

# Risk Policy Report

An exclusive weekly report for scientists interested in environmental policymaking and policymakers interested in science

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## News Analysis **Industry Shift On Major California Green Chemistry Bill Crucial To Passage**

A decision by many industry groups to drop opposition to a major “green chemistry” bill in California was a key factor in securing its final passage, after the legislature and Gov. Arnold Schwarzenegger’s (R) administration recently reached a compromise on the bill that supporters say could serve as a national model.

Nevertheless, a handful of industry representatives — including the American Electronics Association (AEA), General Motors, and the Ford Motor Company — remain opposed to the plan.

AB 1879, introduced by state Assemblyman Mike Feuer (D), would create one of the nation’s first mandatory green chemistry programs and would dramatically expand the California Department of Toxic Substances Control’s (DTSC) authority to regulate consumer products.

California’s Senate approved the legislation by a 24-13 vote Aug. 25, and a companion bill, SB 509, passed the State Assembly the same day. At press time, AB 1879 was expected to go before the Assembly for what is known as a concurrence vote, with SB 509 slated to go before Senate for concurrence. If approved by the two concurrence votes, the legislation will be sent to Schwarzenegger, who is

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## **Likely Change To EPA Ozone/Climate Report May Limit Near-Term Action**

RESEARCH TRIANGLE PARK, NC — Authors of a high-profile EPA report that finds climate change will worsen ozone’s human health effects may modify the report to highlight a disconnect between near-term deadlines to meet ozone standards and the longer-term impacts of climate change – an issue raised by industry and peer reviewers. Dealing with the disconnect may limit near-term state actions to address climate change.

But the peer review group at an Aug. 27 meeting here to discuss the draft report, *Assessment of the Impacts of Global Change on Regional U.S. Air Quality: A Preliminary Synthesis of Climate Change Impacts on*

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## **EPA Seeks Answers To Key Question In Modeling Children’s Exposure**

EPA is offering \$5 million in research grants to tackle the long-running question of how to measure and model children’s exposure to hazards in their environments, especially in schools and daycare centers where children spend many hours but where researchers are often unable to conduct tests.

Developing models or other tools that can estimate children’s exposure in real-world scenarios is crucial to agency risk assessments because exposure is an integral component of the assessments. In addition, children are an important population that EPA considers in many of its safety standards and regulations because they are more susceptible to some environmental hazards than are adults.

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## **EPA Grapples With Risk-Based Approach For Addressing Biosolids**

EPA is seeking to determine whether it can move forward with a new, risk-based approach for addressing biosolids, an approach favored by the wastewater industry which is seeking to move away from the agency’s current technology-based standards.

The agency is “trying to evaluate if there is enough critical mass to use [risk-based standards] for rule making,” according to an EPA source, who says models for determining risks posed by pathogens in the solids raise questions about how to develop rules.

Agency difficulties developing a risk-based standard could be a blow to

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## CRS FINDS ‘LIMITED’ EPA SUCCESS GATHERING DATA ON NEW CHEMICAL RISKS

EPA is having “limited success” gathering information about the risks new chemicals may present to people and the environment using existing Toxic Substances Control Act (TSCA) authorities, according to a recently updated Congressional Research Service (CRS) report that comes amid a growing push to amend the toxics law.

The July 18 report outlines advances in toxicology methods and new knowledge about health effects that TSCA “does not account for,” including hormone-disrupting effects. *The report is available on InsideEPA.com. See page 2 for details.*

“The available evidence indicates that EPA has had limited success using TSCA to gather information about new chemicals, but has demonstrated creativity and expertise in making use of available information to categorize such chemicals based on hazard potential, thereby reducing risks potentially associated with exposure to chemicals entering U.S. Commerce,” the report concludes. “The agency has had some success in gathering information about existing chemicals, but has regulated only a handful.”

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**“When TSCA was enacted, risk assessment was a primitive tool based on simple toxicological models.”**

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An industry source questions the report’s conclusion, noting that criticisms of TSCA have usually been leveled at its inability to obtain information on existing chemicals. “They’ve got a very good new chemicals policy. It’s a pretty robust approach,” the source says, adding that critiques of TSCA’s ability to require information about existing chemicals are “a valid criticism.”

The report is an update to a 2007 CRS report that concluded Congress was unlikely to enact legislation implementing three major international chemical agreements — aimed at restricting the use of persistent organic pollutants and nine pesticides — before tackling the increasingly important issue of amending TSCA to address questions over how the 30-year-old law can be used to regulate new developments, such as nanotechnology.

The updated report reiterates this conclusion, and also finds that new advances in toxicology and risk assessment add momentum to calls for TSCA reform. “When TSCA was enacted, risk assessment was a primitive tool based on simple toxicological models, usually of a single incident of exposure to a single chemical, followed (usually relatively quickly) by an obvious health effect,” CRS says.

CRS also notes a growing interest in TSCA reform, pointing to “recent legal, scientific, and technological developments, which appear to be increasing legislative interest.”

The report points to a rising trend in states restricting the sale or use of chemicals managed under TSCA. The emerging legal patchwork might prompt large companies to “lean toward TSCA reform to preempt state and local regulatory action,” CRS writes. Similarly, international forces are also prompting companies that export chemicals abroad to “advocate for international harmonization of regulations,” according to the report.

The CRS report was requested by Sen. Frank Lautenberg (D-NJ), according to a staff source. In May, Lautenberg introduced S. 3040, a bill requiring EPA to conduct “safety determinations” on chemicals in commerce in the United States, with the first 300 determinations due by 2012 (*Risk Policy Report*, May 27).

S.3040 was referred to the Senate Environment & Public Works Committee, where despite chair Barbara Boxer’s (D-CA) support it has yet to be scheduled for a hearing. “Any report that points out some of the challenges we face with TSCA is helpful in making the case for reform,” the staff source says. “We are still reviewing the report to see exactly how to use it.” — *Maria Hegstad*

### Hot Documents Available on *InsideEPA.com*

Subscribers to *InsideEPA.com* have access to hundreds of policy documents, including draft regulations and legislation, as well as a searchable database of daily news stories and documents. The documents listed below are in addition to the background documents referenced throughout this issue. For more information about *Risk Policy Report*, or for a free trial, call 1-800-424-9068.

