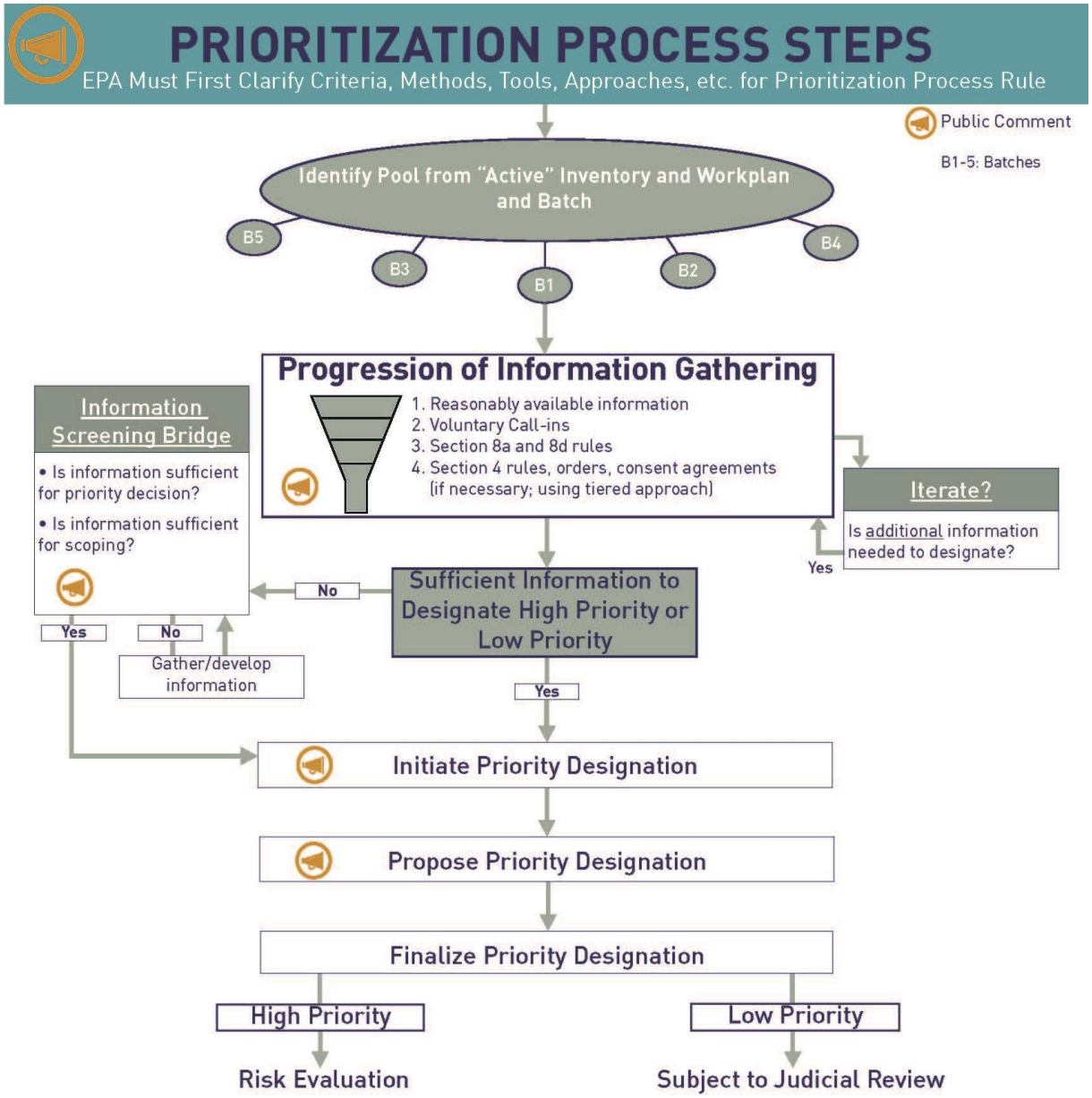


Two-Step Prioritization Process

Second Tier

Rank Ordering within Priority Groups

- Biomonitoring / Environmental Monitoring
- Use in Children's Products
- Emissions (e.g. TRI)
- International Risk Management Actions


PRIORITIZATION PROCESS STEPS
EPA Must First Clarify Criteria, Methods, Tools, Approaches, etc. for Prioritization Process Rule
Public Comment
B1-5: Batches
Identify Pool from "Active" Inventory and Workplan and Batch
B5
B3
B1
B2
B4
Progression of Information Gathering
1. Reasonably available information
2. Voluntary Call-ins
3. Section 8a and 8d rules
4. Section 4 rules, orders, consent agreements (if necessary; using tiered approach)
Iterate?
Is additional information needed to designate?
Yes
Information Screening Bridge
• Is information sufficient for priority decision?
• Is information sufficient for scoping?
No
Sufficient Information to Designate High Priority or Low Priority
Yes
No
Gather/develop information
Yes
Initiate Priority Designation
Propose Priority Designation
Finalize Priority Designation
High Priority
Low Priority
Risk Evaluation
Subject to Judicial Review

March 20, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Submitted electronically via www.regulations.gov

Re: Comments of the American Chemistry Council on EPA's Proposed Rule: *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act*, 82 Fed. Reg. 7562 (January 19, 2017); EPA-HQ-OPPT-2016-0654

Dear Docket Clerk:

The American Chemistry Council (ACC)[1] is pleased to submit the attached comments on the Environmental Protection Agency, Office of Pollution Prevention and Toxics Proposed Rule, Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act.

These comments align with our separately filed comments on the proposed rules describing the processes for inventory reset and prioritization for risk evaluation, and for the development of the scopes for risk evaluation of the first 10 chemicals selected from the TSCA work plan. All comments should be considered together.

Please feel free to contact me with any questions at 202-249-6130 or karyn_schmidt@americanchemistry.com.

Sincerely,

Karyn M. Schmidt
Senior Director, Regulatory and Technical Affairs
American Chemistry Council

cc: Jeffery Morris, Director, OPPT
Wendy Cleland-Hamnett, OPPT
Tala Henry, Director, Risk Assessment Division, OPPT
Susanna Blair, Office of Chemical Safety and Pollution Prevention

[1] ACC represents the leading companies engaged in the business of chemistry. More information about ACC is presented in the body of our comments.

American Chemistry Council

Comments on EPA's Proposed Rule for Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act 82 Fed. Reg. 7562 (January 19, 2017)

March 20, 2017

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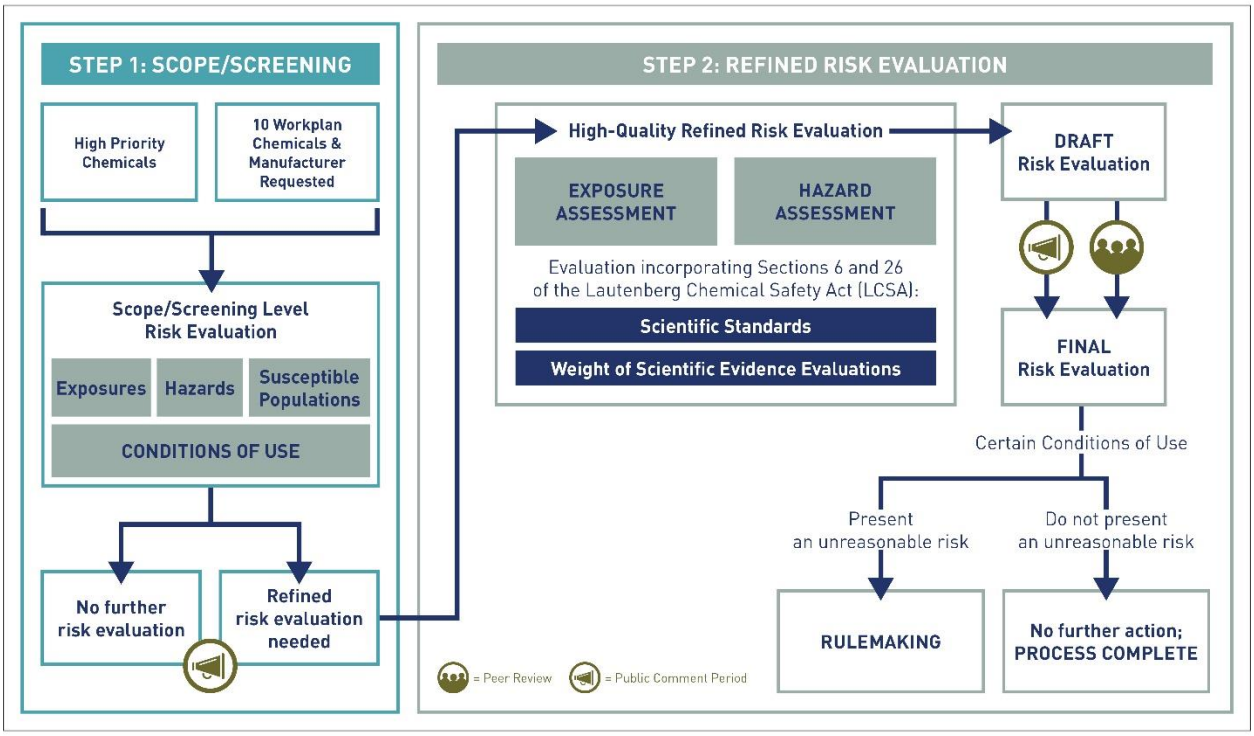
EXECUTIVE SUMMARY

Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), EPA must complete risk evaluations under statutory deadlines and using robust scientific standards. To achieve this goal, EPA must be flexible in its scoping of risk evaluations so it can maintain both pace and quality, and to inform the regulatory decision-making process in the most meaningful way. EPA should conduct its scoping to include conditions of use that are relevant and meaningful to a fit-for-purpose risk evaluation, and well-tailored to the problems and decisions at hand. EPA must incorporate Section 26 science standards throughout the risk evaluation process.

ACC recommends that EPA apply a tiered approach throughout the risk evaluation process. This approach will allow EPA to identify and consider the most relevant and highest risk conditions of use in an efficient and practical manner. The figure below depicts ACC's suggested approach, which is discussed in further detail in Section VI of these comments.



These comments offer overarching comments, specific comments responding to EPA's questions set out in the preamble, and additional specific recommendations for the conduct of risk evaluations under the amended statute. Key observations are:

- EPA must flexibly scope risk evaluations to focus on the most relevant, greatest potential for risk conditions of use.

- EPA should apply a tiered approach throughout risk evaluation, including when identifying and considering relevant conditions of use.

- It is essential that Section 26 science standards are applied to science-based decisions throughout the entire risk evaluation process. These requirements are so central to the function of LSCA risk evaluations that they must be described fully and defined in the regulation so they are applied consistently and stakeholders have adequate notice to participate in the development of the risk evaluations.

- EPA must revise criteria for manufacturer-requested evaluations to align them procedurally with EPA-initiated ones to incentivize their use as contemplated by statute and to make information and certification requests reasonable.

- The rule must ensure that peer reviews strive to provide consensus reports.

- EPA must articulate, with specificity, the scientific approaches and methods it will use in the risk evaluation, rather than simply pointing to Agency guidance which is often outdated, inconsistently interpreted, and inconsistently applied.

- EPA must describe procedures to ensure robust interagency collaborations that include all knowledgeable and potentially affected agencies, and timelines for public comment must be sufficiently robust to allow for a thorough review of EPA analyses.

INTRODUCTION

On behalf of the American Chemistry Council (ACC),[2] we are pleased to submit comments on EPA's proposed procedures for chemical risk evaluation under the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). Risk evaluation is the very heart of LCSA. LCSA envisions a streamlined process whereby all chemicals in commerce are systematically prioritized for, and then subject to, risk evaluation. EPA has described this process as a pipeline. Two critical design elements of LCSA that facilitate movement through the pipeline are the statutorily mandated timelines for risk evaluations and science quality requirements.

Our comments explain why these two design elements of TSCA - the need for timely, high quality risk evaluations – inform the application of a number of key provisions of the amended statute. In short, risk evaluations must be scoped, conducted, and completed in a way that meets statutory deadlines and quality requirements, and these imperatives must govern the way in which EPA applies a number of statutory terms.

Congress intended to redesign how TSCA risk evaluations work, as well as the pace of review. EPA cannot interpret individual provisions and definitions under LCSA to undermine these core objectives.

We offer overarching comments, followed by specific comments responding to EPA's questions set out in the preamble, and conclude with additional specific recommendations on the conduct of risk evaluations.

OVERARCHING COMMENTS

I. EPA Should Flexibly Scope Risk Evaluations to Include those Conditions of Use that Allow Timely Completion of Risk Evaluations and Meet Section 26 Scientific Standards.

Section 6(b)(4)(G) establishes a maximum time period of three years to complete a risk evaluation (subject to a possible extension of six months), with the throughput criterion of having at least 20 risk evaluations on high-priority substances (plus up to 20 risk evaluations of manufacturer-requested chemical substances) underway by December 2019. Congress designed a statute that makes it possible for EPA to meet this throughput requirement by exercising flexibility in scoping risk evaluations, and by selecting the conditions of use targeted for review.

[2] ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

At the same time, risk evaluations must meet Section 26 quality requirements, using best available science and weight of the evidence review.

To achieve the throughput and quality requirements for risk evaluation, Congress designed a process to allow chemicals to be systematically prioritized and evaluated. This design is apparent throughout LCSA. It begins with a reset of the TSCA Inventory -- the full catalog of chemicals in commerce. LCSA requires that the TSCA Inventory be sorted, so that chemicals that are currently active in commerce are separated from those not currently used. This sorting enables EPA to identify only those chemicals that are active in commerce for prioritization and risk evaluation. This statutory design makes eminent sense: it allows EPA to focus resources for its multi-year, time- and resource-intensive risk evaluations on chemicals that are actually being used. From this initial focusing step, LCSA repeatedly requires EPA to further refine its focus throughout prioritization and risk evaluation. EPA must next implement a prioritization process, which further refines the active chemicals in commerce to those that are high priority for risk evaluation. These chemicals must then undergo a scoping exercise to further focus on the conditions of use that will be the subject of the risk evaluation.

In implementing LCSA, EPA has indicated that it intends to identify and consider all conditions of use of a chemical in all risk evaluations, all the time. This interpretation cannot be reconciled with EPA's statutory directive to achieve throughput and quality in risk evaluations. It is inconsistent with the design of the statute; inconsistent with congressional intent to give EPA the flexibility to make case-by-case scoping decisions; and undermines statutory purposes and the effective function of the statute itself.

A. There is No Statutory Mandate to Include All Conditions of Use in the Scope of Every Risk Evaluation Under TSCA § 6(b).

EPA notes in the preamble that, prior to enactment of LCSA, the Agency was "free to and did" conduct risk assessments on selected uses of chemical substances, but that it now interprets the amended statute as "requiring that risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities… [t]hat is to say, a risk evaluation must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance" [emphasis added].[3] ACC strongly disagrees with this interpretation -- EPA is reading a mandate into the statute where none exists. Rather, Congress equipped EPA with the tools to scope risk evaluations in order to achieve statutory purposes, and EPA should use those tools accordingly.

The statute does not require EPA to include "all" conditions of use in any particular risk evaluation, or in each and every risk evaluation. Nowhere in the statute does Congress modify "conditions of use" with "all." EPA has the discretion to interpret the term. It cannot apply this discretion in such a manner, however, as to undercut the operation of the statute or to make it impossible for EPA to meet its statutory objectives of throughput and quality.

[3] 82 Fed. Reg. at 7565.

B. Scoping Necessarily Requires EPA to Select Relevant Conditions of Use for Inclusion, and Scope Accordingly.

LCSA requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under certain circumstances called "conditions of use."[4] Conditions of use are defined as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." The legislative text did not direct EPA to include "all" conditions of use.

The statute creates a scoping process that precedes the risk evaluation itself. For a scoping process to have any reasonable meaning, it must actually "scope" -- on a case by case basis, it must determine which conditions of use are appropriate for inclusion because they are relevant and meaningful to the risk evaluation process. EPA's plan to universally include "all conditions of use" all the time in every risk evaluation is contrary to common sense, conflicts with and undermines the statutory design of TSCA as amended by LCSA, and would lead to an absurd result.[5]

EPA's preamble acknowledges the value of scoping (also called problem formulation) in citing the National Academy of Sciences (NAS) National Research Council (NRC) Science and Decisions Report. The NAS report recommended that EPA focus on the "important roles of scoping or problem formulation so that a risk assessment will serve a <u>specific and documented purpose</u>" [emphasis added].[6] The preamble cites an additional NAS recommendation to EPA that the Agency "develop risk assessments that are well-tailored to the problems and decisions at hand so that they can inform the decision-making process in the most meaningful way." We agree, and urge the agency to apply these recommendations to the scoping process.

C. The Legislative Text Acknowledges that What EPA Will Consider and Include in a Given Scope Necessarily Varies.

The scoping provision requires identification of those conditions EPA "expects to consider,"[7] a clause that would be unnecessary if EPA were directed to simply include "all" conditions of use in a risk evaluation.[8] The future tense also acknowledges that EPA might subsequently change

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[4] TSCA § 6(b)(4)(A).

[5] See Massachusetts v. EPA, 549 U.S. 497, 531, 535 (2007) addressing EPA's application of its Chevron deference to particular statutory constructions: EPA not required to regulate "all" greenhouse gases as "air pollutants" everywhere that term appears in the statute; EPA must ground its reasons for action or inaction in the statute; agency regulation cannot conflict with statutory design, and law cannot be read to compel EPA to regulate in a manner contrary to "common sense."

[6] 82 Fed. Reg. at 7265.

[7] TSCA § 6(b)(3)(D).

[8] Before LCSA was enacted, EPA had published multiple problem formulations under the TSCA Work Plan. EPA explained that its problem formulations served as a means for explaining the scope of a risk assessment: "A problem formulation and initial assessment document will serve to inform the public and other interested stakeholders about EPA's initial scoping of findings and plan for any further risk assessment. Problem formulation and initial assessment is the analytical phase of the assessment in which the purpose for the assessment is articulated, the problem defined and a plan for analyzing and characterizing risk is determined." Many of those completed problem formulations were for limited conditions of use. Like other aspects of the TSCA Work Plan, Congress

its position with respect to what conditions of use to include or exclude. Notably, this construction affords EPA the discretion to include all conditions of use where necessary.

This is consistent with congressional intent. Speaking about the compromise bill that was signed into law, Senator Vitter said that EPA "is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical." This discretion and flexibility "assures that the Agency's focus … is on conditions of use that raise the greatest potential for risk" particularly given that "many TSCA chemicals have multiple uses – industrial, commercial and consumer uses" and EPA is "well aware that some categories of uses pose greater potential for exposure than others and that the risks from many categories of uses are deemed negligible or already well controlled."[9]

D. EPA Should Expressly Exclude Substances that Are Not Regulated Under TSCA from the Scope of Risk Evaluations.

TSCA excludes a number of chemical categories from its statutory scope. LCSA did not change these; accordingly, these categories should not be considered for inclusion in any risk evaluation undertaken pursuant to Section 6:

(i) [a]ny mixture,
(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide;
(iii) tobacco or any tobacco product,
(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),
(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [i.e., firearms and ammunition]…
(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The risk evaluation rule should expressly clarify that because these categories are excluded from the definition of "chemical substance" under TSCA, and they are outside EPA's legislative authority to regulate, they therefore excluded from the scope of risk evaluations under Section 6.

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contemplated that problem formulations from the TSCA Work Plan would serve as the model for EPA actions under the amended TSCA. In this case, the problem formulations were to be the model for the scoping exercise under Section 6(b)(4)(D). This is a strong indication that Congress authorized EPA to determine which conditions of use it would evaluate in a risk evaluation by defining the scope appropriately.

[9] Senate Congressional Record, June 7, 2016, at S3519; available at https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf. Mr. Vitter also clarifies that unreasonable risk/no unreasonable risk determinations made pursuant to the risk evaluation are made use-by-use: "[T]o be clear, every condition of use identified by the Administrator in the scope of the risk evaluation must, and will be either found to present or not present an unreasonable risk." Id. at S3520.

Likewise, the rule should clarify that chemical uses within these exclusions are "conditions of use" that are outside the scope of any Section 6 risk evaluation.