- Environmentalists Sue EPA To Release Studies On Pesticide Risk To Bees (epa2008\_1310)
- Environmentalists Seek Department Of Justice Disability Listing For Chemical Sensitivity (epa2008\_1358)
- EPA Receives Comment On Draft Climate Change Impacts On Ozone Report (epa2008\_1359)
- Report Identifies Gaps In Research On Global Warming, Disease And Allergens (epa2008\_1375)
- CRS Report Finds Increasing Support Among Lawmakers, States For TSCA Reform (epa2008\_1377)

## ACTIVISTS SUE FOR RELEASE OF EPA DATA ON PESTICIDE, BEE DEATH LINKS

Environmentalists have filed a lawsuit trying to force EPA to release data about possible links between the pesticide clothianidin and the widespread death of bee colonies in the United States.

The Natural Resources Defense Council (NRDC) filed the Aug. 18 lawsuit in the U.S. District Court for the District of Columbia after EPA failed to respond to the group's July 17 Freedom of Information Act (FOIA) request for agency documents detailing the toxicity of pesticides and their link to the unexplained deaths of bee colonies, known as colony collapse disorder (CCD). *The lawsuit is available on InsideEPA.com. See page 2 for details.*

According to the suit, beekeepers in the past two years have reported "unexplained losses" of 30 percent to 90 percent of their hives. NRDC says that while there is no confirmed cause for the colony collapses, a new class of insecticides — including clothianidin — "is suspected to play a role." NRDC says EPA has not met an Aug. 15 due date to respond to the FOIA request and wants the court to force the agency to respond.

An NRDC source says the suit hopes to find out "what does the EPA know and what has been submitted" in terms of the pesticide, but also find out more about "how EPA is evaluating the toxicity of pesticides."

NRDC in its FOIA request sought records regarding the use of clothianidin on crops in the United States, including EPA's evaluation of the pesticide's safety for bees. The group also sought studies of the pesticide submitted by clothianidin manufacturer Bayer CropScience that the company was supposed to complete and provide EPA as part of the pesticide registration process. EPA granted the company a "conditional" registration in 2003.

The group notes that the pesticide is "known to be harmful to bees" and its use was suspended in Germany. The source says while the causes of CCD are still unknown, "pesticide exposure is a serious stressor on bees and many people think it is playing a role." The actual cause of CCD "may be a complicated mix of factors," the source says.

Other environmental groups are also pressuring the agency to take a closer look at the effects of the nicotinyl family of insecticides on CCD, the group that includes clothianidin.

On July 30, the Sierra Club sent a letter to EPA's Office of Pesticide Programs (OPP), charging that the agency "has clearly missed the unintended consequences of the nicotinyl insecticides" and saying "serious questions need to be raised by EPA's OPP over the sublethal effects to honey bees." Sublethal effects are adverse health effects of pesticides on animals that can impact the ability of wildlife to reproduce, forage, and can make wildlife more susceptible to predators (*Risk Policy Report*, Aug. 12).

At the time, an EPA spokesperson said the agency was reviewing the Sierra Club letter, but pointed out that the agency is aware of the sublethal effects of pesticides on honey bees, adding that an "acute bee contact toxicity study" is required for many pesticides, which looks at sublethal effects. The EPA spokesperson declined to comment because of the pending NRDC litigation.

## EPA DEVELOPING MORE RELIABLE TEST FOR DETERMINING LEACHING RISKS

EPA is evaluating an approach to leach testing, which it calls more reliable than its existing methods, designed to aid local decision-makers weighing the risks of recycled construction materials leaching contaminants into groundwater when the decision-makers are deciding whether to dispose of a material or reuse it in roads or other construction projects.

But the new approach will not replace a long-standing and much criticized leach test EPA has used since 1990 to determine if waste material is hazardous, an EPA official says.

Industry, environmentalists and EPA advisors have pressed the agency for years to improve its toxicity characteristic leachate procedure (TCLP), a commonly used leaching test. Industry and environmentalists alike have criticized TCLP, arguing that it overestimates or underestimates potential risks. The agency lost two lawsuits in the 1990s over the test, with the U.S. Court of Appeals for the District of Columbia Circuit describing a use of TCLP as "inaccurate," in its 1998 ruling in *Columbia Falls Aluminum Co. v. EPA*.

A year later, EPA's Science Advisory Board (SAB) urged the agency to improve the leaching test, saying TCLP is applied too broadly and may overestimate or underestimate leaching potential. SAB called on EPA to "improve leach test procedures, validate them in the field, and then implement them," in a 1999 letter to then Administrator Carol Browner.

"We pointed out some of the shortcomings of the test: either change the test to accommodate the shortcomings or consider them when interpreting the data," said Domenico Grasso, a former SAB vice-chair who authored the letter in an Aug. 25 interview with *Risk Policy Report*.

EPA's Office of Solid Waste & Emergency Response (OSWER) has been working since to improve leach testing. But the new approach will not replace TCLP, or even become a regulatory test, OSWER's Greg Helms said during a presentation at the Environmental Measurement Symposium in Washington, DC, on Aug. 13. Instead, it will be a decision-making tool for local regulators trying to determine where and if they should reuse materials in roads, concrete construction or other projects, he said.

"Because of the problems with TCLP, we've been looking at alternatives," Helms said. "We're evaluating the

effects of several factors in leaching.”

The new approach addresses SAB’s “concerns that TCLP is used too much for everything,” Helms said. He said waste office staff have begun to compile the records needed to add the new testing approach to EPA’s manual of tests and guidance for evaluating waste material in accordance with the Resource Conservation & Recovery Act. The staff is also planning a study to validate the new approach, but as yet there is no funding to perform it, Helms said.

The new leach testing approach will likely be included in a soon-to-to-be-released publication that EPA’s waste office is drafting. Though not a formal guidance document, the “risk framework for reusing beneficial materials” lays out possible approaches to decide if waste reuse is acceptable, a waste office source says. The document will show decision-making stages before risk analysis, laying out potential exposure, hazard and weight of evidence issues, the source says. It will include some models, data groups and case studies.

But some question why it has taken EPA so long to adopt an approach that is in use in Europe and elsewhere. EPA is considering test methods published in the United States in 2003 and used at the University of New Hampshire’s Recycled Materials Resource Center, said center co-director Kevin Gardner in an Aug. 22 interview with *Risk Policy Report*. He called the method EPA is evaluating “a positive development that’s a long time coming,” and added, “I don’t know why it’s taken them this long to act. This approach is certainly not new.”

The problems associated with TCLP don’t stem from the test itself, Gardner’s colleague Jeffrey Melton said in the Aug. 22 interview, but rather from “people using it inappropriately.” Because TCLP is used to determine if a material is hazardous, “people jumped on that and said if [a material] passes TCLP, it’s safe,” Melton said. “That’s not necessarily the case.”

EPA developed TCLP for the purpose of determining what is hazardous waste. Its design is based on what the agency considers the highest risk scenario: dumping hazardous waste in a municipal landfill. But TCLP became a commonly used leaching test for other regulatory and industry situations, which it was not designed to estimate, according to the SAB’s 1999 letter. “Where important parameters are not considered and the scenario does not relate to actual disposal conditions, decisions based on the test results may not protect the environment or human health,” the letter states.

**EPA faces the “very difficult challenge” of finding an approach that accurately predicts risks** from the use of many non-traditional building materials, such as crushed asphalt, crushed glass, slag or ground-up tires in multiple applications, Melton said. The test used in each instance must be appropriate for the material, its intended use and the location, since varying rainfall in different parts of the country also impact leaching. “The issue is to expand the testing procedure to fit the actual application of the material,” Melton said.

An EPA source explains that TCLP is a “screen test” that does “a pretty good job of indicating what is hazardous but it is not 100 percent.” The source describes the new approach as “a set of tests we think are more tailored and more precise for a particular situation.”

TCLP’s determination that a substance is not hazardous “doesn’t mean that it is innocuous, particularly if you’re going to reuse it,” the source says. As a result, the new approach could become a management tool for local governments, the source says. “We think it will give much more accurate results, and be better for decision-making,” Helms said.

Most leach tests assess leaching at a single set of initial conditions, because the final conditions are unknown, Helms said. In reality, there are many impacts on leaching, including the temperature where the material is disposed or reused, and its reduction and oxidation rates, iron content, infiltration rate, metal solubility and sorption, he said.

Helms described the agency’s work on evaluating an approach that considers several of these conditions, including acidity, the liquid-to-solid ratio, and the physical form of the waste, or size of the waste particles. The new approach considers eight different levels on the acid-alkalinity pH scale ranging from 2 (very acidic) to 13 (very alkaline). TCLP considers two low acid pH levels.

Additional tests in the approach consider the liquid-to-solid ratio and also estimate the impact that the size and shape of the waste particles have on slowing leaching. The approach is designed to be “a bit conservative, because these are still short-term tests,” Helms said. “But it will be more accurate” than TCLP.

“Doing the full suite of testing fully characterizes the material,” Helms said. After Helms’ presentation, one listener noted that the new approach “asked a lot of the regulatory industry.” But Helms said that the new approach will not be a regulatory test and will not be required, adding that “EPA is not planning to revise regulatory use of TCLP.”

“We don’t want to make every project a research project, but we think we can be more accurate,” he said. “Frankly, for someone using a lot of re-use material, it’s a way of reducing liability.”

Melton acknowledges that the approach requires a lot of expensive testing up front. But he suggested that with the material fully characterized, a company could reduce later testing. The manufacturer would only have to perform a single test showing a new batch of material is the same as the previous batch, he said.

A source with the Missouri Department of Transportation (MODOT) says his agency is “definitely not doing anything like” the new leach testing approach. The source says MODOT would be very interested in considering it as a decision-making tool, given the increasing amount of recycled materials used in new road construction. MODOT uses TCLP regularly for “all sorts of things,” though the test “may not be tailored to look at all scenarios,” the source says. — *Maria Hegstad*

## EPA DOWNSIZES ECOLOGICAL SERVICES PROGRAM DUE TO SAB CONCERNS

EPA is downsizing its ambitious, upcoming new program for valuing the services that various ecosystems provide to humans and the environment in response to concerns raised by the agency's Science Advisory Board (SAB) that there are insufficient resources for the plan, an agency source says.

At the same time, EPA continues its work to implement the concept of "ecosystem services" that better fits the government's cost-benefit framework for budgeting and regulatory decisions. For example, EPA is offering small grants for researchers to develop models or other analytical tools that could turn existing information about wetlands into an understanding of the ecosystem services those wetlands provide.

Ecosystem services is a concept that has emerged in recent years to reflect the fact that people depend on ecosystems for water, food production, flood control and numerous other benefits. The concept enables analysts to quantify or even monetize these benefits. EPA is adopting the controversial approach to help decision-makers better calculate the costs from these services' loss or damage. Local decision makers can also use ecosystem services calculations to evaluate trade-offs between land uses and regulatory options (*Risk Policy Report*, Jan. 22).

But overarching budgetary and resource concerns are driving agency staff to revise and reduce the scope of the new direction for the EPA's Ecological Research Program (ERP), the EPA source says. The five-year plan ERP is revising contains a sweeping and ambitious intent of creating a national system for monitoring and collecting ecosystem services data.

ERP staff presented a draft of the plan to an SAB panel in April, where advisors raised concerns about whether EPA could meet the goals of the plan in light of ever-decreasing federal ERP funding. The budget for ERP dropped from \$120 million in fiscal year 1995 to \$72.2 million in FY08. The Bush administration proposed another cut in EPA's pending FY09 budget that would fund the program at \$66 million, according to the agency source.

Due to resource concerns, SAB questions ERP's ability to achieve its ambitious goals, which include mapping, evaluating and modeling ecosystem services at five pilot sites around the country.

ERP staff are completing the implementation plans that will put into place the program's new five-year plan, the EPA source says. In response to SAB's concerns, ERP "will be scoping it down some" in the final implementation plans, the source adds. The version of the five-year plan SAB is reviewing is "aspirational," the source says, adding, "As we write the implementation plans, we know the numbers [of staff and resources] and we'll downsize."

Peer review panels have been selected to review each of the implementation plans, which are expected to be released next month, according to the EPA source. ERP is awaiting the final draft of SAB's review, which the board approved in July pending final changes. A draft review released in June applauded the ecosystem services approach but questioned ERP's ability to take on such a large and complex new direction (*Risk Policy Report*, June 24).

ERP staff are paying "particular attention" to two key areas — decision support and modeling — that were questioned in SAB's draft review, the agency source says. Decision support platforms are means to address local decision-makers' questions about various options and what their potential outcomes might be.