In addition to TSCA, which was modernized by the passage of LCSA in 2016, there is a network of statutes in place regulating the safety of chemicals in various venues and applications. Several other federal statutes are in place to regulate chemicals in products and during activities such as workplace manufacturing. Notably, the Consumer Protection Act, Consumer Product Safety Improvement Act, and the Federal Hazardous Substances Act regulate chemicals in a suite of consumer products, including children's products and toys, and the Occupational Safety and Health Act (OSH Act) regulates chemicals in the workplace.

Chemicals in uses regulated by other federal laws and agencies are often referred to as "non-TSCA" uses. EPA should not include these uses in its risk evaluations under TSCA. In rare cases where inclusion might be justified, the Agency should establish criteria to justify including non-TSCA uses in its risk evaluations and should articulate the steps it will follow to ensure adequate interagency consultation and review at the scoping stage. We discuss this topic in more detail below.

E. EPA Should Generally Exclude OSHA-Regulated Uses from the Scopes of TSCA Risk Evaluations.

Although LCSA specifically includes "workers" as a possible category of "potentially exposed or susceptible subpopulation," it does not designate "workers" as a default category. Any consideration of worker exposure must begin with the recognition that worker exposures are regulated under the OSH Act. Given that Occupational Safety and Health Administration (OSHA) standards are in place for the very purpose of regulating risk to worker populations, it should be the unusual case where unreasonable risk may present to a worker population under conditions of use (e.g., use of personal protective equipment).

Importantly, although Congress recognizes under LCSA that it may be appropriate, under particular circumstances, for EPA to designate workers as a potentially exposed or susceptible subpopulation under TSCA, and to regulate workplace exposures, Congress did not amend the OSH Act at the same time that it amended TSCA. Congress also left Section 9(d) of TSCA intact. This section requires EPA to consult and coordinate with OSHA "for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements on those subject to [TSCA] and for other purposes." EPA should ensure that this consultation occurs before risk evaluations are scoped; in cases where worker exposures do not present a significant risk of health impairment under current conditions of use, EPA should decline to include worker populations within the scope of the risk assessment as unduly burdensome and duplicative. This process will help focus risk evaluations and reduce the resource cost to the Agency.

Following this consultation, if OSHA agrees that EPA-led risk evaluation considering worker exposures is necessary (and not otherwise duplicative), EPA should describe the process it used to consult with OSHA and the basis for its findings in the scope of the risk evaluation.

F. EPA Should Generally Exclude Low Exposure Conditions of Use from the Scopes of TSCA Risk Evaluations.

In the prioritization process, certain scenarios may emerge that are low- to no-exposure. An example is a closed system, intermediate chemical manufacture or processing at an industrial site, where worker exposure is well documented and controlled, and does not present a significant risk. A second example would be *de minimis* levels of an impurity in a consumer product, where the levels and variability are well documented and well understood, and exposures are so low as not to present a significant risk. In such cases, it should be apparent in the prioritization process or before scoping that these use scenarios can readily be excluded from the scope of the risk evaluation.

G. EPA Should Apply the "Reasonably Foreseen" Provision as a Focusing Tool to Help Tailor the Scope of Risk Evaluations – Not to Expand Them.

The statutory definition of "conditions of use" is "the circumstances, as determined by the Administrator, under which a chemical substances is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."[10]

The phrase "intended, known, or reasonably foreseen" limits the conditions of use that may be identified and included in a scope. Clearly, if a particular use is not intended, known, or reasonably foreseen, it is not a statutory "condition of use" and may not be included within the scope of a risk evaluation.

The term "intended" is generally well understood to mean intended by the manufacturer or processor. Intention can be demonstrated through express (e.g., a statement to that effect in a premanufacture notice) or implied evidence (e.g., marketing materials that imply a potential application for the chemical). The term "known" is often considered a backstop for the term "intended," in that manufacturers or processors may not "intend" or support a particular downstream use for a chemical but may have actual or imputed knowledge that a chemical is being used in that application.

The definition of "conditions of use" also includes the term "reasonably foreseen." The concept of reasonable foreseeability is well understood in American and western[11] tort law. Foreseeability is "the determinant for the limits of duty under a conventional risk analysis" [emphasis added].[12] Foreseeability is modified by "reasonably," which makes clear that not every conceivable or speculative use is included. Product misuses and illegal uses, and manufacturing that disregards legal and industrial hygiene requirements, are not "reasonable" and thus not "reasonably foreseen."

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[10] TSCA §3(4).

[11] See, e.g., ANNEXURE T, The Concept of Limited Liability, Existing Law and Rationale (Australia), referring to the limiting tests of reasonable foreseeability and proximity, available at http://www.dpc.nsw.gov.au/__data/assets/pdf_file/0012/11406/T.pdf

[12] Tyrus V. Dahl Jr., Strict Products Liability: The Irrelevance of Foreseeability and Related Negligence Concepts, 14 Tulsa L. J. 338, 343 (1978).

There is a doctrine of "foreseeable misuse" in products liability law, as described in Sections 2(b) and 2(c) of the Restatement of Torts.[13] The purpose of this codification is to allow injured parties an avenue to obtain relief where they have misused a product in a way that the manufacturer should have anticipated. The doctrine, however, presents many fact-based questions for a jury. Generally speaking, foreseeable misuses do not include circumstances where the hazard was clear and a plaintiff disregarded it anyway (e.g., the plaintiff decided to juggle knives knowing that they are sharp and not intended for juggling); where instructions and warnings were clear and a plaintiff disregarded them anyway; where a plaintiff had the skills, knowledge and training to act prudently and failed to do so.

In short, in tort cases, "reasonable foreseeability" is the limit of liability. Courts seek to predict reasonable and expected conduct under the specific factual circumstances presented. Here, EPA is tasked with making much the same analysis. Reasonably foreseen conduct therefore does not include illegal uses or activities, product misuses, and illegal and improper disposal. Such conditions of use are properly outside the scope of a risk evaluation.

This approach is sensible and practical. The purpose of the scoping exercise is to focus the risk evaluation. Including every conceivable scenario, regardless of substantiation, likelihood, and severity whereby someone might misuse or be injured by a chemical substance cannot be the point of a risk evaluation. Indeed, boundless approaches ignore the "reasonably" in "reasonably foreseen." This approach to "reasonably foreseen" also becomes untethered from Congress' focus on risk in risk evaluations; rather than focusing on major risks it chases minor, abstract, and even merely hypothetical ones. It undermines the point of scoping the risk evaluation to achieve this purpose, and is inconsistent with Congress' expectation set out in the legislative history that misuses are outside the scope of risk evaluations.[14]

H. EPA Must Use High Quality, Best Available Information to Identify Conditions of Use For Inclusion in Scoping.

Commodity chemicals and building block chemicals may have hundreds or thousands of discrete and readily identifiable uses. In some cases, "major" intermediate and end uses of chemicals will be readily apparent from reporting already made to EPA or other credible sources of public information. Information of varying quality, integrity, credibility, and reliability is available about "uses" of chemicals on the internet, social media, and online journals. A significant amount of information available over the internet is from anonymous sources or anecdotal in nature. EPA should apply its Quality System[15] to information collected and evaluated to identify conditions of use in the pre-scoping stage, and ensure that it has conducted a data assessment to verify that they are of sufficient quantity and adequate quality for their intended use (to define the scope of the risk assessment).[16]

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[13] Restatement (Third) of Torts: Prod. Liab. §§ 2(b), 2(c) (1998).
[14] ''Conditions of Use'' is … not intended to include ''intentional misuse'' of chemicals." S Report 114-67 at 7 (June 18, 2015).
[15] https://www.epa.gov/quality
[16] See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency (EPA Information Quality Guidelines), Section 4.1, available at https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf

Data quality assurance to confirm identified conditions of use should occur before the scope is released, and certainly must occur before the scope is published as final. It is essential to the quality and integrity of the risk evaluation itself. Use of poor quality or outdated information to "identify" conditions of use taints the ultimate science-based decisions required in the risk evaluation and undermines the statutorily-required application of best available science to exposure assessment.

EPA should describe the process it uses to identify conditions of use in the scope of the risk evaluation, including:

- The source of the information about a condition of use;
- The reliability of the source of information (e.g., whether the information is a first-party, anecdotal report (blog, social media post, product comment or review) or reported to a government or credible third party);
- A description of the Agency's assessment of whether the identity of the source of information is known and verified;
- A description of how the information source has been verified and validated, if appropriate; and
- Whether the information is current.

I. EPA Should Not "Lock Down" Conditions of Use at the Time of Scoping.

The Agency simultaneously insists that it must consider "all conditions of use" in the scope of the risk evaluation, but that it will then not actually consider "all" conditions of use through use of a "lock down" procedure, freezing the conditions of use at the time of scoping. In other words, if a new condition of use is discovered or emerges after the scope is published, EPA will not include it in the risk evaluation, regardless of impact. EPA proposes this "lock down" to help the Agency meet its statutory deadlines.[17]

We think the Agency has this backwards. To stay on its statutory schedule – or to move more quickly - the best tool EPA has available is scoping (the ability to scope its risk evaluations in a flexible manner to focus on the conditions posing the greatest potential risk). EPA should propose a process that allows the Agency to take full advantage of this important tool on a case-by-case basis. EPA should be able to select the conditions of use that it believes are most relevant and meaningful to human health and environmental risk and proceed accordingly.

Likewise, EPA should not commit to "locking" conditions of use at the time of scoping. If EPA has discretion to select the conditions of use that it will include in the scope of a risk evaluation – which it does – then EPA should have the companion ability to remove or add a condition of use as circumstances warrant.[18] For example, following scoping EPA might determine that reports of an isolated use were wrong – and that the condition of use does not actually exist. It would

[17] This proposal leaves in limbo the regulatory status of conditions of use that are excluded from the review. If EPA were to implement this approach, it would also need to clarify that excluded conditions of use go back to the prioritization process, and would also need to clarify that they do not have a high priority designation. This approach is also completely inconsistent with EPA's approach taken for manufacturer-requested evaluations.
[18] Similarly, EPA has a companion ability to redesignate low priorities or high priorities as warranted.

make little sense to continue evaluating that condition of use in the risk evaluation. Otherwise, EPA's final risk evaluation would be of suspect quality, integrity, and reliability.

A better approach would be for EPA to articulate in the rule that after a scope is published, EPA retains discretion to modify it upon a showing of substantial need or changed circumstances, or is otherwise warranted because the addition or removal of a condition of use, properly substantiated, will significantly affect the conduct of the risk evaluation.

J. EPA Must Remove the Comment-or-Waive (Issue Exhaustion) Proposal.

EPA further proposes that it can keep risk evaluations on schedule, notwithstanding its proposal to include "all conditions of use" in every scope, by "providing opportunity for comment on the scoping document and specifying that any objections to the draft scope document are waived if not raised during this process."[19] We urge the Agency to remove this issue exhaustion (waiver) requirement for several reasons.

First, it places an unfair burden on the regulated community. A particular company may not be aware, or otherwise in a position to verify, particular end uses that the company does not support (i.e., a downstream value chain to which it does not sell). A company likewise may not be able to verify occurrences of a chemical from natural sources or the actions of third parties through combustion, spills and discharges, disposal, manufacturing practices or incidents, and the like. When EPA insists on including "all conditions of use" in the scope of a risk evaluation, it moves well past the "major" uses of a chemical and "major" sources of exposure to include fleeting, incidental, minor, isolated, or exceptional cases. Information about these "minor" sources of exposure may be well outside the first-hand knowledge of a manufacturer or processor, making it difficult or impossible to offer meaningful comment during the scoping period.

Second, participation in notice and comment rulemaking is governed by the Administrative Procedure Act (APA) and the judicial review provisions of Section 19 of TSCA. Issue exhaustion requirements can be imposed by statute. Notably, there are only a few statutory issue exhaustion provisions in environmental statutes, the most notable of which is in Section 307(d)(7)(b) of the Clean Air Act. There are none in TSCA.

Congress had the opportunity to impose an issue exhaustion requirement for the scope of a risk evaluation in LCSA amendment – and declined to do so. EPA cannot, by regulation, impose an issue exhaustion requirement that trumps the statutory rights and obligations of stakeholders under the APA and TSCA Section 19.[20] Indeed, ACC believes a waiver provision such as that proposed by EPA may not meet Constitutional muster.

Third, the proposal does not rationally advance its claimed purpose – to meet statutory risk evaluation deadlines. An issue exhaustion requirement is supposed to serve two purposes: it

[19] 82 Fed. Reg. at 7566.

[20] Administrative issue exhaustion requirements are largely creatures of statute, and here we have no such statutory construct. While some agency regulations set out issue exhaustion requirements without a statutory mandate, these tend to be in administrative appeal situations or proceedings that are analogs to adversarial litigation. Notably, the LCSA amendment removed a procedure for formal TSCA hearings.

protects administrative agency authority and promotes judicial efficiency.[21] But here, by requiring inclusion of "all conditions of use" in scopes, the agency impairs the ability of industry to meaningfully comment in the limited time available. EPA seems to be of the view that it would rather include "too much" in a scope than inadvertently omit a condition of use and include "too little," but it is the overly broad, unrefined scope that expands the scale and cost of risk evaluations and slows them. EPA then ties its own hands by proposing to "lock down" overly broad scopes, impeding its ability to update or modify them later in the process. This does not advance efficiency or transparency in the regulatory process.

EPA can avoid these inefficiencies by offering a simple process to identify those major, important conditions of use that are most relevant and meaningful to a high-quality risk evaluation – and to use flexibility in designing the scope accordingly. EPA should offer a rationale of why it selected the uses it did in the scope itself.

II. EPA Must Describe How and When it Will Apply Section 26 Requirements to Risk Evaluations.

Section 26(h) sets out scientific standards that apply to every "decision based on science" while EPA carries out risk evaluation under Section 6 [emphasis added]. Section 26(i) requires EPA to "make decisions" under Section 6 based on the weight of the scientific evidence [emphasis added]. A decision would include any judicially reviewable determination, but also any other decision that requires application of science or scientific judgment by the Agency.

EPA should articulate in the risk evaluation rule, at a minimum, the key decision points that will require compliance with Section 26 requirements. These should include, but are not limited to:

- The proposed scope and final scope for risk evaluation
- Hazard assessment, including, where applicable, the likely operable mode of action
- Exposure assessment
- Selection and evaluation of technical procedures, measures, methods, protocols, methodologies, and models
- Basis for scientific assumptions
- Selection and evaluation of quality assurance procedures
- Decisions regarding variability and uncertainty
- Statistical methods
- The draft and final risk evaluation

EPA should document how it applied Section 26(h) and 26(i) requirements for each decision.

[21] The issue exhaustion proposal does not advance judicial economy either. Determinations of no unreasonable risk, made by the Agency following the completion of the risk evaluation process, are judicially reviewable – but as a practical matter this means that a judicial challenge to such a determination would be unlikely to occur until years after the scope was published (and the risk evaluation completed). Changes to conditions of use, or errors in their identification and inclusion, may not all be evident at the time the scope is originally prepared and published, so applying issue exhaustion at this step makes little sense.

III. EPA's Proposed Risk Evaluation Process Should Offer Greater Specificity Regarding the Use of Systematic Review Approaches.

As discussed in further detail in Section IV of these comments, EPA should articulate a clear regulatory definition of systematic review and commit to implementing a systematic review approach throughout the risk evaluation process. Systematic review is a process to collect and evaluate information in a transparent and reproducible manner.[22] ACC cannot envision any situation where a systematic review definition would unduly restrict the specific science that can be used to conduct a risk evaluation. A systematic review process will allow EPA to be flexible and to adapt with changing science, assuming that the new science meets the necessary high quality standards that are required by LCSA. Articulating a regulatory definition for systematic review is fully consistent with EPA's policy objectives.[23]

RESPONSES TO SPECIFIC QUESTIONS RAISED BY EPA

IV. Responses to Specific Questions Raised by EPA

While EPA is seeking public comment on all aspects of the proposed rule, the Agency specifically requests comments on seven topics. ACC's recommendations on each of these topics are provided below.

Question 1. "Redefining" Scientific Terms

To ensure clarity and consistency, important scientific terms should be clearly defined in the rulemaking.[24] While many of these terms are not novel concepts and are already in use, multiple definitions are in use and may mean different things to different stakeholders. Thus, there is a need for clarity and consistency to ensure that the Agency and all stakeholder groups are using uniform definitions.

For example, EPA notes that extensive descriptions for the phrases "best available science," "weight-of-the-evidence," and "sufficiency of information" can be found in EPA's Risk Characterization Handbook[25] and other existing guidance. However, we are unable to find any clear definitions for "best available science," "weight-of-the-evidence" and "sufficiency of information" in EPA's Risk Characterization Handbook. While there are references to "weight of evidence" and "sufficient information," neither term is clearly described.

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[22] See National Toxicology Program Fact Sheet on Systematic Review, available at https://www.niehs.nih.gov/health/materials/systematic_review_508.pdf.

[23] See 82 Fed. Reg. at 7567 ("Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.")

[24] We do not suggest defining terms in a manner that deviates from accepted scientific understanding, and of course, our suggestions are intended to align with best available science requirements set out in the statute itself.

[25] See https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

Similarly, while EPA's 2005 Guidelines for Carcinogen Risk Assessment discuss what is in a "weight of evidence" narrative, there is no clear definition for what it means to conduct a "weight-of-the-evidence" evaluation.[26] In addition, when discussing "sufficient information," the Guidelines for Carcinogen Risk Assessment note that "[g]enerally, 'sufficient' support is a matter of scientific judgment in the context of the requirements of the decision maker or in the context of science policy guidance regarding a certain mode of action."[27] Neither of these definitions is of sufficient clarity to inform stakeholders as to the meaning of the terms that EPA will be using to inform risk evaluation under LCSA.

Although EPA suggests generally that these terms will evolve over time and continue to change, the Agency points to no particular term and offers no explanation why it believes the meaning of a term will change. ACC struggles to think how these definitions may change. While the data sets used to inform some definitions surely change with advances in high-throughput and high content methodologies, ACC cannot identify instances where these definitions have changed. For example, in 1996, Congress emphasized, and described, using the "best available scientific evidence" for risk information in amendments to the Safe Drinking Water Act (SDWA).[28] We can think of no examples where this description has needed to be modified in the last 20 years, and the description appears to have created no problems for the Agency. Nevertheless, even if there were to be a need to change specific definitions if a term became a problem for the Agency, there is nothing that stops EPA from updating and modifying the definition in a future rulemaking.

As requested by EPA, below we suggest specific definitions or definitions which are alternatives to the language EPA has provided. ACC is not proposing to "freeze" the science, and indeed best available science depends on the converse. Scientific advancements will be important to ensuring the effective and efficient implementation of the LCSA. Each of the definitions below allows for scientific inputs and approaches to evolve and improve over time to inform chemical risk evaluations.

i. Best Available Science.

ACC suggests the following definition:

> *Best available science* means information that has been evaluated based on its strengths, limitations and relevance and the Agency is relying on the highest quality information. In evaluating scientific information, the Agency will also consider the peer review of the science, whether the study was conducted in accordance with sound and objective practices, and if the data were collected by accepted methods or best available methods. To ensure transparency regarding best available science, the Agency will describe and document any assumptions and methods used, and address

[26] See EPA's 2005 Guidelines for Carcinogen Risk Assessment, at 2-49, available at https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.
[27] Id. at 2-42.
[28] See 42 U.S.C. § 300g-1(b)(3)(A, B).

> variability, uncertainty, the degree of independent verification and peer review.

In proposing this definition, ACC has drawn language directly from the 1996 SDWA amendments[29] and from section 26(h) of the LCSA. EPA has already adopted the language from the SDWA amendments in the EPA Information Quality Guidelines.[30] In addition, the concept of evaluating data based on strengths and limitations is consistent with the definition provided in the Senate Congressional Record for LCSA.[31] To ensure a greater level transparency that forces EPA to "show its work," as was envisioned by the authors of the LCSA,[32] this definition covers not only what EPA must consider and evaluate, but also requires that important descriptions and documentation be including in EPA work products developed under Sections 4-6 of TSCA.

ii. Weight of the Evidence (WoE).

ACC suggests the following definition:

> *Weight of the evidence* means a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

ACC agrees that the term WoE has meant different things to different groups. In fact, different NAS studies contradict themselves regarding the use of this term and inconsistently define its meaning. As such, it is critically important that EPA clearly explain what this term means to the Agency. This term cannot and should not be avoided or discounted as Section 26(i) of the LCSA codifies the requirement for EPA to use a WoE approach. As such, a clear and transparent definition is critical.

ACC is recommending the use of the definition that is in the June 7, 2016 Senate Congressional Record.[33] This is the definition we have provided above. This definition is also consistent with the June 2015 House Report Language.[34] While other definitions exist, using the definition associated with LCSA makes the most sense and is a straightforward approach that is clearly linked to the intent of Congress.

Without a clear definition, WoE will continue to mean different things to different experts and stakeholders. An example illustrates that EPA very recently has not interpreted WoE in the same way Congress now intends. In the draft risk assessment of 1-bromopropane (released prior to enactment of LCSA), EPA does not provide information regarding the quality of the individual

[29] Id.
[30] See generally, EPA Information Quality Guidelines.
[31] Senate Congressional Record, June 7, 2016 at S3518.
[32] Id. at S3522.
[33] Id at S3518.
[34] See House Report, at 33, available at https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.

studies.[35,36] Although the assessment identified some quality considerations, EPA did not provide any information regarding its own findings from its quality review of the individual studies.[37] Additionally, no information was provided to describe how quality, relevance, and reliability considerations were applied and what constitutes a study of "high quality" or "good quality." EPA simply chose the value that provided the lowest point of departure and thus would be most health protective. While EPA staff stated that they followed a WoE approach,[38] picking the lowest point of departure, without an explicit consideration of study quality, is not consistent with a WoE approach. Until there is one clear definition, confusion such as this will likely continue and this confusion will stifle the scientific dialogue.

iii. Sufficiency of Information.

ACC suggests the following definition:

> *Sufficiency of information* means that, taking into account the importance of the determination, the Agency has appropriately relied on the best available science, considering the weight of the scientific evidence to make a reasoned and transparent fit-for-purpose determination.

This definition is important as EPA uses this term repeatedly in the preamble of the proposed rule to describe scientific information. We have provided a definition that ties this information directly to the best available science and weight of the evidence standards required in Section 26 of the LCSA. If no definition is provided, stakeholders are left guessing as to what standards will define sufficient information.

In the preamble of the proposed rule, EPA uses related terms including "scientifically valid information" and "sufficient quality." These terms must also be defined. ACC suggests the following:

> *Scientifically valid information* means information that the agency has considered the quality, reliability, and relevance of the information for the decision being made. Consistent with the Agency Assessment Factors Guidance (2003) evaluation of information will include the consideration of the soundness, applicability and utility, clarity and completeness, uncertainty and variability and evaluation and review of the information.

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[35] See Comments of the American Chemistry Council on the TSCA Work Plan Chemical Draft Risk Assessment of 1-Bromopropane, Docket No. EPA-HQ-OPPT-2015-0084, May 9, 2016.
[36] See Chemical Safety Advisory Committee Minutes No. 2016-02, at 41, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0805-0028 ("While the Agency indicates that the literature was thoroughly reviewed for robustness, adequacy, etc., the Committee found that it is not clear what exact methodology was used to systematically rate, rank, and select studies to inform sections of the risk assessment. For example, was a quantitative ranking system developed for study quality?")
[37] See TSCA Work Plan Chemical Risk Assessment Peer Review Draft, at Appendix M, available at https://www.epa.gov/sites/production/files/2016-03/documents/1-bp_report_and_appendices_final.pdf.
[38] See Chemical Safety Advisory Committee Meeting Transcript, at 130, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0805-0027.

> *Sufficient quality* means that the Agency has relied on scientifically valid information to make the determination.

These definitions are consistent with existing Agency guidance. However, to improve transparency and consistency, it is important that EPA clearly define these terms in the final rulemaking.

iv. Unreasonable Risk.

ACC agrees with EPA that a single definition of unreasonable risk is not workable due to the variety of factors that are necessary to consider when making an unreasonable risk finding. However, the risk evaluation rule should list the considerations that must be taken into account in making that finding. More importantly, EPA should commit to describing and transparently presenting how each of these considerations impacted the unreasonable risk finding. The descriptions that support the unreasonable risk finding should be presented in the draft and final risk evaluation documents. ACC suggests the following description be included in the preamble to final rule:

> *Unreasonable risk* means that the Administrator has considered relevant factors, including the effects of the chemical substance on health and the magnitude of human exposure to such substance under the conditions of use; the effects of the chemical substance on the environment; and the magnitude of environmental exposure to such substance under the conditions of use. Factors considered to reach this risk-based determination may include: characterization of cancer and non-cancer risks (including margins of exposure for non-cancer risks and mode of action analyses for cancer risks), characterization of environmental risk, the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard), the irreversibility of hazard, and uncertainties associated with the analyses and data.

This description is generally consistent with the considerations EPA has provided in the proposed rule, and adds a consideration to ensure that environmental risk findings are also considered. Notably, however, EPA inappropriately includes cumulative exposure in its list of considerations.[39] This should be removed. LCSA does not require the consideration of cumulative exposure in the risk evaluation process. Further, there is no generally accepted approach to inform the scientific methods, inputs and tools to evaluate cumulative risk. While EPA and other agencies continue to work on guidance in this area, scientifically robust draft frameworks for the evaluation of cumulative exposure risks are non-existent.

v. Reasonably Available Information.

ACC supports a clear definition of "reasonably available information;" however, we offer specific suggestions (shown in strikethrough and underline) to improve the definition EPA has provided:

[39] 82 Fed. Reg. at 7566.

> *Reasonably available information* means ~~existing~~ information that EPA possesses or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Confidential Business Information provided to the Agency will be treated as reasonably available information.

ACC suggests these edits because it is important that EPA be clear that it will include confidential business information (CBI) in its consideration of relevant information in a risk evaluation. While this information must be protected from public disclosure, it may provide important exposure and use information that the Agency should rely upon during the risk evaluation process.

ACC suggests deleting the term "existing." Due to the advancement of high throughput technologies and *in vitro* methods, it may be feasible and appropriate for EPA to obtain useful *de novo* information in a very short amount of time, thus making it easily useable and accessible considering the deadlines specified in LCSA. For example, in 2010, EPA used *in vitro* ToxCast methods to rapidly generate data on oil spill dispersants.[40]

Similarly, in responding to health and environmental concerns related to the chemical spill in the Elk River in West Virginia in 2014, the National Institute of Environmental Health Sciences (NIEHS) conducted a battery of tests which included short term high throughput screening assays and other *in vitro* assays which were able to generate useful information in a very short period of time.[41] This information was then shared with EPA and other stakeholders to inform the evaluation of risks.

EPA should be clear that this definition implies that data and information, including robust summaries, made available by other regulatory bodies, including international agencies (such as the World Health Organization International Programme on Chemical Safety) and national authorities from other countries (such as the European Union and Canadian government chemical evaluation programs) are considered reasonably available information. This information can inform not only risk evaluation, but also prioritization. The International Uniform Chemical Information Database (IUCLID)[42] is just one example of a robust database of chemical specific information that EPA should be using when reviewing available data on individual chemistries.

Question 2. Margin of Exposure

ACC strongly supports the margin of exposure (MOE) approach for use in the risk evaluation process. This approach is far more transparent than a hazard index or hazard quotient (HQ) approach where the application of uncertainty factors is not transparent and often not scientifically justified. In addition, this approach is consistent with the way non-cancer hazards are currently evaluated, not only within EPA but throughout the Federal government. ACC

[40] See Judson, RS, et al. 2010, Analysis of Eight Oil Spill Dispersants Using Rapid, In Vitro Tests for Endocrine and Other Biological Activity, Environ Sci Technol. 44(15): 5979–5985, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2930403/.
[41] See https://ntp.niehs.nih.gov/results/areas/wvspill/collective.html.
[42] See https://echa.europa.eu/-/more-information-to-be-published-from-reach-registrations.

recognizes that the current MOE approach, similar to the HQ method, creates difficulties for the analysis of costs and benefits; however, it provides an accurate representation of the current state of the scientific approach for evaluating non-cancer hazards. While some have suggested a "linear to zero" approach for non-cancer hazards, it is not a generally accepted scientific approach, and in fact is not supported by an evaluation of biochemical networks.[43] It can be considered a policy decision and as such should be made on a case-by-case basis considering the specific supporting information for an individual chemical hazard. It should not become a new default approach.

When EPA presents MOE exposure values, consistent with EPA's 2000 Risk Characterization Handbook[44] and the EPA Information Quality Guidelines, EPA should present a range of estimates including the central tendency estimate. While EPA tends to present ranges reflecting different exposure scenarios, the range of values presented should be informed by modifying both the exposure and the hazard estimates.

Question 3. Systematic Review

EPA notes in its proposal that it has conducted systematic reviews in the past and that it intends to do so in the future. The Agency has not, however, made a firm commitment to follow a systematic review approach and seeks comment on whether such a commitment in regulatory text is necessary. ACC strongly supports the need for regulatory text describing the systematic review process, and EPA should commit to conduct its risk evaluations consistent with the systematic review definition.

Systematic review is critical part of a WoE approach. As discussed above, it is part of the definition provided in the June 7, 2016 Congressional record and the June 2015 House Report.[45] Congressional intent is to ensure that EPA conducts systematic reviews is clear.

ACC acknowledges that systematic review can mean different things to different groups. A recent publication by Haddaway et al. found that while systematic review is becoming the "widely accepted gold standard in evidence synthesis" not all users of systematic review understand the term in the same way.[46] In this publication, a survey of six publications that claimed to be systematic reviews found that none met all the requirements of a true systematic review.[47] For instance, simply having a system to search for studies does not classify as being a systematic review. Haddaway et al. state:

> A review may include a systematic search or screening, but unless it includes all of the aspects of a full systematic review, such as critical appraisal and full transparency, the

[43] See https://ehp.niehs.nih.gov/1408244/.
[44] See https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.
[45] See Senate Congressional Record, June 7, 2016 at S3518; House Report at 33.
[46] See Haddaway, NR, et al. 2016. "A Little Learning Is a Dangerous Thing": A Call for Better Understanding of the Term 'Systematic Review,' Environ Int 99: 356-360, available at: http://www.sciencedirect.com/science/article/pii/S0160412016303634.
[47] Id.

> review reliability is reduced and it cannot be referred to as systematic….It is unhelpful to classify "narrative reviews" as systematic reviews...[48]

EPA states that it has included systematic reviews in the past; however, it is not clear what exactly it has done and where these reviews can be found.[49] The last completed draft TSCA Work Plan risk evaluation was for 1-bromopropane. The executive summary of the peer review report of this draft evaluation, dated August 22, 2016, states:

> Committee members agreed that the 1-BP risk assessment (and other TSCA chemical assessments to be presented in the future) would benefit by adoption of systematic review practices to increase the transparency of how studies were selected and evaluated. For example, the Committee recommended that it should be explicitly stated what criteria were used to determine "the monitoring was adequate and of acceptable quality" (risk assessment document, page 44). The Committee also noted that it would be useful to reference studies that were evaluated but did not meet baseline criteria to inform the exposure estimates. [50]

In addition, the peer review committee could not determine "what exact methodology was used to systematically rate, rank, and select studies to inform sections of the risk assessment."[51] Peer reviewers also could not find any ranking system developed for study quality.[52]

It is critically important that systematic review mean the same thing to all engaged stakeholders, including Agency staff and peer reviewers. ACC cannot envision any situation where a definition of systematic review would unduly restrict the specific science that can be used to conduct a risk evaluation. A systematic review process will allow EPA to be flexible and to adapt with changing science, assuming that the new science meets the necessary high quality standards that are required by the LCSA. Including a regulatory definition for systematic review is fully consistent with EPA's policy objectives.[53] As such, ACC recommends the following definition be included in the final rule:

> *Systematic review* means that the evidence has been evaluated using a predefined, transparent, and reproducible process to identify, appraise, and synthesize the available body of evidence to answer a specific question. To ensure transparency, systematic reviews should include a Protocol that describes the specific question(s) that will be answered, the literature search strategy and plans for data collection, the methods for evaluating the quality and relevance of the data

[48] Id. at 4.
[49] See 82 Fed. Reg. at 7572.
[50] See Chemical Safety Advisory Committee Minutes No. 2016-02, at 1.
[51] See id. at 41.
[52] Id. at 42.
[53] See 82 Fed. Reg. at 7567 ("Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.")

(including the specific criteria that will be used), the approach for data analysis and integration and also the plans for peer review.

Question 4. Manufacturer Requests

EPA seeks comment on approaches to using its information gathering authorities (such as Section 8(a) or (d) authorities) to ensure that EPA has the most complete information to make its risk determination for a manufacturer requested evaluation. ACC urges EPA to appropriately use its authority.

In its proposal, EPA indicates that it will not accept a manufacturer request where any of the relevant data is not in the possession of the manufacturer but is "with" another entity. EPA also requires a commitment that manufacturers provide all reasonably available information on hazard and exposure for all conditions of use, even if it is not publicly available.[54] These requirements will make it extraordinarily difficult, if not impossible, for a manufacturer to submit a request acceptable to EPA.

ACC believes it is inappropriate for EPA to require that a single manufacturer contact and extract information outside its possession and control – and for which it has no legal authority to obtain – to be able to initiate a manufacturer requested risk evaluation. It is more appropriate that EPA use its Section 8 authority judiciously to collect information to be able to review and make a determination on a manufacturer requested risk evaluation. There are also instances where other governments (e.g., U.S. state or locality, U.S. government agency), universities, non-profits, or other entities may have information that the manufacturer is unable to obtain. There may even be cases where EPA itself has relevant information to inform a risk evaluation, and a manufacturer is incapable of obtaining it, providing it, or referencing it to EPA. These circumstances should not bar a manufacturer from initiating a request.

Manufacturer requested evaluation are further discussed at Section VIII.

Question 5. Peer Review

EPA requests public comment on whether there are circumstances where peer review might not be warranted. When risk evaluations will lead to findings of unreasonable risk, which will then trigger risk management actions, the draft risk evaluation should always be peer reviewed. As conclusions of "no unreasonable risk" for specific conditions of use may likely be part of the risk evaluation, the science supporting these determinations should also be reviewed to ensure public confidence.

Certainly for the first few years of LCSA implementation, as EPA applies new statutory requirements including the Section 26 scientific standards, risk evaluations will be highly influential. For highly influential scientific assessments, the most robust peer review standards

[54] 82 Fed. Reg. at 7569.

should be followed, including the need for panel review that strives to reach consensus. When the panel review is structured to provide individual opinions in a report to EPA, it resembles a letter review, which is appropriate when a draft document covers only one discipline.[55] As the draft risk evaluations developed under the LCSA will be complex multidisciplinary assessments which integrate both hazard and exposure information, robust expertise will be needed and a more rigorous review process is appropriate.[56] The EPA Science Advisory Board (SAB) strives to reach consensus when conducting panel reviews.[57] Reports in which only non-consensus opinions are provided will not be sufficiently helpful to the agency. They will not reflect scientific consensus and this will undermine both stakeholder and risk manager confidence, subsequently impacting the confidence in future risk management rulemakings. Thus we highly recommend that peer review reports to EPA should provide consensus opinions where possible, with the understanding that non-consensus opinions be included in the rare cases where consensus cannot be reached in a timely manner.

ACC agrees with EPA's approach to release peer review plans along with the draft scoping documents. These peer review plans, which will be subject to public comment, should commit the agency to conducting panel reviews which strive to reach consensus. In addition, the peer review plan should confirm EPA's intent to share a draft charge with the public for comment and input. The peer review plan should also ensure that as part of the process the peer review panel will provide responses to the substantive scientific comments that are received from the public.

Question 6. Reliance on Existing Guidance and Procedures for Conducting Risk Evaluations

EPA is seeking input on its proposal to not "codify" any specific guidance, method or model in the regulatory text. As noted above, ACC believes that EPA must, at a minimum, include the definitions for WoE and systematic review in the regulatory text itself. The uses of these evaluation approaches (or methods) should be required for risk evaluations; these are cross-cutting approaches to evaluating evidence. While the type and quality of evidence available will change and evolve over time, what constitutes a good scientific approach has not changed over time and is not likely to change at any pace which could be characterized as "rapid."

With respect to guidance, it is important that EPA not codify in the rule EPA's guidance documents, many of which are outdated. Much of what is in existing guidance includes default approaches that may be outdated (see discussion below) and many of the recommendations in guidance documents are situation-specific and cannot be universally applied.[58] Due to these limitations, neither should EPA cite a list of guidance documents in scoping documents.

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[55] See Office of Management and Budget (OMB), Final Information Quality Bulletin on Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005).
[56] See id. for further details on this distinction.
[57] See EPA SAB, Advisory Committee Meetings and Report Development: Process for Public Involvement, available at: https://yosemite.epa.gov/sab/sabproduct.nsf/WEBSABSO/part-mtgs-reports/$File/sabso_04_001.pdf ("Ideally, the deliberative process should converge on some sort of consensus conclusion.").
[58] For instance, EPA's 1991 Guidelines for Developmental Toxicity, available at: https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf, state, at 38, "for developmental toxic effects, a primary assumption is that a single exposure at a critical time in development may produce an adverse developmental effect, i.e., repeated exposure is not a necessary prerequisite for developmental toxicity to be manifested." This is an assumption that does not put the science first. If EPA were to invoke this guidance, risk

For instance, simply stating that EPA will follow the 2005 Guidelines for Carcinogen Risk Assessment (Cancer Guidelines) or other EPA guidelines does not provide the public with a sufficient level of specificity or granularity to understand what scientific approach and "accepted science policies" will be followed. As has been documented from years of peer review of some EPA hazard assessments (e.g., IRIS assessments), interpretation of even EPA's Cancer Guidelines can vary from expert to expert. For example, EPA's Cancer Guidelines invoke a linear extrapolation approach as a default in the absence of sufficient scientifically justifiable mode of action information, but there has been considerable variability in both EPA's and experts' determinations of when sufficient information exists to require non-linear modeling. For example, for 1,4-dioxane, Health Canada determined that a threshold approach is appropriate to use for characterizing risks to human health,[59] but, in evaluating essentially the same dataset, EPA IRIS program discounted this mode of action and adopted a liner, no-threshold method.[60] In addition, there are very few "accepted science policies" that all stakeholders can agree upon. For example:

- EPA's Cancer Guidelines specifically state that data should be used ahead of defaults; however, the members of the 2009 NAS Science and Decisions committee supported defaults as adequate and appropriate.

- EPA's Cancer Guidelines recommend using mode of action in a risk assessment; however, the members of the 2009 NAS Science and Decisions committee suggested that one of three dose-response approaches is typically going to be appropriate for use. This default approach recommended by these NAS committee members conflicts with EPA's own guidelines.

Rather than merely point to guidance documents, EPA must be more specific with respsed to its process in the rule itself. In the appendices of ACC's August 24, 2016 comments to EPA to inform EPA's proposed risk evaluation framework rule, ACC provides detailed comments on the elements of specific and important steps within the risk evaluation process (e.g., hazard identification, dose-response, risk characterization, peer review).[61] EPA's scoping document should provide a level of specificity that addresses each of these elements. Just providing a list of EPA guidance documents or NAS reports is not only woefully inadequate, it is not sufficiently transparent for stakeholders to understand the actual scientific approach EPA intends to take to evaluate, analyze data and information, and then integrate all the evidence from mechanistic studies, animal toxicity tests, and human epidemiological investigations for WoE decision making.

EPA also seeks input on whether current guidance documents are sufficient or if additional guidance documents that already exist, but are not noted on a particular EPA website, should be

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evaluations would not be consistent with best available science, which puts actual data and information ahead of default approaches. We also note that this is an example of a guidance document which should be updated.

[59] See http://ec.gc.ca/ese-ees/789BC96E-F970-44A7-B306-3E32419255A6/batch7_123-91-1_en.pdf.

[60] See https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0326_summary.pdf#nameddest=woe.

[61] See ACC comments, at Appendices B-E, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0400-0028.

added.[62] EPA's question is too narrow. EPA should ask the more important question regarding whether or not existing guidance is sufficient. Many of the guidance documents on the cited EPA website are extremely outdated, particularly considering the evolution of the science. For instance, EPA's Guidelines for Mutagenicity were last updated in 1986 and Guidelines for Developmental Toxicity are from 1991. These documents, and others, are over 20 years old and the science has evolved considerably over the last 20-30 years. In addition, when these documents were written they put in place policies which were driven by default assumptions based on a lack of data and a lack of understanding at that time of molecular biology, dosimetry, mode of action pathways, and toxicity mechanisms. Many of these "policies" are essentially default approaches that should be replaced by data and up-to-date 21st century knowledge.