ERP "had proposed a decision support platform, an approach that would allow the use of a variety of models depending on the question you're answering," the source says. But SAB reviewers questioned if ERP could successfully accomplish a decision support platform with "limited in-house expertise in decision and behavioral sciences" and in the face of many remaining ecological research needs, according to minutes from a July SAB conference call.

ERP staff are also reviewing modeling options, the source says. Partly in response to concerns from SAB, ERP brought in a group of some 15 part-time consultants. These experts in economics, modeling and law are assisting ERP's planning, the source says. A group of modelers has been formed to consider the best case framework, what models to use and if ERP should use existing models or develop new ones, the source says.

Once ERP receives SAB's final review, staff will finalize implementation plans. An SAB source says the report should be released soon. ERP will also prepare a new version of the five-year plan for SAB review this winter, the agency source says.

**Meanwhile, in another signal of EPA's interest in the ecosystem services approach, the agency** recently advertised a new research grant competition, seeking models or other analytical tools that can quantify wetland ecosystem services, according to a second EPA source. The three year grants, expected to be awarded in fall 2009, will straddle the end of ERP's five-year plan, the source adds.

"We want to use the data already collected because there's a ton of information out there about tree cover, soils, and habitat for species," the second agency source says. "We want to get better at interpreting what it's all good for, such as it prevents flooding or provides a buffer zone."

Released July 21, the request for applicants offers \$950,000 for "research that will develop and refine creative approaches for demonstrating whether and how the growing body of data and information on wetland condition can be related to the provisioning of wetland ecosystem services."

The research is intended to provide new tools for the ERP, but also to link its efforts with those of EPA's research and development and water offices, which are preparing to conduct a massive survey of the nation's wetlands in 2011

along with regional and state partners, EPA sources say.

The idea of ecosystem services is not new to researchers who study wetlands, said EPA ecologist Mary Kentula in an Aug. 27 interview with *Risk Policy Report*. Wetlands are often viewed in terms of the benefits they provide, such as filtering water and protecting communities from flooding, among others, she says.

As EPA prepares for the national survey of wetlands' condition, the grant is expected to provide analytical tools for both ERP and those performing the wetlands survey, Kentula said. The new research grant stems from wanting to know "how can we also use information about wetlands' condition and apply it to services?" she said.

Four of the five sites where ERP intends to pilot its new services approach — the Coastal Carolinas, 13 Midwestern states, the Tampa Bay area and Oregon's Willamette River valley — contain wetlands that will be a focus of the program. In response to SAB concerns that the focus of the pilots was "too wet," ERP recently added a three-state arid pilot, which will be run from EPA's Las Vegas lab, the EPA source says. ERP staff are discussing a possible partnership with a coalition of nonprofits and government agencies already researching the San Pedro River Basin area of southeastern Arizona, the source says. — *Maria Hegstad*

## **LIKELY CHANGE TO EPA CLIMATE REPORT MAY LIMIT ACTION . . . begins on page one**

*Ground-Level Ozone*, also urged EPA to highlight in the final document the fact that modeling shows the ozone-plagued Northeast is particularly sensitive to climate change, and that ozone is predicted to significantly worsen under future warming scenarios.

The draft report is a first-phase synthesis of conclusions from recent EPA-funded studies. The report concludes that global warming will significantly worsen ozone levels and warns that regulators will likely have to impose additional emissions controls to meet strict new national ambient air quality standards (NAAQS) for ozone to address this "climate penalty" than they might otherwise have had to.

The changes EPA is being urged to make to the report would stress that although ozone and climate are inherently linked, achieving health-based ozone NAAQS in the near term has a different time horizon than efforts to address climate impacts on ozone, which are seen as longer term. Depending on the severity of the nonattainment designation, states generally have five to 10 years to meet a new ozone NAAQS, while climate effects are modeled out to 2050.

At the meeting, Howard Feldman of the American Petroleum Institute (API) presented comments urging EPA to include a time frame to show that climate change does not need to be accounted for in near-term state implementation plans (SIPs), which are blueprints for how states will meet federal air quality requirements. The group also urged EPA to refrain from including any policy recommendations in the report at all. *Relevant documents are available on InsideEPA.com. See page 2 for details.*

"Our bottom-line answer is, 'not now,'" Feldman said at the meeting, referring to policy statements in the report that states integrate climate impacts into efforts to meet the ozone NAAQS.

API comments suggest EPA delete the following paragraph of the report: "These studies suggest that [ozone] nonattainment areas and areas just below the [ozone] National Ambient Air Quality Standards (NAAQS) should begin to consider the impacts of climate change as they develop their attainment and maintenance strategies, even for near-term planning horizons. In other words, they may need to account for a 'climate penalty' imposed on their control policies."

Additionally, peer reviewer Yuhang Wang of the Georgia Institute of Technology said, "It would be good to recognize the time frame disconnect in the report."

Further, an EPA staffer attending the meeting, Doug Grano, said the report's conclusions that higher temperatures will impair NAAQS attainment will be difficult to translate into SIPs because of the differing deadlines. "There is a bit of a disconnect," he said.

In response, the authors included in a list of possible changes they would likely make based on the peer review and industry comments, including "address time-scale of air quality action, e.g., mismatch between air quality planning and climate change timescales."

Other criticisms of the draft stressed that future studies should clarify whether states should focus more on lowering one ozone precursor over another to minimize climate effects. Peer reviewer David Allen of the University of Texas at Austin said relative levels of nitrogen oxide and volatile organic compounds are likely to shift under future climate scenarios, and air quality managers "need to know which precursor to control, which is more sensitive to climate change."

At the same time, peer reviewers pointed out that the draft report should emphasize consistent modeling that finds the Northeast stands to suffer more than other regions from increased ozone due to climate change, while also highlighting the uncertainties surrounding the studies, including the disagreements on effects in other regions of the continental United States.

Report author Chris Weaver said EPA in future studies will "look at controlled experiments comparing models"

in order to better explain the differences in outcomes between the models that look at the same areas. Some regions show increases in ozone under some models and decreases under others.

Additionally, EPA is seeking to spur development of long-term models to predict how climate change may affect local air quality, according to a recently announced \$5 million research grant competition. The research will fill a gap in existing climate change models to address long-term changes at the regional and local level.

At the meeting, reviewers also highlighted the lack of inclusion in the report of factors that impact climate change and air quality, such as land-use changes; changes in natural and anthropogenic emissions; and fires and changes in evaporative emissions from soil, given the expected increases in the use of fertilizer.