There are areas where current guidance is simply lacking. For instance, EPA's 2006 Framework for Assessing Health Risk of Environmental Exposures to Children states "the integration of toxicity data and children's exposure estimates is an area for which no guidance exists but is needed."[63] As there will likely be cases where children are a susceptible population of concern, this is certainly an area where guidance is needed.

EPA states "EPA may also develop additional guidance(s) for risk evaluation in the future."[64] This statement is inadequate. Section 26(l) of the LCSA requires that by June 22, 2018 EPA develop any policies, procedures, and guidance necessary to carry out LCSA.[65] This section also requires that not later than June 22, 2021, and not less frequently than once every five years thereafter, EPA review the adequacy of policies, procedures and guidance. EPA should immediately begin to engage the public, in an official stakeholder process, to begin identifying areas where guidance should be developed. ACC also urges EPA to begin the process of evaluating all existing risk assessment related guidance documents for accuracy and relevance. Guidance documents that need to be updated should be identified and prioritized. There will likely be a significant amount of guidance that will need to be created and updated within the next two to five years. Assessments that are being started now should be consistent with these new and updated guidance documents. It is in the interest of all stakeholders that EPA's guidance be updated to reflect current science and that all assessments initiated after the enactment of LCSA be developed in compliance with updated guidance.

Question 7. Interagency Collaboration

As discussed in more detail in section I(E) of these comments and consistent with TSCA § 9, EPA is obligated to consult and coordinate with OSHA. EPA must describe the process it uses to consult with OSHA and the basis for EPA's findings in the scope of the risk evaluation.

Ensuring appropriate collaboration with other agencies is as important as it is with OSHA. While EPA notes that it is committed to ensuring engagement and dialogue with interagency

[62] See 82 Fed. Reg. at 7573.
[63] See EPA 2006 Framework for Assessing Health Risk of Environmental Exposures to Children, at 6-2, available at https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=158363.
[64] See 82 Fed. Reg. at 7570.
[65] See TSCA Section 26(l).

experts, EPA is reluctant to provide a general description of the process and timing it will use.[66] EPA states that codifying a process in the regulation may limit potential interagency collaboration. ACC does not agree. Offering a general description of the interagency collaboration process in the rule would set a baseline which EPA would be free to exceed; it would not limit collaboration.[67] More importantly, it helps explain to stakeholders which agencies will be consulted and when. This transparency helps stakeholders understand what to expect, and it also helps them ensure that relevant information is shared among agencies.

EPA should commit to ensuring an interagency coordination process as soon as a chemical is designated a high priority. At this early stage, interagency coordination should be used to inform the development of the scope document and then to review the scope document. In addition to including OSHA and the National Institute for Occupational Safety and Health (NIOSH) if workplace exposures may be considered, EPA should also include relevant agencies such as the Small Business Administration (SBA) Office of Advocacy and any other agencies that may be impacted by a particular condition of use (e.g., Department of Defense (DOD), Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA)).

EPA should also include other agencies that are members of the National Science and Technology Council's Committee on Environment, Natural Resources, and Sustainability's new Toxicity Assessment Committee. These agencies may likely have chemical-specific knowledge which may inform EPA's risk evaluation. Note, however, ACC does not support the use of the existing OSHA–MSHA–NIOSH–NIEHS–EPA (OMNE) committee. Use of this committee alone excludes important agencies with not only relevant expertise but also potential experience as users of chemicals, such as DOD, DOE, NASA and the SBA Office of Advocacy.

Once the scoping step is complete, the full interagency group should be afforded an opportunity to review and comment on draft risk evaluations before they are released for public comment and before the assessment is finalized. While a risk evaluation is not a regulation, it is an influential science document that will inform regulatory activities, potentially at multiple agencies. As such, interagency review coordinated by OMB may be appropriate. With this approach, a neutral arbiter would be coordinating the review and ensuring that all interagency concerns are voiced and appropriately addressed.

SPECIFIC RECOMMENDATIONS

V. Timelines for Public Comment

The proposed rule describes a risk evaluation process that has three opportunities for public comment. These include a period for comment on draft scoping evaluations, a period for comment on draft risk evaluations, and period to comment on manufacturer submitted requests for risk evaluations. ACC supports these public comment opportunities; however, longer

[66] 82 Fed. Reg. at 7573.

[67] This is to be distinguished from a detailed recitation of when and how agency consultation will occur, which is not necessary.

comment periods are needed to ensure stakeholder engagement and robust well-supported results.

A. Comment Period on the Draft Scope

ACC recommends that EPA allow a period of 60 calendar days for commenting on the draft scope. EPA's proposal of 30 calendar days is far too short to allow for sufficient evaluation of hazard information, exposure information, and planned methods.

For organizations like ACC, time is needed not only for staff to review the draft document, but also to ensure coordination with multiple member companies who will be potentially be impacted by the forthcoming risk evaluation. Time is needed to ensure that comments developed are not only representative, but also constructive and informative to EPA. A 30-day comment period is simply unworkable, particularly if EPA intends to include all conditions of use. EPA will likely also rely on pre-existing evaluations to inform screening level evaluations and a detailed review of this underlying information will take time. As draft scope documents will likely be complex, ACC recommends that the default comment period be 60 calendar days and that extensions of the comment period be allowed only for particularly complex scoping assessments.

B. Comment Period on the Draft Risk Evaluation

Once the scoping evaluation is complete, EPA will likely spend two years conducting the risk evaluation. When the draft risk evaluation is complete, EPA proposes a 30 day calendar period for public comments. ACC recommends that this comment period be at least 90 calendar days. The draft risk evaluation is expected to be a complex, science and data rich evaluation that is the culmination of over two years of work by EPA staff and contractors.

This evaluation will likely also consider multiple populations, including susceptible populations such as workers, and multiple exposure scenarios for each individual condition of use. The document may be made more complex by the fact that EPA may be evaluating multiple conditions of use and, as required by the LCSA, will include a detailed and transparent weight of the evidence evaluation of hazard and exposure information for each condition of use. The data and calculations presented in the document will also need to be scrutinized, and modeling results independently verified. This document will be far more complex than the scoping evaluation and sufficient time will be needed to review, coordinate, and prepare constructive comments for EPA.

EPA must ensure that this public comment period occurs before the draft risk evaluation undergoes peer review as the peer reviewers should be informed by the public comments. In addition, when EPA releases the draft risk evaluation, a draft charge for the peer reviewers should also be released and made available for public comment. The final charge sent to peer reviewers should be informed by and revised, as needed, following public comment on the draft to ensure that the peer review will address areas where there is significant stakeholder disagreement. This approach is consistent with the EPA SAB staff commitment to ensuring that

the committee discusses the charge in a public venue and also ensures that the charge is not unduly narrow.

C. Comment Period on Manufacturer Requested Evaluations

Once EPA receives a manufacturer request for a risk evaluation and deems it to be valid, EPA proposes a comment period of no less than 30 calendar days. ACC is concerned that this open-ended comment period could potentially delay EPA's determinations. Based on EPA's proposal, a valid manufacturer request will need to contain all the exposure and hazard information for multiple conditions of use. The information presented will be similar to what EPA would present in a draft scoping evaluation. As such, ACC recommends that EPA align this comment period with the comment period provided for the draft scoping evaluation. ACC recommends that this be 60 calendar days and that extensions of the comment period be allowed only for particularly complex manufacturer requests.

VI. The Risk Evaluation Process

In describing what the risk evaluation process will look like under the LCSA, compared to previous assessments, EPA notes that key differences include considerations of conditions of use, timelines, and determinations of unreasonable risk.[68] While these are indeed new considerations, EPA fails to mention the importance of relying on best available science and using a WoE approach, which should incorporate systematic review practices. ACC believes that these requirements, from Section 26 of the LCSA, do indeed require a new risk evaluation process—one that is much more transparent, objective and reproducible. ACC has addressed the importance of Section 26 previously in these comments and will focus in this section on the steps in the risk evaluation process.

When generally discussing the risk evaluation process, EPA points to specific NAS committee reports and EPA guidance documents to describe how the Agency will follow "accepted science policies" and approaches. As ACC has discussed previously, in responding to question 6 (see Section IV, above) this approach is not sufficiently transparent and much more specificity will be needed for stakeholders to understand the approach EPA intends to provide in the scoping document.

A. Scoping

EPA's risk evaluation process begins with the development of the scope. In the scope, EPA intends to include the conceptual model and the analysis plan. ACC suggests that this scope also include the literature search terms and results, and a screening level risk evaluation. Consistent with systematic review approaches, discussed above, EPA should ensure that the analysis plan includes the protocol for the systematic review that will be conducted in the refined risk evaluation step.

As shown below in Figure 1, in order to ensure that the in-depth risk evaluation is focused on the conditions of use of greatest potential concern, EPA must use a tiered approach that includes a

[68] See 82 Fed. Reg. at 7565.

screening level quantitative risk analysis in the scope phase. Screening-level assessments require less data and information, and are typically deterministic and based on conservative, health protective assumptions and methods. When a screening assessment indicates low risk for a particular condition of use, the Agency should have a high degree of confidence that the potential risks are much lower than the calculation and, therefore, the actual risks are lower and/or perhaps non-existent. Examples of low risk conditions of use could include occupational uses already regulated under OSHA, *de minimis* uses, or feedstock uses where the use is already regulated, as discussed above in Sections I(D)- I(F) However, when a screening-level risk assessment indicates a potential concern for an adverse effect, this does not mean that the actual risks are significant and warrant action. Rather, it indicates the Agency should take a second step in the risk evaluation process to refine the evaluation to more accurately quantify potential risks.

This tiered, iterative approach is consistent with EPA's exposure assessment practices, where screening level tools, which are "protective by design," may be used initially, and then if needed, higher tier tools, which are "more complex and allow for more realistic exposure assessments" can later be employed.[69]

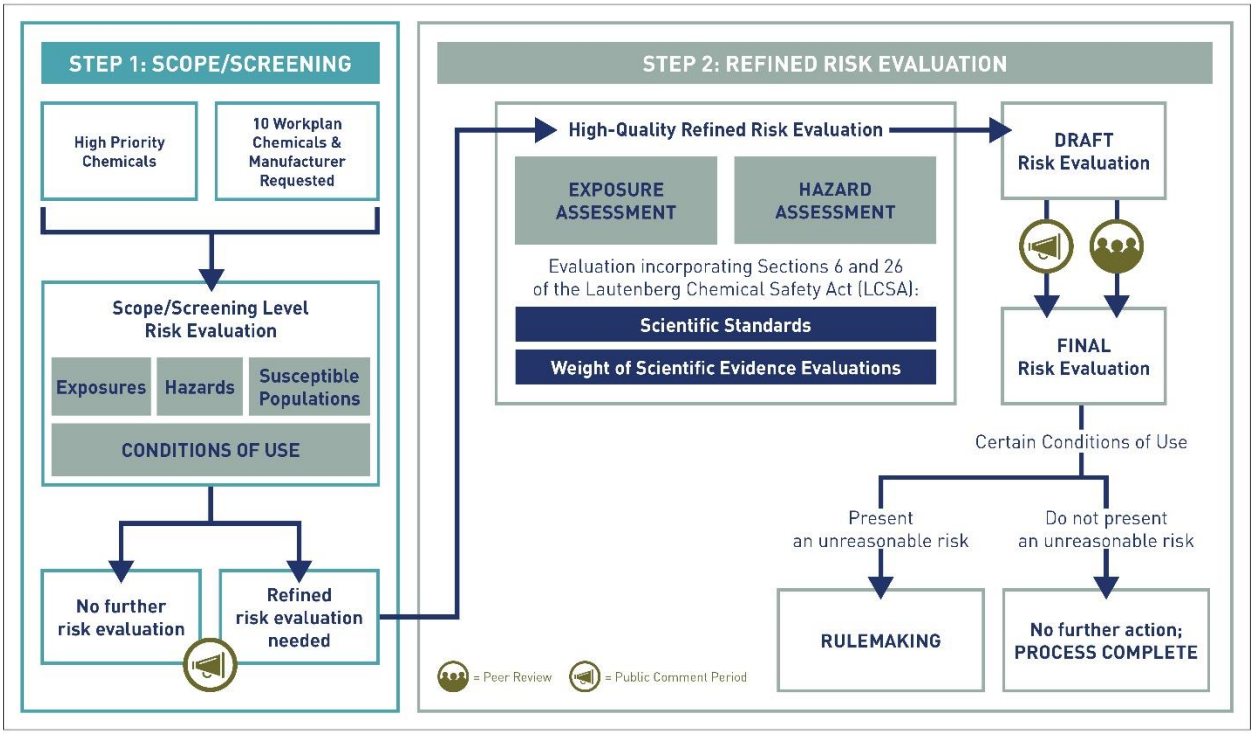

Figure 1. A Two-Step Process for Conducting Risk Evaluations
Note this is a simplified version of the process, see text for more detail

i. Conditions of Use Requiring No Further Evaluation

Once the draft scope is complete, there will likely be conditions of use which will not require any further evaluation as they are unlikely to present an unreasonable

[69] See https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca.

risk to human health or the environment. After EPA takes comment on these findings and finalizes the scope document, EPA should formally announce the conditions of use that "do not present an unreasonable risk."

While EPA may make additional findings of "does not present unreasonable risk" after the refined risk evaluation is complete, for those conditions of use that do not require further evaluation after scoping, there is no reason for EPA to wait the 3 to 3.5 years to complete the refined risk evaluation before announcing these findings. Once announced, the determination of "does not present unreasonable risk" for the specific condition(s) of use should be considered final agency action.

ii. Ensuring Sufficient Information to Conduct a Refined Risk Evaluation

While EPA intends to only conduct risk evaluations on those chemicals for which sufficient information exists, there will likely be a few cases where, once a screening level evaluation is complete, EPA will realize that certain data needs preclude conducting a refined risk evaluation. In such cases, where EPA may need to use test rules, orders or consent agreements to gather existing or new information, EPA should pause the risk evaluation process. This pause will allow the needed data to be generated in a scientifically robust manner. When this is necessary, EPA should announce this pause and its expected length in the Federal Register.

EPA should also use the Federal Register to notify the public when the pause ends and the risk evaluation commences. ACC expects that EPA will not need to pause assessments frequently, but EPA should be aware that there may be cases that necessitate the use of a pause. As ACC discusses in our comments on the Prioritization Framework, during the prioritization process, it is not appropriate for EPA to collect data to conduct full risk evaluations.[70]

B. Refined Risk Evaluation

The additional steps of the risk evaluation process include hazard assessment, exposure assessment, risk characterization, public comment, and peer review. Further details regarding the specific elements that should be in different sections of the risk evaluation are included in the appendices of ACC's August 24, 2016 comments.[71] As they were clearly presented to the Agency and are in the public docket, while they are still relevant, we will not reiterate them here.

While previously emphasized in these comments, ACC reiterates that it will be important throughout the refined risk evaluation process that EPA always rely on the best available science and follow a WoE approach that incorporates systematic review processes.

[70] See ACC comments on the Prioritization Framework Rule, submitted on March 20, 2017.
[71] See ACC comments, at Appendices B-E, available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0400-0028.

Comments on the sections of the risk evaluation process that have not been previously addressed above are presented in this section.

i. Hazard Assessment

When conducting refined hazard assessments for human health or environmental endpoints, EPA must rely on the data (reasonably available information that is scientifically valid, as defined in Section IV of these comments) first and foremost. When additional data are needed, EPA may rely on models and extrapolations. All assumptions and uncertainties associated with these models and extrapolations must be transparently discussed. When EPA is faced with conflicting data or data that could be interpreted in multiple scientifically plausible ways, EPA should strive to present the full range of scientifically supportable analyses for consideration.

As the types of data that will be available for the agency to consider will vary for each chemical and as science advances (e.g., high throughput screening tools), EPA should not specifically mandate the types of data that will be used. There will likely be cases where these data do not exist or are not of sufficient quality.

In addition, EPA states that it will evaluate, as appropriate, "acute, subchronic, and chronic effects during various stages of reproduction or life stage."[72] We urge EPA to ensure that these evaluations are necessary for the relevant conditions of use. Otherwise the Agency will spend too much time focusing on subpopulations or durations that are not relevant or critical to the refined risk evaluation. EPA must also verify that scientifically valid information exists to inform each of these scenarios and that consistent with WoE and systematic review practices, data are evaluated based on their strengths and limitations. The criteria that will be used to evaluate the strengths and limitations of studies from different streams (epidemiologic, toxicologic, mechanistic), should be presented in the protocol that is released with the scope document.

EPA states that dose-response assessments will be included where possible.[73] EPA should describe transparent criteria that will be used throughout the risk evaluation process to determine if the data are of sufficient quality for dose-response assessment. Conducting dose-response assessment on data of inadequate quality will likely lead to misleading and unreliable findings in the risk characterization step.

For environmental hazard assessment, EPA notes that the agency may rely on incident data.[74] ACC cautions EPA on this approach as incident data is very situational specific, requires a deep understanding of the particular situation and may not be of sufficient quality for use in other situations. Therefore, EPA should

[72] See 82 Fed. Reg. at 7579.
[73] Id. at 7571.
[74] Id. at 7579.

judiciously use this information and must be extremely transparent regarding all assumptions and uncertainties when incident data are used.

Similarly, EPA states that the Agency may also consider ecological field data.[75] ACC appreciates that EPA will consider using these data over modeling data as this is consistent with EPA's data preference hierarchy.[76] Consistent with this hierarchy, EPA must ensure that the data are valid, reliable and relevant for the decision being made.

ii. Exposure Assessment

For refined exposure assessment, above all else, EPA must ensure that it is using high quality representative data that are reflective of current uses for the conditions of use that are of concern. Similar to the necessity to clarify how the strengths and limitations of hazard information will be evaluated, EPA should also clearly present the approach that will be used to evaluation exposure information. As data and models permit, EPA must strive to use probabilistic exposure analyses.[77]

iii. Risk Characterization

To ensure that risk characterization is robust and consistent with not only EPA's 2000 Risk Characterization Handbook[78] and EPA Information Quality Guidelines, we recommend that EPA include the following description in the regulatory text, which is consistent with those documents:

> In the risk characterization, particularly when there are findings that a chemical presents an unreasonable risk, for each condition of use evaluated, EPA will present (i) each population addressed by any estimate of applicable human health risk or each risk assessment endpoint, including populations if applicable, addressed by any estimate of applicable ecological risk; (ii) the expected risk or central estimate of risk of the human health risk for the specific populations affected or the ecological assessment endpoints, including populations if applicable; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of risk and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data.

[75] Id. at 7571.
[76] See https://www.epa.gov/tsca-screening-tools/non-cancer-screening-approaches-health-effects.
[77] This recommendation is consistent with the comments from the CSAC on the 1-bromopropane review, see Chemical Safety Advisory Committee Minutes No. 2016-02, at 13.
[78] See EPA Risk Characterization Handbook, available at https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

In addition, the risk characterization summary should be consistent with the Section 26 science standards. As such, EPA should also include the following language at §702.41 in the regulatory text:

> This summary will include, as appropriate, a discussion of (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

EPA notes, in particular, that the Agency may exercise its discretion to include discussion of any alternative interpretation of results.[79] This statement should be clarified. To resolve differences of scientific opinion, when reasonable judgments may lead to different interpretations or alternative methods (e.g., linear and non-linear cancer modeling), the Agency should always err on the side of presenting all scientifically valid approaches. Presentation of alternatives should be the norm, not the exception.

For environmental evaluations, EPA notes that the Agency may consider "effects at the individual, species and community level..."[80] Environmental assessments are typically focused on protecting populations, not necessarily individual environmental organisms.[81] EPA must clearly justify any environmental assessments that are conducted at the individual level.