Meeting participants emphasized that the draft report is a “good first step” in looking at the question of how climate change impacts air quality and vice versa while emphasizing that much more research is needed. “It is a field in its infancy,” Russel Dickerson of the University of Maryland said. — *Jenny Johnson*

## **EPA FINDS LARGE GAPS IN RESEARCH ON CLIMATE’S EFFECT ON ALLERGENS**

EPA has identified large research gaps in how global warming may affect allergic diseases and is offering almost \$2 million in grants to study the subject, following the release of an agency review of scientific literature on links between climate change and levels of airborne substances like pollen, mold, and indoor allergens.

Sources involved with the peer review of the agency document say that the review highlights the “limited data” available about the connection between disease, climate change and the substances, called aeroallergens. “This kind of document helps to highlight that things are changing,” that “factors are suggestive” about a link between climate change and aeroallergen levels and that “there is a need for more research,” according to a source familiar with the document and its peer review. “The literature is pretty sparse.”

EPA’s document, *A Review of the Impact of Climate Variability and Change on Aeroallergens and Their Associated Effects*, compiles existing research and identifies gaps where more data is needed about climate change and aeroallergens in the United States, an EPA source says. The report was completed and reviewed internally in June 2006, an external peer review was released in December 2006 and the final version came out last week. *The document is available on InsideEPA.com. See page 2 for details.*

Peer review sources say there is little research on the connections between climate change and aeroallergens, though the agency points out that the available data offers some “tentative conclusions.”

These conclusions include the possibility that pollen production is likely to increase throughout much of the United States, that there is an earlier start of the flowering season for pollen-producing plants, that there will be changes in pollen-producing plant life, that new aeroallergens may be introduced to the United States, and that allergen content in some of the aeroallergens will increase.

These conclusions still require addition research drawing on different scientific disciplines, the peer review source says, though one good study of pollen content or when the flowering season is starting could contribute data across the board.

The EPA review concludes that “integrated long-term data series on all aeroallergens is necessary to clearly document future changes in aeroallergen production and distribution, as well as allergen content.” The review also says more data on mold and indoor allergens would be “of particular value,” as well as future experimental and field studies to see how content and distribution of allergens is affected by climate change.

There are “not enough studies in the U.S. with a long-running database that you can look at and say, ‘Over 30 years we’re seeing oak pollen increase or we’re seeing oak pollen not increase,’” says a second peer review source. In addition to more “large-scale experiments” looking at the affects of warming on plants and trees, the second source says studying the relationship between mold and weather would be valuable, as well as additional studies looking at the affect of temperature gradient on pollen production in trees.

The source also recommends looking at relevant research, including long-term data on lilacs, for instance, as a way to learn more about aeroallergens and global warming. “You have to use some of those pieces of evidence” that may not be directly related, the source says.

The first source says that the United States lags behind Europe in looking at the health effects of global warming. Many government health agencies are doing research that is “relevant, but not directed” at the connection between adverse health effects and global warming, the source says. In contrast, the source points to the West Nile virus and how its discovery quickly lead to research into the disease and its adverse health effects.

EPA’s Global Change research Program, which developed the literature review, worked with the agency’s Science to Achieve Results grant program to develop a request for research proposals for two grants to look at “the impact of global change on the development and severity of allergic airway disease from exposure to pollen, mold, and other plant-derived allergens,” according to the agency’s Web site. Announced July 1, the agency looks to award \$900,000 for each proposal, with an Oct. 1 deadline.

Of particular concern to EPA is the “role of climate on the production, distribution, dispersion and allergic

potency of allergens produced by grasses, weeds, trees and molds in the United States.” The agency is also interested in how the “changes predicted for plant- and mold-produced aeroallergens” will impact the “development and severity” of diseases like asthma and hay fever in different regions of the U.S. and throughout the seasons, according to grant documents.

The EPA source says that the review “is truly a preliminary effort” and that the agency wants to support the work of the academic community through the grants. The agency plans to develop and publish a “journal-friendly” version of the review, which would “lay out the next steps” and illustrate the current research gaps to those in the scientific and academic community. — *Aaron Lovell*

## **EPA CONSIDERS RISK-BASED BIOSOLIDS STANDARDS . . . begins on page one**

the wastewater sector, which is ramping up efforts to develop a new approach for demonstrating the safety of land-applied biosolids, which are solid waste derived from the wastewater treatment process.

EPA’s current biosolids regulatory framework is technology-based because, when the framework was established, scientific knowledge was too limited to establish a risk-based approach. A risk-based approach uses algorithms to quantify the potential exposure to an individual or the risk of an individual getting sick from pathogens in the biosolids and may eventually determine whether biosolids could be land applied based on the presence of a defined number of pathogen indicators.

Wastewater industry officials are looking to move away from the current technology-based approach as a way to improve public perceptions that land-applied biosolids are safe. Sanitation groups support the development of the risk-based standards, saying the additional information would “exonerate, not implicate” biosolids, according to a source with the California Association of Sanitation Agencies (CASA).

The Water Environment Research Foundation (WERF), a group that researches wastewater and stormwater issues, is currently working to develop by 2010 a model to assess the risks posed by pathogens in biosolids, which WERF sources have said is intended to bolster public confidence in the safety of applying biosolids to farmland and determine whether new regulatory controls are needed.

The California source says the model would provide more information on whether treatment techniques are working as planned, as well as looking at land-applied biosolids from an epidemiological perspective. The group is also incorporating risk communication “as an integral part of the process,” according to a WERF source, who points out that a technical risk assessment on its own “may not address the concerns of the citizens” about the risks from land-applied biosolids.

Industry officials are also arguing that land-applied biosolids are beneficial to agriculture, an argument officials are making to Senate environment committee Chairwoman Barbara Boxer (D-CA) ahead of an upcoming hearing on the issue. The WERF source says EPA could use the results of the new risk assessment to do a “double-check” of the existing regulations, while states could use the assessment standards for special conditions or situations at the state or project level.

A second EPA source says the WERF project could end up being a tool that publicly owned treatment works and local jurisdictions can use to provide information to the public.

The agency is also seeking to develop risk-based standards as part of the response to a 2002 report from the National Academy of Sciences that included recommendations for how the agency’s biosolids regulatory program could be improved. The panel’s report urged EPA to upgrade its risk approaches and conduct human health studies to broaden research in the area due to anecdotal, but not medically documented, reports that people may have been harmed by exposure to biosolids after it was applied to farm and forest land.