Finally, risk characterization should strive to present what is commonly termed a "reality check." EPA should ensure that its final estimate of risk is reasonable and is scientifically sound considering what is widely known about the chemical and its condition(s) of use. A good example of this can be found in a few earlier assessments that EPA conducted.[82]

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[79] See 82 Fed. Reg. at 7571.
[80] Id.
[81] See EPA's Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, 1997, available at https://semspub.epa.gov/work/HQ/157941.pdf.
[82] See for example EPA's 1985 Mutagenicity and Carcinogenicity Assessment of 1,3-Butadiene, at 6-70 and 6-71 available at https://nepis.epa.gov/Exe/ZyNET.exe/30001EUB.txt?ZyActionD=ZyDocument&Client=EPA&Index=1981%20Thru%201985&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&UseQField=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File

C. Publicly Available Information

Consistent with Section 26(j) of the LCSA, EPA commits to making information available to the public. ACC concurs with this approach and has a few suggested additions for what should be made available.

Consistent with our comments on peer review, EPA should ensure that there is an opportunity for the public to provide comments to peer review panels on key areas of the assessments that warrant detailed review, and the peer reviewers should subsequently provide responses to substantive scientific public comments that they receive. These public comments and the peer reviewer responses should be included in the final peer review report that is placed in the public docket.

In addition to providing a response to public comments received on the draft risk evaluation, EPA should provide a similar response to public comments received on the draft scope document. Both sets of agency responses should be in the public docket.

To ensure that CBI is appropriately used in the risk evaluation process, EPA should use an appropriate third party to review this information. The report from this review should also be placed in the public docket, safeguarding all CBI. This approach will help to facilitate the agencies use of CBI in the risk evaluation process, as appropriate.

D. Reassessment

EPA states that the Agency may reassess a final unreasonable risk determination at any time.[83] EPA should clarify that EPA may reassess a finding of "no unreasonable risk" or a finding of "unreasonable risk" based on a review of available information. There is no justification for reassessment to apply only to findings of "no unreasonable risk." The requirements for reassessment must be applied equally to both positive and negative risk findings. EPA should put in place a transparent petition process that will allow the public to comment on chemicals and conditions of use that may require reassessment. In addition, ACC recommends that when a determination is made to reassess a chemical substance, the Agency begin with prioritization before proceeding to risk evaluation.

E. Third Party Assessments

While EPA has not yet released guidance to assist persons interested in developing and submitting draft risk evaluations which shall be considered by the Administrator, EPA should expect to receive some risk evaluations from third parties for consideration in the process. The

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[83] See 82 Fed. Reg. at 7580.

final rulemaking should describe the process the Agency will use for internally reviewing these risk evaluations and for moving them to peer review expeditiously.

When submitted evaluations follow the same policies and procedures that will be described in the final risk evaluation rule, EPA should commit to reviewing draft risk evaluations within 90 days. This timeframe is consistent with the period of time ACC proposes that EPA allow for public comment on risk evaluations developed by the Agency. ACC also recommends that public comment be simultaneous with internal EPA review. Once the review process is complete, these assessments should move to peer review.

VII. Additional Definitions

The proposed rule discusses other important definitions. Some are new, while others are redefinitions of existing terms. Below ACC provides recommendations to inform EPA's use and interpretation of a few of these definitions.

A. Aggregate Exposure

While EPA provides an appropriate definition of aggregate exposure, consistent with the definition in the EPA Exposure Factors Handbook, ACC is concerned that when considering aggregate exposures, EPA may go beyond the intended scope of what should be in a risk evaluation under the LCSA. Risk evaluations conducted under the LCSA should be consistent with the scope of the LCSA. For instance, the LCSA does not cover the evaluation of pesticides, foods, food additives, drugs, cosmetics, tobacco products, etc. As such, it would be inappropriate for consideration of aggregate exposure to lead to a risk evaluation of non-LCSA products. If EPA felt it necessary to consider such products, any assessment conducted should be done only on a case specific basis and in consultation with the appropriate Agency or program with the statutory authority for the review and assessment of that product. EPA should commit to including relevant authorities and experts when there are such cases. We expect the need to conduct these consultations to be the exception rather than the norm.

B. Categories of Chemical Substances

The term "category of chemical substances" is clearly defined in Section 26(c) of the LCSA. In the proposed rule, EPA specifically notes that, where appropriate, a risk evaluation may be conducted on a category of chemical substances. ACC supports this approach.

EPA explicitly seeks comment on areas where additional transparency, public accountability, and opportunities for public comment can be improved.[84] To be consistent with cross-cutting requirements in Section 26(h), and to be consistent with EPA's general commitment to transparency and public accountability, when EPA finds that it is appropriate to consider a category of chemical substances, this finding should be clearly explained. The justification should include all the factors and considerations which led to the determination that a category approach was appropriate. When such an approach is taken, before EPA begins their risk evaluation, EPA should solicit public comment on its determination that it is appropriate.

[84] See 82 Fed. Reg. at 7565.

C. Potentially Exposed and Susceptible Populations

This term is clearly described in the statute. There is no need for EPA to reinterpret it or broaden the definition. The edits below bring the proposed definition in the regulatory text in line with the statutory definition:

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Agency who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, ~~including but not limited to,~~ such as infants, children, pregnant women, workers, or the elderly. ~~EPA may identify a susceptible subpopulation in an individual risk evaluation upon consideration of various intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits) or acquired (e.g., pre-existing disease, geography, workplace) characteristics that may affect exposure or modify the risk of illness or disease.~~

EPA has suggested modifying the statutory definition for two stated reasons: to clarify that EPA may identify additional populations where warranted, and to include specific authorization for EPA to consider broader factors (e.g., consideration of various intrinsic or acquired factors) when identifying this population.[85] The term "such as" is sufficiently clear to allow EPA to identify additional subpopulations when needed. Had Congress intended to explicitly include other subpopulations, Congress would have chosen different language. Similarly, if Congress felt the need to explicitly define what factors EPA must consider (e.g., intrinsic and extrinsic factors), these factors would have been included in the definition. This is not an area in need of clarification in the regulatory definition.

Similarly, EPA broadens the definition to include explicit consideration of those with illness or disease. While such considerations may very well be appropriate in case-by-case situations for particular conditions of use, had Congress intended this consideration for each condition of use evaluated under the LCSA, the language would have been included in the statute. EPA's proposed revision is clearly intended to broaden the scope of EPA's evaluation. Congress did not support such a broad scope, nor does ACC. We recommend that EPA finalize the definition provided in the statute.

D. Sentinel Exposure

EPA provides a definition for sentinel exposure and notes that while it is not a novel way of characterizing exposure, it is a new term for EPA.[86] EPA does not identify the source for its definition.

ACC is concerned that EPA's proposed definition does not reflect a fundamental understanding of how the concept of sentinel exposure has been used by other national authorities, such as Health Canada or the European Union (EU). In fact the term and use of sentinel exposures is not new in either jurisdiction; as such, it is not new to U.S. chemical manufacturers. The concept of

[85] Id. at 7576.
[86] Id. at 7658.

"sentinel exposure" or "sentinel product" is common in the EU. As was stated in a 2007 publication:

> [A]n interesting, valuable concept is that of the so-called "sentinels of exposure" or "sentinel products". The concept involves identification of a specific product (sentinel product) within a broad category (e.g. liquid laundry detergents within the broad category of household cleaning products) whose usage leads to the highest level of exposure relative to all other products within the category. Therefore, establishing that exposure to the sentinel product is "safe" (lower than an appropriate reference, e.g. a DNEL) allows to conclude that exposure derived from any other product within the category is also safe. This concept is proposed by the Canadian Health Authorities in their 2005 document entitled: "A proposed integrated framework for the health-related components of categorisation of the Domestic Substances List under CEPA 1999" (Health Canada, 2005). The same concept is also described and proposed by the US Soap and Detergent Association (SDA) as one useful approach for what they call "screening-level assessments" (SDA, 2005). This concept can be also applied to specific types of activities within one single type of product to determine the one that is associated with the highest exposure (e.g. laundry pre-treatment of clothing could be the "sentinel activity" among the different potential activities associated with a laundry detergent, such as hand wash, fabric wear, and so on). A similar approach has also been described for cosmetic and personal-care products by the European Cosmetic and Toiletry Association (COLIPA), in collaboration with US Research Institute for Fragrance Materials (RIFM) and the Brussels-based International Fragrance Association (IFRA). In this case, the dermal route is identified as largely predominant and a small number of product types are shown to contribute disproportionately to the exposure. Accounting for the exposure contributed by those key products is all that is really needed for a sound risk assessment.[87]

The definition above is consistent with the approach used by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) in its Targeted Risk Assessment User Guide,[88] which has been used extensively in REACH and is accepted by ECHA, and is also consistent with the approach used by Health Canada.[89] In the approach developed by Health Canada, a quantitative upper bound exposure estimate is used. However, in none of the descriptions provided, does the sentinel exposure equate with the "maximal" exposure to an individual or population. It is a term used to describe the type of product for which exposures will be highest compared to other products or exposures within the similar category. It does not imply that the maximal exposure (which could be the 99.99th percentile or higher) is used for risk evaluation. Thus, EPA's definition is not consistent with the common use of "sentinel exposure." EPA should consult with its Canadian and European chemical regulatory counterparts to improve the definition and approach EPA is intending to use.

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[87] See Van Engelen JG, Heinemeyer G, Rodriguez C. 2007. Consumer exposure scenarios: development, challenges and possible solutions, J Expo Sci Environ Epidemiol. Suppl 1:S26-33, available at http://www.nature.com/jes/journal/v17/n1s/full/7500577a.html.

[88] See ECOTOC User Guide, available at: http://www.ecetoc.org/wp-content/uploads/2014/06/Ecetoc_Tra_Standalone_Consumer_Tool_User_Guide_Jun2014.pdf.

[89] Health Canada developed the ComET^{tm} tool which is described at http://www.tera.org/Peer/Exposure/ExposureMeetingMaterials.htm.

Perhaps for simplification purposes, EPA has provided a succinct definition. However, as noted above, this definition does not appropriately capture how the sentinel exposure approach is currently used. Relying on the highest exposure scenario does not mean that the "maximal" exposure is used. Reasonable values from that highest exposure scenario should be used instead. A risk evaluation should not use a "maximal" exposure value as these values are typically unstable. More appropriate language would include the term "plausible exposure" or "plausible upper bound exposure." In the environmental toxicology field, it is common to use the 95th percentile under average exposure conditions. The "plausible maximum exposure" is not used. Significant revisions are needed to EPA's definition to capture the appropriate use of the sentinel exposure concept.

E. Uncertainty

EPA provides a definition for uncertainty and cites EPA's 2014 Human Health Risk Assessment Framework as the source.[90] However, as written, the definition EPA provides is actually not consistent with the source. EPA's definition should conforms to the edits below to ensure the definition is fully consistent.

> *Uncertainty* means the imperfect knowledge or lack of precise knowledge of the real world, either for specific values of interest or in the description of ~~a~~ the system.

VIII. The Process for Manufacturer Requested Evaluations

A. EPA-Initiated and Manufacturer-Requested Evaluations Should Follow the Same Review Process.

LCSA allows chemical manufacturers to request EPA to conduct a risk evaluation at Section 6(b)(4)(C)(ii). By law, a manufacturer may only request a risk evaluation of a chemical it manufacturers (not of a competitor). By rule, EPA is to specify the "form and manner" for manufacturer requests, as well as to prescribe the criteria for the risk evaluation.

In our view, EPA should largely follow the same process – and apply the same criteria – to manufacturer requested risk evaluations as it does to EPA-initiated risk evaluations arising out of the prioritization process. There is one notable difference: EPA has authority under LCSA to flexibly scope risk evaluations for chemicals with high priority designations to focus on conditions of use that are most relevant and meaningful to risk, and it should do so on a case-by-case basis. The result of this process might be that some risk evaluations cover all conditions of use; others a few; others only one.

In the case of manufacturer-requested risk evaluations, a manufacturer may support only certain conditions of use – in other words, it may sell the chemical only for use in certain kinds of products or processes. A manufacturer may strongly support risk evaluation of its chemical under the conditions of use it supports, but may not be willing to fund evaluation of its chemical for uses supported by its competitors. While we believe EPA can expand the scope of a risk evaluation beyond that requested by a manufacturer, the agency should not impose fees on a

[90] See 82 Fed. Reg. at 7568.

company that requests a risk evaluation in a manner that enriches its competitors. (Similarly, if only one manufacturer requests a risk evaluation on a chemical in a particular condition of use, it would not be appropriate to impose costs on manufacturers that did not request the risk evaluation). It will be important for EPA to address fees equitably in the upcoming fees rule; if not, the agency will discourage manufacturer requests.

This is an important observation, because Congress contemplated that EPA would receive manufacturer requests for risk evaluation, and mandates that a certain number of them be accepted. At full implementation, the law anticipates that EPA will be undertaking 5-10 manufacturer-requested evaluations (assuming that not more than 20 EPA-initiated evaluations are underway). EPA should therefore promulgate criteria that make it sufficiently attractive and possible for manufacturers to avail themselves of the option. EPA should not promulgate criteria that make it largely unworkable and impossible to seek and obtain manufacturer-requested evaluations. EPA's insistence that manufacturer-requested evaluations must include "all" conditions of use obviates the use and utility of the law's provision that allows – and requires EPA to accept manufacturer-requested evaluations in the first place, leads to an absurd result, and undermines the function and purposes of the statute.

B. EPA Should Respond Within Six Months from the End of the Comment Period to the Time it Notifies a Manufacturer of Acceptance of a Request.

EPA should align the six months established for scoping EPA-initiated risk evaluations with those requested by manufacturers. EPA should not require more than 6 months to decide whether to accept or deny a request from a manufacturer for review.

C. EPA Should Not Award "Preference" to Any Manufacturer-Requested Risk Evaluations Until the Statutory Cap is Met.

EPA is required by statute to give preference to manufacturer-requested evaluations for which EPA determines that restrictions by one or more states have the potential to have a significant impact on interstate commerce or health or the environment.[91] There is no other statutory basis for differentiating between requests. EPA proposes to treat this as a required "initial prioritization," after which it will further prioritize chemical substances for risk evaluation "based on initial estimates of exposure(s) and/or hazard(s) under one or more conditions of use or any other factor that EPA determines may be relevant."[92] ACC believes this suggested approach, which could result in manufacturer requests being inappropriately rejected by EPA, is inconsistent with legislative intent, and the efficient flow of risk evaluations under LCSA. We believe that until EPA's cap on manufacturer-requested risk evaluations is met, and except for mandatory preference under TSCA 6(b)(4)(E)(iii), the Agency should accept requests for manufacturer-requested risk evaluations on a first-come, first-served basis. EPA arguably cannot, and should not, deny any otherwise compliant request until 5 evaluations are underway, since there may not be a rational basis to be able to compare requests for evaluation. After EPA has 5 manufacturer-requested evaluations underway, it should apply the same prioritization criteria set out in the prioritization rule for selection of chemicals for evaluation. It should not

[91] TSCA 6(b)(4)(E)(iii).
[92] 82 Fed. Reg. 7569.

impose new criteria of "high hazard" and "high exposure" divorced from the criteria established in the prioritization rule.

We also strongly urge EPA to delete the catch-all provision, "any other factor EPA determines may be relevant." For the manufacturer-requested risk evaluation process to function, manufacturers must have fair notice of the criteria they must meet to have a request considered. An open-ended catchall provision not only undermines congressional intent; it eliminates fair notice to manufacturers of what information they need to gather and prepare in order to have a request considered. This is particularly the case given that manufacturers may need to conduct testing and incur significant costs before they request a risk evaluation.

D. EPA Should Not Require Submission of "All" Prior Risk Assessments by Manufacturers as a Precondition to Accepting a Manufacturer Request.

Section 702.37(b)(4) proposes that manufacturer requests must include a commitment to provide to EPA any referenced information on request, an appropriate request (subject to CBI protection, if applicable). This section provides further, however, that a manufacturer must submit any previous risk assessment conducted by a manufacturer as well as any it "possesses" or "can reasonably obtain." While we appreciate that TSCA § 26(k) requires EPA to take into consideration reasonably available information as part of Section 6 risk evaluations, this should not devolve into a blanket request for certain proprietary reviews undertaken by manufacturers. Many risk assessments fall into that category.

EPA may properly request manufacturers to produce information with a manufacturer request for a risk evaluation where the Agency has legal authority to make the request and the information is otherwise relevant to the risk evaluation, meets data quality standards, and meets Section 26 scientific standards. EPA cannot, however, create new legal authority for itself to demand otherwise protected information as a condition of considering a manufacturer request for risk evaluation.

This is to be contrasted with health and safety results, which may be inputs in a risk assessment but are distinct from a risk assessment. ACC, in fact, has long had a policy in its Chemical Products and Technology Division to make publicly available the final reports or validated final results of environmental, health, and safety research managed or sponsored under the group (subject to exceptions needed to preserve legal rights, such as proprietary rights, data compensation rights or to protect confidential business information).

EPA also may appropriately request a manufacturer to provide, as part of its request, any information that EPA could otherwise require under TSCA Sections 8(a), 8(c), 8(d) (health and safety studies), and 8(e) (which would already have been reported to the agency).

We urge EPA to revise the proposal accordingly to clarify that manufacturers will be expected to produce information relevant to the risk evaluation, and that EPA confirm it will protect CBI and respect other legal doctrines protecting against disclosure.

E. EPA Should Limit Public Comments Accepted on a Manufacturer Request to the Expected Scope of the Risk Evaluation.

As EPA properly notes in the preamble, the agency must grant any manufacturer request that complies with EPA's criteria, until the statutory minimum of 25 percent has been met. EPA may set criteria by rule. Section 702.37(e)(2) proposes a public comment period on valid manufacturer requests for risk evaluations which injects inappropriate criteria – the public is invited to submit comments and information "relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment."

For EPA-initiated risk evaluations, the legal standard that begins the risk evaluation process is EPA's determination that a chemical "may present" an unreasonable risk of injury. A determination that a chemical "presents" an unreasonable risk is not made, if at all, until the end of the risk evaluation process. A determination that a chemical "presents" unreasonable risk triggers risk management action by EPA.

EPA's proposal to accept public comment on whether the chemical "presents an unreasonable risk of injury" is thus inappropriate for three reasons. First, it applies a standard that should not apply at all to manufacturer-requested risk evaluations. These requests bypass the prioritization process, and are not subject to the same requirement that EPA make a high-priority designation based on a particular risk finding. Instead, Congress intended a separate path for manufacturer-requested evaluations, and the only statutory criteria is that EPA must give preference to chemicals where restrictions by one or more states could have a "significant impact" on interstate commerce or health or the environment. EPA's proposed regulations must respect this statutory mandate for prioritizing manufacturer requests.

Second, under no circumstances should EPA apply the legal standard for risk management to its decision whether to accept a chemical for risk evaluation. The "presents" standard is thus inappropriate.

Third, determinations whether a chemical "may present" or "presents" unreasonable risk belong to EPA alone, by statute. The public should not be invited to opine on whether this legal standard has been met.

EPA should revise this proposal. EPA should treat a valid manufacturer request for a risk evaluation as equivalent to a draft scope, and publish the document and accept public comment accordingly.

F. EPA Should Remove the Certification Requirement for Manufacturer-Requested Risk Evaluations.

Section 702.37(b)(5) requires manufacturers to include a signed certification that the information contained in the manufacturer request is "complete" and "accurate." This requirement is impossible to meet; manufacturers cannot simultaneously be asked to provide all reasonably available information, regardless of accuracy, and then be asked to certify its accuracy. Manufacturers cannot reasonably certify the accuracy of information produced by third parties,

or even EPA itself; they can only be asked to certify the accuracy of their own corporate information they collect and manage. They cannot reasonably be asked to provide a citation list and certify the accuracy of the internal information within every citation.

Likewise, manufacturers cannot be reasonably requested to certify the "completeness" of studies or other information, or even internet searches. The very fact that EPA proposes to publish manufacturer requests and seek public comment supports this point – if manufacturers were themselves capable of locating and producing third party information, there would be no need or value for public comment.