Despite the industry efforts, EPA officials say their own efforts to move to a risk-based approach still face hurdles. For example, one agency source says officials are unsure how to develop a model to consider risks posed by pathogens in biosolids.

There are no “carcinogen-style triggers” with biosolids risk as there are with chemical exposures, the agency source says, so “someone will need to make a decision about what level of disease is acceptable” and determine “what level of treatment is needed to deal with that level of disease.” The source says the new model could help determine that current levels of sewage sludge treatment are sufficient for protecting public health or it could show that increased exposure to certain pathogens is acceptable.

“Pathogens present a whole set of additional, interesting challenges” with regards to determining exposure endpoints, says the second EPA source. The agency will need to determine, for example, which are the right pathogen indicators and “how many pathogen units have to be present to cause the disease,” the source says.

Compared with risk assessments of chemicals, the possible endpoints for biosolids are less severe, EPA and research sources say, including issues like gastrointestinal illness. Still, a source involved with risk-based pathogens research says there are potentially more serious endpoints that also need to be considered, including *E.coli* 0157, which can lead to kidney failure, and *cryptosporidium*, which can be deadly to people undergoing chemotherapy, suffering from HIV or otherwise have a weakened immune system. EPA will have to decide if it should “try to build a rule around the most susceptible population,” the first source says. — *Aaron Lovell*

## INDUSTRY HELPS PASS GREEN CHEMISTRY BILL . . . begins on page one

expected to sign it.

As reported recently by *Inside EPA*, the bill is the result of a compromise between Feuer and the Schwarzenegger administration. It amends Feuer's original bill to merge in key provisions of California EPA's (Cal/EPA) draft Green Chemistry Initiative, among other changes.

An overview of the bill released by the state toxics department says AB 1879 would allow DTSC to "create, in regulations, a process to identify and prioritize chemicals of concern that warrant further scrutiny." That review process would inform future DTSC regulatory decisions. The revised AB 1879 retains a provision that says DTSC can decide the various ways it wants to regulate products and gives the agency the power to ban chemicals. SB 509, the companion bill, calls for chemical information to be placed in a new Toxics Information Clearinghouse. DTSC would develop the clearinghouse, and the state health hazards office would provide scientific expertise.

The Chemical Industry Council of California (CICC), which earlier opposed the bill, signed on in support after the compromise was announced. DuPont has also become a supporter of the bill.

Other major business groups that earlier opposed the bill offered their support in recent days, a move that dramatically boosted the legislation's prospects. Groups that dropped their opposition include the Western States Petroleum Association, the American Chemistry Council, the California Chamber of Commerce and the California Manufacturers & Technology Association.

CICC Executive Director John Ulrich said in an interview that the group opposed a list of chemicals that Feuer's bill as originally introduced would have required DTSC to regulate, including: phthalates, mercury, lead, cadmium, arsenic, polybrominated diphenylethers (PBDEs), and hexavalent chromium.

The list would have set up a statutory process where the state legislature in future years could dictate to state scientists what their priorities should be, Ulrich claimed. The list would have been a "dangerous precedent," Ulrich said. Feuer agreed to remove the provision as part of the compromise.

The revised bill also places DTSC's authority under the purview of the Cal/EPA Environmental Policy Council (EPC), which is a stronger process, Ulrich said. EPC is charged with reviewing the regulations developed by DTSC, which is made up of Cal/EPA department heads.

Nevertheless, there remain a few industry opponents of the bill. Explaining AEA's opposition, a source with the group says the high tech and electronics industry is already regulated under the European Union's (EU) so-called RoHS Directive that restricts the use of certain hazardous substances in electrical and electronic equipment. AEA sought a provision in AB 1879 that would have exempted the industry by allowing the industry to comply solely with the EU program, but the provision was not included. — *Kathleen Haley*

## ACTIVISTS SEEK STRICT PESTICIDE STANDARDS THROUGH DISABILITY LISTING

Environmentalists are urging the Department of Justice to list chemical sensitivity (CS) as a disability under the Americans with Disabilities Act (ADA), claiming that EPA's existing pesticide standards are insufficient to protect sensitive people from chemicals used in public spaces.

Beyond Pesticides sent an Aug. 18 letter to the Department (DOJ) on behalf of a broad environmental and public health coalition saying that listing CS as a standard disability is vital because EPA does not consider CS in its risk assessments used to determine which pesticides can be registered for use.

However, industry officials are already expressing resistance to the call, saying there is no general medical consensus on what constitutes or causes CS, making any regulation under the ADA impossible. "Until the mainstream medical community resolves the issue, it would be inappropriate to attempt to regulate it," a spokeswoman for the pesticide industry group CropLife America says.

One environmentalist says an ADA listing for CS would not require EPA to change its risk assessment methodology. Rather, it would require owners of buildings and public spaces to accommodate people with CS by replacing pesticides, cleaners and fragrances used in those spaces with non-chemical alternatives to avoid triggering environmental illness in sensitive people.

Nevertheless, a source involved in the activist coalition says a disability listing could pressure EPA to consider people with CS as a sensitive subpopulation when conducting pesticide risk assessments, and may open the door to citizen suits against the agency for registering pesticides if those pesticides are ultimately found to cause adverse health effects in people with sensitivity to the chemicals.

CS is a medical condition that is triggered through exposure to high levels of a chemical and that later causes a physical reaction from exposure to a wide range of chemicals, even at low concentrations.

"One common mis-perception is that pesticide registration means that a pesticide is 'safe.' . . . There are myriad examples of pesticides for which this is not the case," the activist coalition's letter says. "EPA's risk assessments for pesticides allow toxicity, and do not ensure regulation to protect those who are disabled by chemical sensitivity." *The*

letter is available on *InsideEPA.com*. See page 2 for details.

The coalition — which also includes Farmworker Justice, Friends of the Earth and Pesticide Free Zone, among others — sent the letter as comments on a proposed DOJ rule to complete a periodic review of its existing ADA regulations.

“While the proposed rulemaking recognizes CS as a disability on a case-by-case basis, in its failure to adopt a uniform response to CS disability and identify accessibility issues and accommodation for those with CS, it violates the spirit, intent and letter” of the Americans with Disabilities Act, the letter says.