IX. Information Collection Request (ICR) Burden Estimates

Associated with the proposed rule, EPA is taking comment on ICR No. 2559.01. ACC is concerned that the burden estimates provided by EPA are far too low. For each manufacture request, EPA estimates that the burden on the public will be 96 hours and $6,935. EPA assumes the hourly wage of the person submitting the request will be $72.22. The information that EPA expects industry to provide in a manufacturer request is similar to compiling all the information that EPA will provide in prioritization and scoping. As scoping will take approximately six months, acknowledging that EPA intends to collect all the data during prioritization, it is fair to assume that it will take at least as long for manufacturers to collect, assemble, review and ensure the integrity of all the hazard and exposure information for all the conditions of use that are relevant. Consistent with EPA's approach,[93] compiling all this information will require staff with expertise in human health, ecotoxicology, fate, engineering and exposure assessment. EPA assumes, for its own staff, conducting a full risk evaluation will take 5,920 hours per chemical. If we divide this over 3 years, that is approximately 1973 hours/year. If we assume scoping takes six months, that equates to approximately 987 hours excluding any contractor resources which EPA will likely also use ($75,000/chemical). Based on this calculation, ACC cannot understand why EPA thinks the collection, assembling, review, integrity assurance, and reporting will take a manufacturer only 96 hours. This assumption appears extremely low, in fact perhaps 10 fold too low.

In addition, as manufacturers will be certifying their submissions, to ensure accuracy and completion, any submission to EPA will need to be reviewed at the highest levels of an organization. EPA assumes that this work will be done at the equivalent of a GS-13 step 5, or $72.22/hour.[94] Looking at the most recent Office of Personnel Management website, for the Washington DC area, a GS-13, step 5, in 2017 will earn an annual salary of $107,435.[95] Considering the importance of this information, as well as the review required to inform the certification, it is likely that senior employees of manufacturers will complete this task. Using the Ninth Triennial Toxicology Survey as our source,[96] it appears that in the chemical industry,

[93] See EPA ICR Attachment 1 in the rulemaking docket.
[94] ACC notes that this value seems incorrect as the most recent OPM tables show a Washington DC employee at the GS-14 step 5 level making an hourly rate of $51.48. See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB_h.pdf.
[95] See OPM salary tables, available at: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB.pdf.
[96] See Ninth Triennial Toxicology Salary Survey, Table 25, available at https://www.toxicology.org/careers/docs/Gad%20salary%20survey%202016%20IJT.pdf, see table 25.

those with experience above 9 years (thus likely more senior) make a salary ranging from $141,000-177,000, with over 50% of the respondents in this bracket making more than $165,000. Not only is EPA's estimate of the hours needed to develop a manufacturer request too low, but the wage rate is also far too low based on the most recently available published survey results. ACC would be happy to engage further with EPA to assist the Agency in making much needed refinements to both the hours needed and wage estimates assumed in the ICR.

Record of EPA Meeting with Society of Chemical Manufacturers & Affiliates (SOCMA)

May 24, 2017 2:00 – 2:30 pm

Administrator's Office, US Environmental Protection Agency, Washington, DC

Topic: Introduction to the Society of Chemical Manufacturers and Affiliates and the specialty chemical industry, discussion of "new" TSCA and Risk Management Program

EPA attendees:

Scott Pruitt, EPA Administrator

Patrick Davis, Deputy Assistant Administrator, Office of Land and Emergency Response

Nancy Beck, Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention

SOCMA attendees:

Robert F. Helminiak, SOCMA, Managing Director of Government Relations

Jennifer Abril, SOCMA, President and CEO

Steel Hutchinson, GFS Organic Chemicals, Owner and President
(SOCMA's Previous Chairman)

Beth Bosley, Boron Specialties, LLC.Owner and President

John Foley, KMCO, KMTEX LLC, President and CEO

David Grimme, Baker Hughes, Vice President, Supply Chain

David Doles, Lonza, Senior Vice President, Global Head of Business Unit - Materials Performance & Protection (SOCMA Chairman)

Meeting Handout from SOCMA attached

working

- Mtg w/ Ryan: ~~Valid~~ - synopsis of TSCA simple & Adm. plus 3rd party
- Sign & scan & email today.

5/10

- Conds of Use:
  - Legacy out - not part of conds - out of scope
  - Definitions
  -

PREPARED BY

DATE 5/12

PAGE NO.

PROJECT ACTION NOTES

PROJECT PLANNING NOTES

o FW Check-In

- OMB Briefing
  - OGC - David F.
    - Logical outgrowth - A range of risk - depending on which change. Save ver

o OMB Re: RE & Pri Rules

- Prioritization: Pre-prioritization
  - If definitions in preamble, may still hv log. outgrowth issues, per OMB OGC.
- RE: - Conds of Use - Removed "all"; will sk mult. uses but not 1000's, as discussed today.
  - Mfr - requested - a u fees
  - Scitor MS: - Syst. Rev. is Lauly's issue. Wants more defin.
  - Interagy collab. - Adding leg text re early appr
  - Mk'g mi'ble risk determ. (defin.)
    - Commenters liked "considerations"
    - Will amend them in preamble.
- EO 13777 - Lk'g for ~~[illegible]~~ de minimis burden exemption. Danielle talked to Angela; Danielle needs to consult further. Lauly: E.O. uses ex. of $50,000 annual cost as low burden.
- Guidance: can submit as supplemental doc or submit as sep. doc. Need to discuss further.

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PROJECT ACTION NOTES

THU 6/1

- Call Mike Flynn re V/V

PROJECT PLANNING NOTES

Kurt - St. Sci.
Melanie
Olga

EWG: RE RULE

- COU genl'y & how applied in mfr-requested.
- Preambleto proposal was H. - must eval. subst. as a whole. All uses.; entire lifecycle.
- R'bly foreseen. - Some "off label" uses can be foreseen. E.g., use of shredded tires in athletic fields. Can expedite cert high risk uses.
- Non-TSCA uses. CHPAC rec'd. Ex. of fluoride in pest's prog. less clear than all TSCA uses being covered.
- Accidents/spills - shd be covered to extent possible.
- Always consid potent'ly exposed sub-pops.
- Shd not use lack of info as reas to exclude a spec. cond of use. Use auths to ntk sure we have info bef. init eval.
- Mfr-Requested: Agree w/proposal th there be soft info bef EPA accepts. Must go thru same proc as other evals.

EPA'S PROPOSED CHEMICAL SAFETY RULES, CHEMICAL INDUSTRY COMMENTS AND EPA'S FINAL RULES

PROPOSED RULE JAN. 19, 2017	AMERICAN CHEMISTRY COUNCIL COMMENTS	FINAL RULE, JUNE 22, 2017
PRIORITIZATION		
"Pre-prioritization" period for information gathering	Get rid of pre-prioritization	No pre-prioritization period
Has high-priority chemicals as default	Get rid of default high-priority chemical designation	Deletes majority of references to high-priority default
No reference to science standards in prioritization, giving EPA needed discretion and flexibility	Reference science standards in prioritization rule	Includes direct references to science standards
Not much emphasis on low-priority "safe" designations	More emphasis on low-priority designations	More emphasis on low-priority designations
No tiered approach to information gathering	Use tiered approach to information gathering	Includes tiered approach to information gathering
RISK EVALUATION		
Risk evaluations must include all uses and exposures	Do not include all uses or exposures in risk evaluation	EPA may exclude uses from risk evaluations
No indication non-TSCA uses will be excluded	Exclude non-TSCA uses	EPA may exclude non-TSCA uses
No indication OSHA-regulated uses will be excluded	Exclude OSHA-regulated uses	EPA may exclude uses assessed by other agencies like OSHA
No indication low-exposure uses will be excluded	Exclude low-exposure uses	May exclude "de minimus" exposures or uses in a closed system, may exclude impurities
Declined to include science standards in rule to provide EPA with needed discretion and flexibility	Define science standards in rule	Science standards defined in rule
Expanded definition for vulnerable populations	Do not expand definition for vulnerable populations	Removed expanded definition of vulnerable populations
Manufacturers must submit a request for the whole chemical and all its uses	Allow manufacturers to make requests on specific uses only	Manufacturers may submit a request on only a small set of uses, EPA responsible for rest
Preference for most hazardous requests	No hazard-based preference for manufacturer requests	Preference will be given to requests in order received
Manufacturers must include all reasonably available information	Manufacturers should not have to include all prior risk assessments in request	Manufacturers can exclude some prior risk assessments on the chemical

News Releases from Headquarters

EPA Marks Chemical Safety Milestone on 1st Anniversary of Lautenberg Chemical Safety Act

Agency Meeting Statutory Responsibilities and Deadlines

06/22/2017

Contact Information:
(press@epa.gov)

WASHINGTON – (June 22, 2017) Today, on the one-year anniversary of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Administrator Scott Pruitt announced that EPA has met its first-year statutory responsibilities under the law. This includes issuing three new rules, providing a guidance document for external parties, and releasing the scoping documents for the first 10 risk

evaluations that will be conducted.

“The activities we are announcing today demonstrate this Administration’s commitment to providing regulatory certainty to American businesses, while protecting human health and the environment,” said Administrator Pruitt. **“The new process for evaluating existing chemicals outlined in these rules will increase public confidence in chemical safety without stifling innovation.”**

The Act amends the nation’s primary chemicals management law known as the Toxic Substances Control Act (TSCA). The legislation received bipartisan support in the U.S. House of Representatives and the Senate, and provides significant new responsibilities and authorities to EPA to advance chemical safety.

EPA has completed the following implementation activities at this one-year anniversary:
Finalized a rule to establish EPA’s process and criteria for identifying high priority chemicals for risk evaluation and low priority chemicals for which risk evaluation is not needed. In response to public comments, this final rule affirms EPA’s commitment to following the best available science, engaging stakeholders in the prioritization process, and recognizing the value of designating chemicals as low priority when appropriate. Read more: http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation

- Finalized a rule to establish EPA's process for evaluating high priority chemicals to determine whether or not they present an unreasonable risk to health or the environment. In response to public comments, this final rule clearly defines important scientific terms to ensure transparency and confidence in the risk evaluation process while retaining flexibility to allow for new scientific approaches to be incorporated as they are developed. Additionally, the final rule clarifies EPA's authority to determine what uses of a chemical are appropriate for risk evaluation, ensuring that the Agency's resources are focused on those uses that may pose the greatest risk. Read more: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-chemicals-under-tsca
- Finalized a rule to require industry reporting of chemicals manufactured or processed in the U.S. over the past 10 years. This reporting will be used to identify which chemical substances on the TSCA Inventory are active in U.S. commerce and will help inform the chemicals EPA prioritizes for risk evaluation. In response to public comments, EPA streamlined the reporting requirements for manufacturers and processors in the final rule to help reduce regulatory burden. Read more: https://www.epa.gov/tsca-inventory/tsca-inventory-notification-active-inactive-rule
- Released scope documents for the initial ten chemicals for risk evaluation under the amended law. These documents identify what uses of the chemicals will be evaluated and how the evaluation will be conducted. Read more: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-chemicals-under-tsca#ten
- Released guidance for external parties interested in submitting draft risk evaluations to the EPA for consideration. Read more: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-assist-interested-persons-developing-and

This past year has been marked by many EPA accomplishments to implement the amended law. More information on EPA's progress to date and a full list of all the TSCA implementation activities can be found here: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-5

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Environmental Topics **Laws & Regulations** **About EPA**

Subject: Retirement Announcement

Colleagues,

I'm writing to let you know that I have decided to retire from federal service at the end of August. My last day in the office at EPA will be Thursday, August 24th.

August 12th will mark 38 years at the EPA for me. I started work in the TSCA program right after law school, so I'm very pleased to be able to end my EPA career as the Office Director for OPPT and as the Principal DAA/Acting AA for chemical safety. Between my bookend stints in the chemical safety program, I also spent parts of my career in the Administrator's Office during the George H.W. Bush/William Reilly Administration, in the Policy office, and in OEI.

I have enjoyed my career at EPA immensely. It is hard to imagine a better opportunity to serve the American public, pursue a vitally important mission, learn an enormous amount, and work with incredibly smart, dedicated and collegial people. I hope to have the opportunity to see and talk with many of you before I retire.

All the best,
Wendy

Wendy Cleland-Hamnett
Acting Assistant Administrator
Principal Deputy Assistant Administrator
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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

Alliance of Nurses for Healthy Environments, *et al.*, Petitioners, v. United States Environmental Protection Agency, *et al.*, Respondents.	Nos. 17-1926 & Consolidated Cases (MCP No. 149)

[CORRECTED] MOTION OF AMERICAN CHEMISTRY COUNCIL ET AL. FOR LEAVE TO INTERVENE ON BEHALF OF RESPONDENT

Pursuant to Rule 15(d) of the Federal Rules of Appellate Procedure and Local Rule of Appellate Procedure 12(e), the American Chemistry Council, American Coatings Association, American Coke and Coal Chemicals Institute, American Fuel & Petrochemical Manufacturers, American Forest & Paper Association, American Petroleum Institute, Battery Council International, Chamber of Commerce of the United States of America, EPS Industry Alliance, IPC International, Inc., doing business as IPC – Association Connecting Electronics Industries, National Association of Chemical Distributors, National Mining Association, Polyurethane Manufacturers Association, Silver Nanotechnology Working Group, Society of Chemical Manufacturers and

Affiliates, Styrene Information and Research Center, and the Utility Solid Waste Activities Group (collectively, "Movants"), by and through undersigned counsel, respectfully move to intervene in support of Respondents the U.S. Environmental Protection Agency ("EPA") and its Administrator in each of the petitions for review consolidated under the lead case *Alliance of Nurses for Healthy Environments, et al. v. EPA,* No. 17-1926 ("Petitions").

These Petitions were originally filed in three separate courts of appeals and were recently consolidated before this Court by the United States Judicial Panel on Multidistrict Litigation. Consolidation Order at 1, MCP 149 (Sept. 1, 2017) (Doc. No. 3). The consolidated Petitions seek review of the "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act," 82 Fed. Reg. 33,726 (July 20, 2017); 40 C.F.R. § 23.5(a) ("Risk Evaluation Rule"), a rule promulgated by EPA under the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§ 2601-2697, the primary federal statute that regulates the manufacturing, processing, distribution, and use of chemical substances and mixtures in the United States.

Movants' timely request to intervene in support of EPA's final rule should be granted. Movants are associations that represent industries directly regulated and affected by the Risk Evaluation Rule, because they manufacture, process, distribute or use chemicals, and the procedures and criteria EPA has set in the Risk

Evaluation Rule will ultimately affect what chemicals their members may manufacture, process, transport and use, and under what restrictions, if any. Petitioners object to the approach EPA has taken and a ruling by this Court, the practical effect of which would be expanding the chemicals and uses that would be covered and restricted by the risk evaluation process and otherwise negatively affecting the market prospects of existing chemicals. Hence, the consequences of any relief Petitioners might obtain would be borne directly by Movants' members, for whom chemicals regulated by TSCA are essential to the very conduct of their businesses. As such, Movants have direct, substantial, and legally protectable interests in the outcome of these consolidated petitions, which seek to overturn the Risk Evaluation Rule. These are interests that Respondents do not adequately represent.

Counsel for Movants contacted counsel for the each of the Petitioners and for Respondents in these consolidated cases. *See* Local Rule 27A. All of the parties responded that they take no position on the motion at this time.[1]

[1] Specifically, counsel for Respondents stated that "EPA will reserve taking a position until after reviewing the potential intervenors' motion." Counsel for Alliance for Nurses for Healthy Environments, et al. stated that "Alliance of Nurses for Healthy Environments, Cape Fear River Watch, and Natural Resources Defense Council take no position on the motion at this time, but reserve their right to oppose the motion based on its content." Counsel for the Environmental Defense Fund stated that "[t]he Environmental Defense Fund takes no position on this motion at this time."

BACKGROUND

TSCA was amended in 2016 to require EPA to select a minimum number of chemicals in commerce for risk evaluations. The amended statute requires EPA to promulgate three regulations to achieve its mandate, *see* 15 U.S.C. § 2605(b)(1), (4), all of which have now been promulgated. The first (known as the "Inventory Reset Rule"[2]) sorts the master list of chemicals, called the TSCA Inventory, based on whether the chemicals are active or inactive in commerce. The second (known as the "Prioritization Rule"[3]) sets out procedures for the agency's designation of High Priority chemicals for purposes of risk evaluation. The third (the "Risk Evaluation Rule" at issue here) mandates a risk-based determination for the evaluated chemicals. Although these rules are separate, they are designed to function together; for example, the risk evaluation process cannot start until chemicals are prioritized. Although only the Risk Evaluation Rule is at issue in the instant matter, all three rules are described below for context to evaluate this Motion.

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[2] TSCA Inventory Notification (Active- Inactive) Requirements, 82 Fed. Reg. 37,520 (Aug. 11, 2017). Environmental Defense Fund has separately petitioned for review of this rule. *Envtl. Def. Fund v. EPA*, No. 17-1201 (D.C. Cir.).

[3] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act," 82 Fed. Reg. 33,753 (July 20, 2017). Petitioners here have separately petitioned to review this rule. *See Safer Chemicals Healthy Families, et al. v. EPA, et al.*, No. 17-72260 and consolidated cases (9th Cir.) (MCP No. 148).

Inventory Reset Rule. The Inventory Reset Rule establishes the procedures EPA will follow to "reset" the TSCA chemical inventory. Only chemicals listed on the TSCA inventory are legal for use in the United States. Under the new rule, EPA has directed chemical manufacturers to identify the chemicals they manufacture that are currently in commerce. If a chemical is not identified as active, it will be listed as "inactive." Only active chemicals would be subject to prioritization and, potentially, EPA's risk review procedures.

Prioritization Rule. The Prioritization Rule establishes the procedures and criteria EPA will use to designate "High-Priority Substances" for risk evaluation, or "Low-Priority Substances" for which risk evaluations are not necessary until such time as determined by the Administrator. This Rule "describes the processes for formally initiating the prioritization process on a selected [chemical substance], providing opportunities for public comment, screening the [substance] against certain criteria, and proposing and finalizing designations of priority." 82 Fed. Reg. at 33,753. The Prioritization Rule also clarifies EPA's authority to determine what "conditions of use"[4] of a chemical are appropriate for risk evaluation.

[4] "[C]onditions of use" is a term of art, *see* 15 U.S.C. § 2602(4) (the term "means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of") and is not the same as the term "use."

Risk Evaluation Rule. A risk evaluation cannot occur until a chemical has been designated High Priority. In its Risk Evaluation Rule, EPA establishes the procedures and criteria it will use when conducting those risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use for that chemical. The Risk Evaluation Rule specifies procedures for the following steps of the risk evaluation process that must be followed: scoping, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. Subsequent risk management action may result in new requirements being placed on the use of a chemical based on the risk determination. EPA has further elaborated on the risk assessment in guidance.

The Movants are associations that represent industries and members that the Risk Evaluation Rule directly regulates and affects, because they manufacture, process, distribute or use chemicals that will be affected by the Risk Evaluation Rule and the related Prioritization Rule. These include:

- Movant American Chemistry Council ("ACC"). ACC represents a diverse set of nearly 150 leading companies engaged in the business of chemistry, including by participating on behalf of its members in administrative proceedings before EPA and in litigation arising from those proceedings that affects member company interests. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy.

- Movant American Coatings Association ("ACA") is the national nonprofit trade association working to advance the paint and coatings

industry and the 287,000 professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals who produce over $30 billion in paint and coating product shipments. ACA members use and produce chemicals subject to regulation under TSCA, including the Prioritization and Risk Evaluation Rules.

- Movant American Coke and Coal Chemicals Institute ("ACCCI") is an association for the metallurgical coke and coal chemicals industry. ACCCI members include U.S. merchant coke producers and integrated steel companies with coke production capacity, as well as the companies producing coal chemicals in the U.S. Coke and coals chemicals are subject to regulation under TSCA, including the Prioritization and Risk Evaluation Rules.

- Movant American Fuel & Petrochemical Manufacturers ("AFPM") is a national trade association whose members include over 400 refiners and petrochemical manufacturers that produce gasoline, diesel, jet fuel, other fuels and home heating oil, as well as the petrochemicals. AFPM members use and produce chemicals subject to regulation under TSCA, including the Prioritization and Risk Evaluation Rules.

- Movant American Forest & Paper Association ("AF&PA") serves the sustainable pulp, paper, packaging, tissue and wood products manufacturing industry in the United States. AF&PA member companies make products essential for everyday life from renewable and recyclable resources. The forest products industry accounts for approximately four percent of the total United States manufacturing Gross Domestic Product, manufactures over $200 billion in products annually, and employs approximately 900,000 men and women. AF&PA's members use chemical substances subject to TSCA to manufacture or process their products, including chemicals subject to the Prioritization and Risk Evaluation Rules.

- Movant American Petroleum Institute ("API") is a national trade association representing all aspects of America's oil and natural gas industry. API has more than 625 members, from the largest major oil companies to the smallest of independents, from all segments of the industry, including producers, refiners, suppliers, pipeline operators and marine transporters, as well as service and supply companies that support

all segments of industry. API's members are involved in all major points of the chemical supply chain—from natural gas and crude oil production, to refinery production of fuels and other products, to service companies using chemicals. API's members are affected by all of EPA's activities under TSCA, both directly as companies subject to regulation and indirectly as customers of regulated companies. API members manufacture and use chemicals subject to the Prioritization and Risk Evaluation Rules.

- Movant Battery Council International ("BCI") promotes the interests of the battery industry whose members include lead battery manufacturers and recyclers, marketers and retailers, and suppliers of raw materials and equipment. Components used by the industry are subject to regulation under TSCA, including the Prioritization and Risk Evaluation Rules.

- Movant Chamber of Commerce of the United States of America is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. The Chamber's members include companies in all of the sectors covered by each of the other intervenors—chemicals, coatings, refiners, petrochemicals, petroleum, forestry, wood products, batteries, electronics, energy, and electricity, among many others. These companies use chemicals subject to regulation under TSCA, including the Prioritization and Risk Evaluation Rules.

- Movant EPS Industry Alliance represents manufacturers of expanded polystyrene ("EPS"). EPS and the chemistries used to produce it are subject to TSCA jurisdiction, including the Prioritization and Risk Evaluation Rules.

- Movant IPC International, Inc., doing business as IPC – Association Connecting Electronics Industries ("IPC"), is a not-for-profit association consisting of 4,200 member facilities that manufacture electronics or supply equipment and materials to industries manufacturing electronics. The majority of IPC members use chemicals to manufacture products or sell products containing chemicals, but a small percentage manufacture and/or distribute chemicals to electronics manufacturers. As manufacturers, distributors and users of chemicals, IPC members are

affected by TSCA rulemaking. The Risk Evaluation and Prioritization Rule proscribe the process under which the chemicals used by our members will be regulated in the future. The development and manufacture of electronics is directly affected by restrictions on the chemical used to manufacture them and thus effect IPC members.

- Movant National Association of Chemical Distributors ("NACD") is an association of chemical distributors and their supply-chain partners. NACD's members process, formulate, blend, repackage, warehouse, transport, and market chemical products for over 750,000 customers. The chemical distribution industry represented by NACD employs over 70,000 people and generates $5.14 billion in tax revenue for local communities. The products distributed by NACD members are subject to EPA's TSCA jurisdiction, including the Prioritization and Risk Evaluation Rules.

- Movant National Mining Association ("NMA") is a national trade association that represents the interests of the mining industry—including the producers of most of America's coal, metals, and industrial, and agricultural minerals, as well as the manufacturers of mining and mineral processing machinery, equipment, and supplies—before Congress, the administration, federal agencies, the judiciary, and the media. NMA has more than 300 members, many of which manufacture, process, and/or use chemical substances subject to TSCA, including the Prioritization and Risk Evaluation Rules.

- Movant Polyurethane Manufacturers Association ("PMA") is the association dedicated to the advancement of the cast polyurethane industry. Its members include processors, suppliers and other members in the cast urethane industry. The chemicals which are used to manufacture polyurethanes are substances subject to EPA's TSCA jurisdiction, including the Prioritization and Risk Evaluation Rules.

- Movant SOCMA – Society of Chemical Manufacturers and Affiliates ("SOCMA") is the U.S.-based trade association dedicated solely to the specialty chemical industry. SOCMA's 200 members produce intermediates, specialty chemicals and ingredients used to develop a wide range of industrial, commercial and consumer products. SOCMA's manufacturing members all produce chemicals subject to regulation under TSCA that could be addressed by the Prioritization and Risk

Evaluation Rules, and all of its members could be impacted by EPA's actions under the rules. SOCMA was actively involved in the legislative and rulemaking processes leading to issuance of the Prioritization Rule and the Risk Evaluation Rule, filing comments on the proposed versions of both.

- Movant Silver Nanotechnology Working Group ("SNWG") is an industry-wide effort to advance the science and public understanding of the beneficial uses of silver nanoparticles in a wide-range of consumer and industrial products. Silver nanotechnology is subject to EPA's TSCA jurisdiction, including the Prioritization and Risk Evaluation Rules.

- Movant Styrene Information and Research Center ("SIRC") is a nonprofit trade association that collects, develops, analyzes, and communicates information to guide industry and government on health and environmental issues associated with styrene and ethylbenzene. Member companies manufacture or process styrene and ethylbenzene. Associate member companies fabricate styrene-based products. Styrene and ethylbenzene are chemical substances subject to TSCA, including the Prioritization and Risk Evaluation Rules.

- Movant Utility Solid Waste Activities Group ("USWAG") is responsible for addressing solid and hazardous waste and chemical management issues on behalf of the utility industry. USWAG was formed in 1978, and is a trade association of over 130 utility operating companies, energy companies and industry associations. USWAG engages in regulatory advocacy pertaining to TSCA, among other policy areas. The industry uses substances subject to the requirements of TSCA, including the Prioritization and Risk Evaluation Rules.

ARGUMENT

I. Movants Satisfy the Standards for Intervention as of Right

In this Circuit, a court shall grant intervention as of right if an intervenor makes a timely motion and can show (1) an interest in the subject matter of the action, (2) that the protection of this interest would be impaired by the disposition

of this action, and (3) that the interest is not adequately represented by existing parties to the litigation. *See* Fed. R. Civ. P. 15(d); Fed. R. Civ. P. 24(a); *In re Sierra Club,* 945 F.2d 776, 779 (4th Cir. 1991) ("must show interest, impairment of interest, and inadequate representation"); *Teague v. Bakker,* 931 F.2d 259, 261 (4th Cir. 1991) (*citing Virginia v. Westinghouse Elec. Corp.*, 542 F.2d 214, 216 (4th Cir. 1976)). These requirements should be interpreted broadly, as "liberal intervention is desirable to dispose of as much of a controversy involving as many apparently concerned persons as is compatible with efficiency and due process." *Feller v. Brock*, 802 F.2d 722, 729 (4th Cir. 1986).[5]

[5] Although this Court has not resolved the issue, a majority of the courts of appeal has correctly held that intervenors are not required to satisfy the requirements for Article III standing, so long as they are not seeking additional relief and satisfy the requirements for intervention as of right under Rule 24(a). *See e.g., King v. Governor of the State of New Jersey,* 767 F. 3d 216, 246 (3d Cir. 2014) (parties seeking to intervene as of right need not have independent standing so long as another party with standing on the same side as the intervenor is in the case, citing case law); *accord Town of Chester v. Laroe Estates,* 137 S. Ct. 1395 (2017) (requiring standing when intervenor sought relief different from plaintiff). *But see Jones v. Prince George's County, Maryland,* 348 F. 3d 1014, 1017 (D.C. Cir. 2003). This Court need not resolve the issue, because Movants have Article III standing to intervene here. Movants' members would have standing (as members of the regulated community directly impacted by the rules at issue who stand to be injured by this litigation), the subject of the litigation is germane to the Movants' interests, and no individual member's participation is necessary for the litigation. *See* Declaration of Michael P. Walls (Attachment A) ("Walls Decl."); Declaration of Jim McCloskey (Attachment B) ("McCloskey Decl."); *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333 (1977).

Here, Movants satisfy these requirements, and this Court should grant this Motion so that they may protect their important interests.

A. The Motion to Intervene is Timely

Petitioners in this consolidated case filed their petitions for review on August 10 and August 11, 2017. This motion is therefore timely because Movants filed within the time allotted by the Federal Rules. Fed. R. App. P. 15(d) (requiring parties to move for intervention within 30 days of the filing of a petition for review) and 26(a)(1) (when, as here, a deadline lands on a weekend, the filing is on the "next day that is not a Saturday, Sunday, or a legal holiday"). In addition, allowing Movants to intervene will not, as a practical matter, disrupt the proceedings or prejudice the parties because they are seeking to join this case at the earliest possible stage. *Alt v. EPA*, 758 F.3d 588, 591 (4th Cir. 2014) (timeliness based on "how far the underlying suit has progressed" and whether the other parties would suffer "prejudice").

B. Movants Have a Significant Protectable Interest in the Subject of the Petitions

The Federal Rules do not define what "interest" is required to support intervention of right. In the Fourth Circuit, for an interest to be "protectable," it must be a "significantly protectable interest." *Teague*, 931 F. 2d at 261 (finding significant interest because the intervenors "stand to gain or lose" by outcome); *see also Sierra Club,* 945 F.2d at 779 (environmental group had protectable interest in

subject matter of waste management company's challenge to state rule restricting new waste treatment, storage or disposal facility); *United Guar. Residential Ins. Co. of Iowa v. Phila. Sav. Fund Soc'y*, 819 F. 2d 473, 475 (4th Cir. 1987) (interest in insurance rights sufficiently significant).

Here, unquestionably, Movants have a significantly protectable interest in the subject matter of these consolidated Petitions. Movants' members manufacture, process, distribute, or use chemicals that are essential to their industries and businesses and are subject to the Risk Evaluation Rule. *See, e.g.,* Walls Decl. ¶¶ 5. 20(a)-(p); McCloskey Decl. ¶¶ 4-5, 8. After determining the priority of chemicals for evaluation, EPA will follow the process and criteria in the Risk Evaluation Rule for high priority chemicals to determine whether the chemical presents an unreasonable risk of harm to health or the environment under any foreseeable conditions of use, the result of which determination could lead to restrictions on such chemical's use, up to and including a ban. These same procedures and criteria must be followed when manufacturers request an EPA-conducted risk evaluation of any existing or new chemical substance.

Accordingly, Movants potentially "stand to lose" access to chemicals that are at the core of their operations, or to have that access restricted, depending upon the results of EPA's evaluations under the Risk Evaluation Rule. Likewise, Movants could lose millions of dollars and years of research invested in a

chemical, if an EPA risk evaluation ultimately results in restrictions. Further, enormous uncertainty could be created if the Petitioners were to prevail and would affect users' confidence in planning new uses for existing substances. Thus, how EPA conducts these risk evaluations, including what conditions of use of a particular chemical EPA must assess during these evaluations, are crucial to Movants. Movants have a direct interest in Petitioners' challenge, which seeks to overturn the process set by the Risk Evaluation Rule and expand the conditions of use that EPA would be required to consider in a risk evaluation.

Movants have also demonstrated the significance of their direct and protectable interest in the Risk Evaluation Rule by participating in the rulemaking that culminated in the final rule.[6] When a group seeking intervention had participated "in the administrative process leading to the governmental action," the group has a direct and substantial interest in the litigation. *Michigan State AFL-CIO* v. *Miller*, 103 F.3d 1240, 1245-46 (6th Cir. 1997).

In sum, Movants have the significant interest needed to intervene.

[6] *See, e.g.*, Walls Decl. at ¶ 13; McCloskey Decl. at ¶ 6. Other examples can be found at www.regulations.gov, docket number EPA–HQ–OPPT–2016–0654.

C. The Disposition of These Consolidated Petitions Could Impair or Impede Movants' Ability as a Practical Matter to Protect Their Significant Interests in the Risk Evaluation Rule

Further, resolution of these consolidated Petitions could impair or impede Movants' ability to protect their interests in the Risk Evaluation Rule. In this Circuit, it is sufficient that a judgment "would impair or impede the … Intervenors' ability to protect their interest in the subject matter of th[e] litigation." *Teague,* 931 F.2d at 261 (the intervenors' significant interest in recovery would be impaired even if still retained rights of action and potential effect was contingent in part on other litigation); *United Guar.,* 819 F. 2d at 475 (sufficient impairment if disposition of the pending case "might well" deprive the proposed intervenors of a significant insurance benefit). Moreover, it is sufficient that the outcome could "as a practical matter" impair or impede the proposed intervenor's interests in a separate administrative proceeding. *Sierra Club,* 945 F.2d at 779 (if court were to enjoin certain sections of regulation, it "will impede Sierra Club's ability to protect its interest in the administrative proceeding").

As detailed above, Movants' members manufacture, process, distribute, use and otherwise rely on chemicals in the conduct of their businesses, and Petitioners seek a court order that would require EPA to change the process and criteria established in the Risk Evaluation Rule to make the process more onerous for Movants in order to impose additional restrictions on how chemicals are

manufactured, processed, distributed and used. Movants' interests in sustaining their members' operations could be impeded or impaired if the disposition of this action results in the changes in the Risk Evaluation Rule that Petitioners are pursuing here. Only if this Court allows Movants to participate in this action will Movants be able to protect fully their interests in the evaluation approach in the Risk Evaluation Rule.

D. Existing Parties Do Not Adequately Represent Movants' Interests

The existing parties do not adequately represent Movants' interests in this case. In general, the Supreme Court has held that a movant seeking to intervene as of right need only show that representation of its interests "may be" inadequate, and the burden of showing so is "minimal." *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 (1972); *see Sierra Club,* 945 F.2d at 779-80 (citing *Trbovich* for adequacy standard, emphasizing that this requirement is met if applicant shows "representation of its interest *may be* inadequate") (emphasis in original); *Teague,* 931 F.2d at 262 (citing *Trbovich* for adequacy standard); *see also United Guar.*, 819 F.2d at 475 (same). In *Sierra Club,* for example, this Court found an organization that supported the state agency's defense of its regulation was not adequately represented by the preexisting parties, because while the state agency ostensibly represented "all of the citizens," the organization represented "only a subset of citizens concerned" with the subject matter of the action and did

"not need to consider the interest of all … citizens." 945 F.2d 780 (reversed denial of intervention as of right, even though interests of Sierra Club and state agency "may converge"). The same is true here. *See also*, *Sierra Club v.* EPA, 557 F.3d 401 (6th Cir. 2009); *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 735 (D.C. Cir. 2003); *Military Toxics Project v. EPA*, 146 F.3d 948, 954 (D.C. Cir. 1998); *Conservation Law Found. of New England v. Mosbacher*, 966 F.2d 39, 41-44 (1st Cir. 1992). *But see Stuart v. Huff*, 706 F.3d 345, 351 (4th Cir. 2013).[7]

Here, Movants are not represented at all by the Petitioners, who are directly adverse to Movants. Nor do Respondents adequately represent Movants' interests, as EPA does not represent the distinct private interests of Movants and their members. Movants exist in part to ensure that the companies they represent are able to manufacture, process, distribute, or use chemicals as needed, and thereby operate the nation's manufacturing and energy facilities, preserve and create jobs, and produce successful businesses, all in an environmentally sound manner.

[7] *Stuart* involved intervention in a district court case concerning the constitutionality of a state statute where intervention could have significantly increased the burdens on the government and the court. *Id.* at 350-51 ("motions to intervene can have profound implications for district courts' trial management functions;" additional parties would "complicate the discovery process," and "complicate the government's job" due to the "prospect of a deluge of potential intervenors"). By contrast, the Court here will decide the Petitions based on EPA's administrative record at the appellate level. Movants would not unduly complicate the litigation process and have made a significant, and we believe successful, effort to join interested industry participants in a single motion.

Movants cannot rely solely on a public agency to safeguard these narrower concerns. *See Sierra Club*, 945 F.2d at 780. EPA may well be focused to a greater extent than Movants on issues of administrative convenience and flexibility. Likewise, Movants are likely to be focused to a greater degree than EPA on the potentially deleterious consequences that particular agency actions may have on Movants' members' chemicals or operations.

Indeed, as other courts have held, EPA's more expansive obligation under federal laws like TSCA is to represent the general public interest, not the private interest of Movants' members. *See, e.g.*, *Fund for Animals*, 322 F.3d at 736 ("[W]e have often concluded that governmental entities do not adequately represent the interests of aspiring intervenors."); *Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 973-74 (3d Cir. 1998) (federal agency and private businesses seeking to intervene had "interests inextricably intertwined with, but distinct from" each other and, thus, agency could not adequately represent private interests); *Sierra Club v. Espy*, 18 F.3d 1202, 1208 (5th Cir. 1994) (industry intervention allowed because "[t]he government must represent the broad public interest, not just the [concerns of the industry group]").

Thus, Movants and their members have significant interests distinct from the EPA's more general mandate that could be impaired or impeded by the disposition

of these Petitions.[8] Accordingly, Movants urge this Court to grant them leave to intervene as of right to represent fully their legitimate interests.

II. In the Alternative, the Court Should Grant the Movants Permissive Intervention Under Rule 24(b)

In the alternative, Movants seek leave for permissive intervention. Fed. R. Civ. P. 24(b)(1) authorizes permissive intervention when a party files a "timely motion" and "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1); *see Sierra Club,* 945 F.2d. at 779 ("in exercising its discretion, the court shall consider whether the intervention would unduly delay or prejudice the adjudication of the rights of the original parties"). Permissive intervention neither requires a showing of the inadequacy of representation, nor a direct interest in the subject matter.

Movants clearly also satisfy the standard for permissive intervention. First, as demonstrated above, Movants' motion to intervene is timely, as Movants filed

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[8] Because Petitioners have not yet identified the precise arguments they intend to raise, it is premature to offer definitive examples of actual differences between Movants' arguments here and those of Respondents. In addition to jurisdictional arguments, examples of potential divergence or emphasis may include issues of statutory interpretation and the scope of agency deference, and, more specifically: Movants' interests in the manufacturer-requested risk evaluation process (where EPA's interests are likely to minimize the number of such manufacturer requests because of the resource implications in managing them, even though Congress addressed that issue); and Movants' interest in the application of the definitions of "best available science" and "weight-of-the-scientific evidence" in risk evaluations (where EPA's interests in policy and/or political decisions may influence the view of what constitutes such scientific information or evidence).

within the required timeframe established by the Federal Rules. Fed. R. App. P. 15(d). Second, if allowed to intervene, Movants will address the issues of law and fact that the Petitioners present on the merits and detail why the Risk Evaluation Rule satisfies TSCA and is otherwise lawful. Because Movants and Petitioners maintain opposing positions on these common questions, Movants meet the standards for permissive intervention as well. Third, permitting intervention will not "unduly delay or prejudice the adjudication of the original parties' rights," as no such delay or prejudice will occur if the Court permits intervention at this early juncture in these Petitions. With the three petitions only recently consolidated by Multidistrict Panel's order, this Court has taken no significant steps to begin scheduling any briefing on the merits of Petitioners' claims.

As intervention would contribute to the just and equitable adjudication of the legal questions presented, it should be permitted.

CONCLUSION

For these reasons, Movants' Motion to Intervene should be granted.

Dated: September 11, 2017

Respectfully Submitted,

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of the United States of America

Lipton, Eric <[redacted]>

Following up on request to speak with Dean Graham....Story about ORIA and EPA that also discusses Nancy Beck.

Graham, John D. <[redacted]> Wed, Sep 27, 2017 at 1:54 PM
To: "Lipton, Eric" [redacted]>

Eric:

I am happy to chat with you. Let me start by offering you some broad contextual remarks and then provide some interesting background on Nancy Beck, who emerges as a central figure in the current saga on TSCA reform implementation. We can then follow-up via e-mail or telephone. All of this message is on the record.

1. I agree with your central premise that the efforts of OIRA, though important and influential, have only a modest impact on regulatory agencies. There are multiple reasons for OIRA's modest influence but one of the most important is that OIRA does not typically engage with regulators until the agency has already decided what it wants to do, has invested in the development of a complex regulatory package (rulemaking language and supporting technical documents), and has persuaded the agency's political leadership to support the initiative. To stop or redirect a determined bureaucracy in the endgame is very difficult indeed, even for an office affiliated with OMB within the Executive Office of the President. (Clarification: OMB and OIRA are not White House offices like the National Security Council or the Domestic Policy Council; indeed, OMB and OIRA are staffed primarily by career civil servants, even though they are led by Senate-confirmed political appointees).