Listing CS under the ADA is crucial because of the gaps in EPA’s risk assessment process concerning people with CS, the letter says. As a result, EPA allows registration of chemicals that are not safe to use around people with chemical sensitivity, the letter claims.

A listing under the ADA could mandate the use of Integrated Pest Management (IPM), which requires non-toxic methods for controlling pests at schools, hospitals, prisons and other public facilities, the comments say. Although EPA has recommended use of IPM at schools in order to protect children, the agency has not mandated the practice, the comments say, also underscoring the need for a disability listing.

Imposing stricter restrictions than those enforced by EPA for specific pesticides or in certain areas has a precedent in state and municipal regulations of pesticides, the coalition argues. “In many states, pesticides approved by EPA are not approved by the state pesticide regulators because of local environmental or public health issues, sensitive areas or exposures not considered by EPA,” the letter says.

However, the CropLife America spokeswoman says it is not possible to regulate the health risks associated with CS because there is no consensus on either what constitutes or causes CS and there is no way to definitively diagnose it. Therefore, listing CS as a disability would result in an inability to regulate it as a health endpoint as part of the pesticide registration or reregistration process, the spokeswoman says.

While listing CS as a disability would not force EPA to include the subpopulation in its pesticide registration process, it could give people with CS a stronger voice in EPA rulemaking, according to another activist.

For example, an ADA listing could pressure EPA to expand the types of sensitive subpopulations it must consider during pesticide risk assessments, the source says. Currently, the agency assesses additional risks posed to children, but the agency could also weigh risks to people with conditions such as CS, the source notes. A listing could also push EPA to consider CS as an environmental justice issue, the source adds.

In addition, a listing would give people with CS access to more legal recourse if the syndrome is listed under the ADA, the source says. The Federal Insecticide & Fungicide and Rodenticide Act, the law governing pesticide regulation, bars citizen suits whereas the ADA allows them, the source says. An ADA listing for CS could also open the door to citizen suits against EPA for registering pesticides that harm people with the disease, the source adds. — *Kate Winston*

## **EPA SEEKS TO ANSWER CHILDREN’S EXPOSURE QUESTIONS . . . begins on page one**

EPA announced Aug. 20 that it anticipates awarding as many as five grants of a maximum of \$1.5 million each next year. The grants are intended to fund up to four years of research.

Children’s exposures to chemicals and other contaminants in their daily environments “are expected to be different, and in many cases, greater than those of adults,” according to EPA’s request for applicants’ research proposals (RFA). This is partly because of physiological differences between adults and children and due to children’s behavior, such as playing on the floor and mouthing toys or other objects. There is currently a lack of “robust data on children’s environmental exposures,” especially information on how these exposures may change as they age and spend more time away from home, according to the RFA.

There are few studies of school-aged children’s exposures to environmental hazards because such studies are hard to conduct, according to an EPA source. Though there are many children’s health studies, testing their blood or urine for contaminants, few studies consider how school-aged children are exposed, the source says. These studies have traditionally been difficult because researchers need to test children’s schools, daycare centers, playgrounds and buses, in addition to their homes, the source says.

“Once children go to a daycare setting, they can spend eight or nine hours in that setting,” the EPA source says. Sampling in those locations “requires a whole set of permissions, and often schools are very unwilling.” As a result, many studies focus on children’s exposures in their homes, and their exposures at school or daycare are unknown, the source says.

If researchers try to include these exposures, they usually approximate them with models instead of sampling because of the time and expense involved in testing multiple sites, the source says. “But there are no really good models,” the source says.

EPA often uses modeled estimates of exposure distributions to conduct risk assessments, according to the RFA. “High quality exposure and exposure factor data are needed to evaluate and improve these models and estimates.”

EPA is asking researchers to submit applications describing tools they could develop that would assess the exposure estimates from non-residential environments to children aged 2 to 11 years, according to the RFA.

“These approaches could include the use of targeted direct and indirect exposure-related measurements, biological

markers (biomarkers), questionnaires and surveys, community and regional-level measurements, mathematical models and classification schemes,” according to the RFA. “The methods and/or tools developed and evaluated could include an “exposure index” that could be used to characterize and classify individual exposure status (for example, high, medium, or low) of children for exposure to chemical agents and other environmental factors across life stages.”

This kind of classification approach should consider various aspects of the children’s environments, such as air pollution levels, the proximity of pollution sources like roads, industrial plants or Superfund sites, in addition to their homes and schools, the EPA source says.

The risk assessment tools that the agency intends the grants to help develop would be very useful to important long-term studies of children’s environments and health, according to sources at EPA and the National Institute of Environmental Health Sciences (NIEHS).

EPA and NIEHS are cooperating on the largest such study to date — the National Children’s Study, which is slated to launch in January 2009. Researchers will track 100,000 children from preconception through age 21, amassing information on the environmental risks facing children and the connections between those risks and specific health effects.

## EMERGING CONTAMINANTS: RISKS AND IMPACTS . . . begins on page 12

nontoxic, odorless gas. Using the results of the impact assessment, the Department can then focus resources in the areas of highest risk and begin to adapt to a pending change in advance of national or international requirements. Given the long lead time required to respond to a change (e.g., phasing it out, replacing it, or stockpiling it) the identification of risks in specific areas is critical in the formulation and implementation of a risk mitigation strategy.

The “decisions” step at this juncture in the DoD protocol hinges on whether the impact assessment finds significant or only minor impacts on DoD functions, leading to a decision to either drop the chemical from further analysis or continue evaluating it. If the impacts are equivocal or moderate, the chemical may remain under consideration for further information gathering. But high impact chemicals, such as SF<sub>6</sub>, can be nominated for placement on an Action List where they are subject to a more in-depth quantitative impact assessment which elicits greater detail on impacts to the five functional areas identified above.

If the potential impacts are significant, the experts identify and develop a set of risk management options to avoid, minimize, or mitigate the potential adverse impacts posed by the emerging contaminant. The options can involve restrictions on use, additional research to fill key uncertainties, the development of substitute materials with better environmental profiles, and establishing new Best Management Practices in the field.

The preliminary Impact Assessments and engagement with internal and external stakeholders generates awareness within the Department that new strategies for special handling and use reductions may be warranted. It can also trigger research efforts to develop and test substitutes. DoD had already taken a variety of steps to reduce emissions of SF<sub>6</sub> and its related climate impacts before the July 2008 listing of the compound on

ECD’s Action List. The listing will broaden efforts to reduce and replace uses of the gas.

The DoD is currently refining its information on where, how, and how much SF<sub>6</sub> is used. New procedures have been implemented for loading and tracking the gas that have reduced use of the chemical by 52,000 pounds a year (the equivalent of retiring 572,000 tons of carbon dioxide annually). A Small Business Innovation Research (SBIR) grant was awarded to develop techniques for reducing or replacing reliance on the chemical.

It appears that there may be viable substitutes for SF<sub>6</sub>, such as nitrogen or chemical mixtures using nitrogen. The DoD will continue to review its current and planned uses of SF<sub>6</sub> to determine where alternative gases can be used while still meeting performance requirements. In addition, the focus will continue on activities where emissions can be reduced through recapture and reuse. DoD is supporting work to develop new infrared leak detection techniques, new equipment for reclaiming the gas during maintenance procedures, and using materials for strengthening the seal of containers of the gas — all efforts to minimize military releases of the gas.

The impact assessment process developed by the DoD embodies the core concepts of probability of events and severity of impacts and relies on many of the key principles identified by the Presidential/Congressional Commission in anticipating and planning for important changes. Many organizations have a range of formal or less formal ways of assessing potential impacts to their operations and the environment. The principles used in the DoD approach could be a model to address other organizations’ unique niches, operations, and priorities.

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## **Guest Perspective**

### **MANAGING RISKS AND IMPACTS OF EMERGING CONTAMINANTS**

*By Andrew Rak*

There is growing public interest in emerging contaminants across the federal government, from regulatory to science and other agencies. Emerging contaminants are chemicals or materials that have pathways to enter the environment and present potential unacceptable human health or environmental risks. They either do not have regulatory peer-reviewed human health standards or the regulatory standards are evolving due to new science, detection capabilities, or pathways. Because they can pose significant public health and environmental risks and can be mismanaged due to the paucity of data, challenges exist in coordinating how federal agencies and private entities identify, assess, and respond to them. One model of a formal program for assessing emerging contaminants is presented along with an example of how a greenhouse gas — sulfur hexafluoride (SF6) — was evaluated under the program.

In the broadest sense, risk is any exposure, event or development that has the potential to threaten or compromise the successful functioning of an organism or organization. For this reason, government agencies, businesses, and non-governmental organizations — like living things — keep an eye out for emerging threats.

Modern practitioners of risk assessment have developed tools that help organizations understand how they contribute to, or are affected by, new or changing threats. Organizations that develop processes to anticipate changes in a chemical's or material's risk profile can proactively adapt to changing regulations and/or market availability. The risk profiles must be multi-dimensional and be comprised of the probability and severity posed by a chemical's or material's availability, health effects, or environmental impact.

Building on fundamental principles from the 1997 report by the Presidential/Congressional Commission on Risk Assessment and Risk Management, the Defense Department's (DoD) Emerging Contaminants Impact Assessment protocol evaluates new risk information on chemicals or materials that may directly or indirectly affect DoD personnel and operations. Here, "risk" broadly refers to impacts on the DoD enterprise, which encompasses the totality of the department's national security mission and is not limited to environmental and safety risks. The impact assessment process culminates in the identification of specific risks along five key criteria and identifies risk management actions to minimize adverse impacts on DoD.

The DoD Emerging Contaminants Impact Assessment paradigm relies on experts' input and other sources of information to deliver science- and experience-based analyses of the potential impacts posed by an emerging contaminant. Tracing the evaluation of SF6 is illustrative of the process and may show how impact assessments can prompt new approaches and actions in addressing enterprise and environmental risks.

SF6 is a chemical that contributes to climate change at 23,900 times the global warming impact of carbon dioxide, the most commonly cited greenhouse gas. It also has an atmospheric lifetime of 3,200 years, which extends this impact. Implementing new practices to reduce the use of one pound of SF6 is equivalent to retiring 11 tons of carbon.

The preliminary steps of the impact assessment protocol

involve identifying, examining, and selecting chemicals or materials for further scrutiny should the department's needs and priorities warrant more detailed review and response.

As new risk information is identified, a determination is made whether to conduct a qualitative impact assessment. Engaging experts from across DoD brings key internal stakeholder groups together to address risk, regulatory and scientific information and current DoD processes and practices. During the impact assessment, experts respond to a set of probing questions to examine how potential new risk information may affect five DoD functional areas: 1) readiness and training; 2) acquisition, research, development, testing and evaluation (RDTE); 3) environment, safety, and occupational health (ESOH); 4) production, operations, maintenance, and disposal (POMD); and 5) cleanup/restoration. These five distinct yet cross-cutting functional areas encompass the entirety of the department's mission and responsibilities. Defining risks in these five areas assists the department in determining where resources should be placed to better position the department to continue meeting mission requirements.

While SF6 has been recognized by the electric power industry as an emerging issue for several years, the potential impacts on DoD resulting from tighter risk reduction efforts were only highlighted after SF6 was singled out during the identification process. A nontoxic, odorless gas, SF6 is produced for various industrial, electronic and military purposes and in the production of magnesium and aluminum. About 80 percent of its usage by volume is by the electric utility industry in equipment to regulate high voltage transmissions of electricity across regional grids, but it also has several military applications. The identification process for SF6 prompted further review of the chemical based on the climate risks it poses and the possibility it will be regulated.

The experts are provided with the results of an analysis that examines the probability and consequence of changes in federal, state, and sometimes international agencies' risk and regulatory findings, as well as applicable scientific developments such as new detection capabilities. The analysis includes preliminary information on how a material or chemical is used by the DoD across a range of activities. Researching how a material is used can be quite challenging as the department has a broad industrial base, extensive manpower and occupational categories, internationally based installations, and cutting-edge and often classified technologies. For this reason, expert input is crucial for a large and complex organization in order to understand the applications, sources, supply chains, and potential ways to mitigate impacts or find substitutes for chemicals of concern. The analysis — which is strengthened by active engagement with DoD's internal and external stakeholders, such as industry, academics, other federal agency representatives and professional associations — provides an overall characterization of the potential impacts to the DoD.

In the case of SF6, the impact assessment identified particularly high potential impacts to the "training and readiness," and the "acquisition/RDTE" functional areas. Moderate risks to the POMD and ESOH functional areas were recorded. Adverse impacts to the cleanup program are minimal as SF6 is a

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