2. A key problem that OIRA seeks to address is agency ambitions that have a poor grounding in evidence, whether that be science, engineering or economics. This problem is richly documented in a series of NAS reports over thirty years and in a variety of academic books and articles. I made some contributions to this literature during my tenure leading the Harvard Center for Risk Analysis (1990-2001). The issue is often framed politically as one of a lack of cost-benefit balance (or the need for more cost-effective alternatives) but the underlying evidence issues that OIRA faces relate to economics in only a limited percentage of cases. For the health, safety and environmental agencies, the key evidence issues often relate to risk. In the case of risk assessment, the evidence may come from toxicology, epidemiology, atmospheric science, public health, medicine, and a variety of other disciplines. If agency or OIRA staff misinterpret the evidence related to risk (e.g., understate or overstate the risk, or conceal uncertainty about the nature or magnitude of the risk), then the entire benefits analysis for the regulation will be misleading to regulators and the public.

3. When I came to OIRA, I tried to address what I perceived to be a shortage of expertise at OIRA in the sciences related to risk. My boss, OMB Director Mitch Daniels, authorized me to hire several new staff (as the level of staffing at OIRA had declined in the Bush 41 and Clinton years). Four of those new hires were Ph.D.-level experts in various aspects of risk: Edmond Toy in safety engineering and public policy, Margo Schwab in epidemiology and public health, Fumie Yokota in pharmaceuticals and health policy, and Nancy Beck in toxicology and public health. During my 5+ years at OIRA, I worked hard to integrate this group into the established team of 40+ analysts at OIRA with backgrounds in policy analysis, economics, business, statistics and law. Please note that these were civil servant hires; they were not "politicos"; their credentials were uniformly outstanding (more on Beck below).

4. To supplement OIRA's end-of-pipe regulatory review role, our team adopted new procedural strategies to enhance science quality and risk assessment practice at the agencies. While not all of these new procedural strategies were implemented or successful, several key ones were enacted during Bush 43 and retained by the Obama administration. Those initiatives included (1) a new regulatory analysis guidance document (OMB Circular A-4) that emphasized how to properly incorporate health, safety and environmental evidence into cost-benefit analysis for rulemaking, (2) OMB's government wide information quality guidelines that were followed by agency-specific guidelines, including new mechanisms for the public to seek correction of published agency documents, (3) OMB's Peer Review Bulletin that establishes procedures for appropriate practices of peer review for scientific information distributed by government agencies. Our effort to establish OMB risk assessment guidelines was not as successful. With the benefit of hindsight, I think we should have worked on draft guidance with the agencies first, before going to NAS for review. Had we done so, I think OMB's initiative would have been reviewed more constructively by NAS. But all was not lost. OMB, in collaboration with OSTP, did move forward with an official OMB Memorandum on Risk Analysis. And there is much more to be done in this area, some embedded in new legislative proposals circulating in the Senate and House. Note that all of these initiatives are aimed at improving the quality of agency evidence from the outset, rather than fixing problems in rulemaking documents at the end of the process.

5. Since Nancy Beck emerges as a key figure on the risk aspects of TSCA reform implementation, I thought I could help you by providing some substantial detail on her personality, background, education and experience. An overarching observation that I would offer is that Dr. Beck is easy to underestimate. Why is she easy to underestimate? She is petitely statured, she does not need to be the most vocal person in a group (i.e., does not seek limelight), and she looks young for her age. By personality she is a Jersey gal with street smarts and thick skin. She also brings some hefty credentials and experiences to her role at EPA.

6. Nancy earned an undergraduate degree in microbiology at Cornell (minor in economics); then an MS and Ph.D. in environmental health (toxicology focus) at University of Washington School of Public Health and Community Medicine (Seattle). She is Board-certified in toxicology (Diplomat American Board of Toxicology - DABT). If you do only one thing with my input for your story, I respectfully request that you provide a clear and complete statement of her scientific credentials as they relate to her current role.

7. After finishing her doctorate, Nancy won a highly-competitive fellowship award from the American Association for the Advancement of Science to serve for two years at EPA in the Office of Research and Development, National Center for Environment Assessment. She worked on toxicology projects related to the susceptibility of children, especially toxicokinetics (fate of chemical in the body) and toxicodynamics (interaction of chemical with human tissues at the target organ).

8. Toward the end of her fellowship, she applied to our OIRA position and I hired her into OMB from a highly competitive applicant pool. She worked at OIRA for roughly a decade. From 2001-2006 she played a crucial role in the information-quality and peer-review initiatives as well as the risk-assessment guidance effort. She also helped me manage a variety of risk assessment disputes involving specific chemicals such as perchlorate, mercury and tricholorethylene. And she assisted OIRA's international cooperative efforts on precaution and risk assessment.

9. After OIRA, Dr Beck did regulatory "science policy" (risk assessment) for the American Chemistry Council for five years, before taking on her current challenge at EPA. ACC is where Nancy learned an enormous amount about the legislative reform effort on TSCA, as this issue was not hot in the GWB years. As valuable as her ACC experience was, I think she is much more of a public servant at heart, and is delighted to be back in the government. I bet she especially enjoys working these issues on the EPA side, rather than playing the reviewer role at OMB.

10. Now, with regard to the thesis you are pursuing, what do you see as the connection between the risk-related initiatives undertaken at OIRA under GWB and the key issues Dr. Beck is now facing at EPA on TSCA reform? I am not sure that the connection is as strong as some people think it is.

With regard to next steps, we can either do some e-mail communications or proceed directly to a phone conversation, whichever is more productive for you. Take care and I hope that I may have the honor to meet you in the forseeable future. Take care.

Dean Graham

Obama on the Home Front: Domestic Policy Triumphs and Setbacks
IU Press
Click cover for more info

John D. Graham, Ph.D. | Dean | Indiana University

School of Public & Environmental Affairs

[redacted]

Bloomington, IN 47405

[redacted] Phone [redacted] Fax

[redacted]

[redacted]

Lipton, Eric [redacted]>

Specific questions re chemical safety at EPA and Dr. Beck. Response needed by Monday at noon.

Bowman, Liz [redacted] Fri, Oct 13, 2017 at 11:57 AM
To: "Lipton, Eric" [redacted] >
Cc: "Beck, Nancy [redacted]

No matter how much information we give you, you would never write a fair piece. The only thing inappropriate and biased is your continued fixation on writing elitist click bait trying to attack qualified professionals committed to serving their country.

Sent from my iPhone

On Oct 13, 2017, at 11:21 AM, Lipton, Eri [redacted] > wrote:

Hello Liz and Dr. Beck

As you both know, we have been trying for weeks now to speak with Dr. Beck or to someone at the E.P.A. to ask questions about TSCA and also about Dr. Beck's career. You have declined to engage with us. Before we move ahead with publication of the story, I did want to send you this detailed list of questions, so that you could question here in this format any factual issues you think might have with material raised here and also fill in any information you might want to, in an effort to offer your point of view. So here are a number of very specific questions. I look forward to your response, in writing, or in a phone conversation or in person, as you prefer. We need your responses **by Monday at noon**. Our preference, as you know, would have been to speak with Dr. Beck in person to go through all this.

Please keep these questions private, although of course I know this email is subject to FOIA.

Thank you in advance for your help.

I can be reached at anytime by dialin[redacted] that rolls to my cellphone if I am away from my desk to clarify any of this or discuss it with you.

Eric

1. The Office of Water, in a May 30 memo from Michael Shapiro that we have a copy of, raised concerns about changes made the procedures for chemical risk evaluation, related to the narrowing of uses, specifically, the removal of legacy uses, arguing that this could make it harder for the EPA Office of Water to properly regulate substances like PFOA, and potential related water contamination. But the rule was still changed, against the advice of the Office of Water. Why did this happen? Is this not a legitimate concern?
2. Similarly, the General Counsel's office raised questions in a May 30 email written by Laurel Celeste, that the changes in definitions made Chemical Risk evaluation--urged by the ACC and by Nancy Beck, after she arrived at the EPA--represented a "logical outgrowth" problem that would leave the rule vulnerable to legal challenge. Why did the agency not address this? We also have this email.
3. EPA staff were told in April 2017 time frame, after there had been a consensus among staff, after the public comment period ended, that the risk evaluation and prioritization rules were in good shape, that the two rules should be moved to OIRA for sign off as is. But they were then told to wait until Nancy Beck arrived. Dr. Beck arrived and in a series of meetings, asked for a number of changes to be made in both rules, changes that echoed comments ACC and Dr. Beck herself had made when she was at ACC, regarding narrowing uses and adding more specific definitions, like best available science. Certain EPA staff involved in the process strongly objected to these changes. Dr. Beck persisted and at one point was in fact re-writing parts of the proposal rule on her own. And the changes she wanted were incorporated into the draft and sent to OIRA and then adopted as the final rule. Employees involved with this were outraged. Was this ethically appropriate to allow Dr. Beck to play this role? Any comment on this summary of the events?
4. During this process, before the two rules were sent to OIRA, we were told that EPA staff were instructed not to issue a "non concurrence" memo. They were allowed to raise issues but instructed not to actually do a non concur. Why was this done? Is that appropriate?
5. Dr. Beck was hired in April 2017 under an administratively determined position, meaning she was exempt from the Trump ethics pledge. Was this done intentionally, so that she could intervene the way she did? Was it appropriate to give her a impartiality determination, given the intense and specific role she played in pushing the EPA on the exact rules she then helped redraft immediately after arriving at EPA?
6. When Dr. Beck worked at ORIA during the Bush administration, and the Renovation, Repair, and Painting Program Proposed Rule was moving toward final adoption, in the 2006 period, I was told by two people involved in this process that Dr. Beck raised concerns that the cardiovascular impacts associated with lead paint exposure were not sufficiently established and should be removed from the cost benefit analysis. The language in the report issued before the final rule was released reflected this change. I am fact checking this anecdote.
7. When Dr. Beck worked at OIRA during the Bush administration, she is listed as the author and point of contact for the OMB Proposed Risk Assessment Bulletin, which proposed new technical guidance on risk assessments produced by the federal government. The proposal was withdrawn after the National Academies of Science, among others, strongly criticized the proposal as fundamentally flawed. Any comment on this?
8. One person who worked with the EPA in this period said that Dr. Beck, during the Bush administration, while at OIRA, acted like she was trying to throw "sand in the gears" to slow or block restrictions on chemicals. Any reaction to this?
9. Dr. Beck has over the years frequently been critical of the way that EPA goes about defining risk. She has talked about weaknesses in the process that she believes result in "phantom" risks or unclear or exaggerated findings regarding risk. Can you elaborate on this please?

10. Is it the goal of the EPA, during the new administration, to bring better balance and accuracy to the way the EPA handles risk assessments? Can you explain this.
11. After President Obama was elected, Bob Sussman and Lisa Jackson went to the White House and specifically asked that OIRA no longer be allowed to “interfere” with EPA scientific assessments, pointing the blame on Dr. Beck’s actions during the Bush administration. Sussman said he was given assurances that this request would be honored. Any reaction to this?
12. Dr. Beck grew up in Long Island. Can you tell me a bit about her family history? What part of Long Island? What did her parents do? Did she have an interest in science while in high school? Any details from that experience that you could share? The story discusses Dr. Beck's career and also her commitment to science. We want to make her into a real person and welcome any additional biographic details. I tried already to call almost everyone on your list you suggested. And did get some help, particularly from John Graham.
13. Dr. Beck worked at Estée Lauder from 1988 to 1990, in Melville, NY, where she helped develop preservatives used to extend the shelf life of cosmetics, and also designed laboratory tests to determine if products caused adverse reactions when applied to skin. Fact checking. Any additional description of this work you can provide?
14. During a June 1 meeting with an environmental group to discuss the final rules for TSCA, (DCRoomEast3156 1 p.m) the discussion turned to the consideration of adding specific definitions for terms like “best available science” The environmentalists objected to this change. Dr. Beck responded by saying “I just don’t understand what the big deal is.” Fact checking this.
15. Staff involved in the final drafting of the risk assessment and prioritization rules said that Nancy Beck handled herself during these processes as if she was Wendy Hamnett’s boss, as she seemed to be the superior, not someone who reported to Ms. Hamnett. Any reaction to that?
16. A senior EPA official who was in charge of the toxic chemicals and pesticides program has told us that she was instructed in March 2017 by Ryan Jackson to change her position on chlorpyrifos petition, and that she had wanted to approve the petition, consistent with the recommendation of EPA staff, but was overruled. Any comment on this?
17. Two EPA staff members told us that Ms. Beck has made clear that she would like to see additional research and evaluation of the proposed January 2017 actions related to methylene chloride and TCE, as she feels like the agency is not ready to move ahead with the January 2017 recommended actions and that the recommendation needs to be reconsidered. Any comment on this?
18. An EPA staff member told us that when a conversation related to methylene chloride came up, with Dr. Beck, and concerns about deaths that have occurred during its use, Dr. Beck asked a point about whether this was a “1 percent” matter, meaning a very small percent of users, and also that the problem may be that users are not following the label that required ventilation, meaning it was perhaps a user problem, not a product flaw or product issue. Any comment on this?
19. Dr. Beck on June 8th was given an “impartiality determination” letter by Kevin S. Minoli. The memo specifically says: “Under the federal ethics regulations, you are permitted to participate in matters of general applicability (such as rulemaking) even if individual members of your former employer will be affected by that particular matter. Until now, you have recused yourself from participating personally and substantially in those comments to rulemaking that were offered by ACC. This impartiality determination confirms that you are permitted to participate in any discussions or consideration of comments submitted by ACC to rulemaking or other matters of general applicability. You may also attend meetings at which ACC is present or represented, but only if the following conditions are met: (a) the subject matter of the discussion is a particular matter of general applicability, (b) other interested non-federal entities are present besides only ACC, and (c) you are not the only Agency official at the meeting. This authorization will remain in effect for the remainder of your cooling off period.” Here is my question. I am aware that Dr. Beck participated in meeting at EPA prior to June 8 in which ACC comments on the TSCA implementation were discussed. For example, at at June 1 2017 meeting with Environmental Working Group, the discussion related to the proposed inclusion of new definitions in the final rule--a position advocated by ACC--was discussed, as was ACC’s advocacy of this change. Was this a violation of the ethics rules? Any comment on this?
20. Why is it appropriate and ethical to have someone who just a few months ago was working for the ACC in a job in which she was trying to influence the outcome of the TSCA rulemaking process to now be in a position in which she is influencing as an EPA employee the TSCA implementation effort. Please address why this is not a conflict?
21. If someone suggested that Dr. Beck's presence at the EPA could end up saving the chemical industry billions of dollars, in reduced regulatory cost, given the more balance approach to TSCA implementation she will take, what would be her reaction to this?
22. What are Dr. Beck's goals for reformed TSAC implementation?
23. Why has she committed her life to working on chemical safety?
24. Anything else you want to address?

Thank you again for taking the time to address each of these questions.

If you want to provide written answers to the questions individually or as I said above, talk through it in person or on the phone, that would be great.

Eric

Eric Lipton
The New York Times
Washington Bureau
[redacted]

Lipton, Eric [redacted]@nytimes.com>

Can you confirm re Dourson, re adviser to the administrator.

26 messages

Lipton, Eric <[redacted]@nytimes.com> Thu, Oct 19, 2017 at 2:41 PM
To: "Bowman, Liz" <[redacted]@epa.gov>

1) Can you confirm this please. "Dr. Dourson's title is adviser to the administrator," an EPA spokesman said yesterday evening.

2) Can you tell me what day he started in this role, please.

Thanks in advance

Eric

Eric Lipton
The New York Times
Washington Bureau
[redacted]
[redacted]@nytimes.com

Bowman, Liz <[redacted]@epa.gov> Thu, Oct 19, 2017 at 2:49 PM
To: "Lipton, Eric" <[redacted]@nytimes.com>
Cc: "Wilcox, Jahan" [redacted]@epa.gov>

1) Can you confirm this please. "Dr. Dourson's title is adviser to the administrator," an EPA spokesman said yesterday evening.

We will refer you to this story in USA Today: https://www.usatoday.com/story/news/nation-now/2017/10/18/controversial-nominee-not-yet-confirmed-already-working-trumps-epa/778310001/

2) Can you tell me what day he started in this role, please.

E&E News reported this and you should cite them: https://www.eenews.net/assets/2017/10/19/document_gw_05.pdf

Lipton, Eric [redacted]@nytimes.com> Thu, Oct 19, 2017 at 2:53 PM
To: "Bowman, Liz" <[redacted]@epa.gov>
Cc: "Wilcox, Jahan" <[redacted]@epa.gov>

Thanks for this.
So that to me is confirmation from the EPA that he is working at EPA and that he arrived this week.
Appreciate your help.

Eric

Eric Lipton
The New York Times
Washington Bureau

Wilcox, Jahan <[redacted]@epa.gov> Thu, Oct 19, 2017 at 2:57 PM
To: "Lipton, Eric" <[redacted]@nytimes.com>, "Bowman, Liz" [redacted]@epa.gov>

If you want to steal work from other outlets and pretend like it's your own reporting that is your decision.

Lipton, Eric [redacted]@nytimes.com> Thu, Oct 19, 2017 at 2:59 PM
To: "Wilcox, Jahan" <[redacted]@epa.gov>
Cc: "Bowman, Liz" [redacted]@epa.gov>

My job is to get direct confirmation of facts.
I do not rely on other news outlets, repeating what they have reported, without getting direct confirmation.
You avoid Fake News that way.

Eric Lipton
The New York Times
Washington Bureau
[redacted] office
mobile
[redacted]@nytimes.com

On Thu, Oct 19, 2017 at 2:57 PM, Wilcox, Jahan <[redacted]@epa.gov> wrote:

> If you want to steal work from other outlets and pretend like it's your own reporting that is your decision.

---------- Forwarded message ----------
From: **Wilcox, Jahan** <[redacted]@epa.gov>
Date: Thu, Oct 19, 2017 at 3:10 PM
Subject: RE: Can you confirm re Dourson, re adviser to the administrator.
To: "Bowman, Liz" <[redacted]@epa.gov>, "Lipton, Eric" <[redacted]@nytimes.com>, "Shesgreen, Deirdre" <[redacted]@usatoday.com>, Hannah Northey <[redacted]@eenews.net>

Adding the two outlets who you want to steal their work from to this email.

working

- Mtg w/ Ryan: ~~[illegible]~~ - synopsis of TSCA impl. & Adm. plus 3rd party

- Sign & scan & email today.

5/10
- Conds of Use:
  - Legacy out - not part of conds - out of scope
  - Definitions
  -

PREPARED BY

DATE 5/12

PAGE NO.

PROJECT ACTION NOTES

PROJECT PLANNING NOTES

FW Check-In

- OMB Briefing
  - OGC - David F.
    - logical outgrowth - A range of risk - depending on which change. Same ver

OMB Re: RE & PI Rules

- Prioritization: Re-prioritization
  - If definitions unpreamble, may still hv log. outgrowth issues, per OMB OGC.
- RE: - Cards of Use - Removed "all: will use Multi. uses, but not 1000's
  - Mfr - requested as discussed today.
  - Sciterms: - Syst. Rev. w links issue. Wants more
  - Interagy collabs. - Addi
  - Mk'g risible risk determ. (defin.)
    - Commenters liked "considerations"
    - Will amend then in preamble.
- EO 13777 - Ltr'g for de minimis burden exemption. Danielle talked to Angela; Danielle needs to consult further. Daily: E.O. uses ex. of $50,000 annual cost as low burden.
- Guidance: can submit as supplemental doc or submit as sep. doc. Need to discuss further.

PREPARED BY

DATE 6/1

PAGE NO.

PROJECT ACTION NOTES

THU 6/1

- Call Mike Flynn re V/V

PROJECT PLANNING NOTES

Kurt-St. Sci
Melanie
Olga

EWG: RE RULE
- COU gen'ly & how applied in mfr-requested.
- Preambles proposal ws M. - must eval. subst. as a whole. All uses; entire lifecycle.
- R'bly foreseen. - Some "off label" uses can be foreseen. E.g., use of shredded tires in athletic fields. Can expedite ceot high risk uses.
- Non-TSCA uses. CHPAC rec'd. Ex. of fluoride in pest's prog. less dem than all TSCA uses being covered.
- Accidents/spills - shd be covered to extent possible.
- Always consid potent'ly exposed sub-pops.
- Shd not use lack of info as reas to exclude a spec. cord of use. Use auths to ret sufficient info beg. risk eval.
- Mfr-Requested: Agree w/proposal th there be soft info beg EPA accepts. Must go thru same proc as other evals.