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EPA Regulation Of 'Ultrafine' PM Still Distant Prospect Despite Health Risks

Air quality experts at a recent scientific workshop on "ultrafine" particulate matter (UFP) agreed that tiny particles pose significant health risks compared to larger fine particulate matter (PM2.5) and coarse particulate matter (PM10), but any EPA regulation of UFP appears to be a distant prospect given doubts about how to craft such rules.

UFP penetrates cells in the body more readily than larger particles, experts said, making it potentially more dangerous. While several experts at the workshop agreed on UFP's risks to the public, they thought it unlikely that regulators would be able to set federal or state air standards for the pollutant in the near future.

Questions that remain to be answered prior to regulation of the particles include how to define the components of UFP, what size of UFP to regulate, and how to measure concentrations of UFP emissions.

Without more scientific evidence on UFP to answer those questions, it "would be premature" for EPA to pursue a first-time national ambient air quality standard (NAAQS) for UFP separate from its existing NAAQS for PM2.5 and PM10, said Alberto Ayala, deputy executive

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Senate Revisions To TSCA Reform Bill Aiming For Preemption Compromise

Senators spearheading efforts to reform the Toxic Substances Control Act (TSCA) are revising a bill released late last year, focusing on crafting "more refined" legislation that is likely to narrow the provisions that would preempt state chemical authority in an effort to gain broader bipartisan support, sources tracking the issue say.

The issue of preempting state chemicals programs has long been a major hurdle to advancing TSCA reform, with previous Republican-led bills drawing opposition from Democrats for blocking state efforts.

Sen. David Vitter (R-LA) is working with Sen. Tom Udall (D-NM) to

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USDA Advisors Urge EPA, FDA To 're-Evaluate' Tuna Consumption Advice

Scientists advising the U.S. Departments of Agriculture (USDA) and Health and Human Services (HHS) on their pending 2015 Dietary Guidelines for Americans are recommending in a newly released report that EPA and the Food and Drug Administration (FDA), which jointly publish fish consumption guidelines for pregnant women, "re-evaluate" their recommendation regarding tuna.

The Dietary Guidelines, released every five years, carries authority beyond all other agencies' dietary advice. In addition to providing the public with nutritious eating advice, the guidelines also inform policy on which foods

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Backing State Bee Protection Plans, Growers Oppose EPA Pesticide Limits

Cotton growers are urging EPA not to limit pesticide use in states that are crafting plans to protect pollinators, raising concerns that a forthcoming federal strategy for implementing President Obama's memo on pollinator protection could curb state efforts to protect bees through better communication between growers and beekeepers.

EPA and the U.S. Department of Agriculture (USDA) are leading a federal Pollinator Health Task Force that is expected to release in the coming weeks a strategy for implementing President Obama's June 20 memo on stemming pollinator declines by improving their habitat; assessing how

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IG Rebukes Region 8 For Failing To Inspect Pesticides In North Dakota

EPA's Inspector General (IG) is criticizing Region 8 officials for failing to conduct or oversee federal-level inspections by state agencies of pesticides plants in North Dakota for 14 years, and for failing to inspect pesticides imported into the United States via North Dakota since 2011.

The report, "EPA Pesticide Inspections Must Resume in North Dakota to Determine Compliance and Protect Human Health and the Environment," released Feb. 23, indicates that EPA leadership agreed with all of IG's findings and promised to take corrective actions. *The report is available on InsideEPA.com. See page 2 for details. (Doc. ID: 179118)*

The report explains that Region 8 is not conducting inspections at North Dakota pesticide production facilities or at importation into the state, and the Peace Garden State's only federally licensed pesticides inspector retired in 2013 without replacement.

"As a result, federal inspections of establishments that produce pesticides in North Dakota have not occurred for 14 years," the report says. "Since 2011, EPA Region 8 has also failed to conduct inspections of pesticides imported into North Dakota. Since that time, approximately 1,300 pesticide imports to the United States have come through North Dakota and none have been inspected. EPA Region 8's failure to inspect imported pesticides to ensure compliance with federal law creates a potential risk not only for residents in North Dakota but residents in other states and locations in the United States."

The report explains that because federal inspections are not occurring, pesticides "produced, mixed, formulated or repackaged in North Dakota may not be in compliance with all [Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)] rules for safe packaging, handling, labeling and sampling to verify that each compound matches its label."

Region 8 staff told IG inspectors that they did not perform inspections because North Dakota officials did not want them to do so. IG did not accept the explanation. "The North Dakota Director of the Pesticides and Fertilizer Division asserted that its state producer establishment inspections were sufficient to ensure FIFRA compliance, and that Region 8 officials were also in agreement. However, EPA Region 8 has the responsibility to conduct FIFRA producer establishment and import inspections in all of Region 8's states, including North Dakota. The state's preference that federal inspections not be carried out in North Dakota should not be accepted by Region 8."

The report also raises concern over uneven compliance, noting that while inspections have not occurred in North Dakota for years, Region 8 "conducts inspections of all pesticide-producing facilities in Colorado on a 3-year review cycle."

Tensions between state and federal pesticide inspectors have also flared recently in the area of agricultural worker protection. While EPA headquarters has encouraged increased enforcement, New York officials raised concerns that a 2013 Region 2 proposal to conduct use inspections without state assistance violated a primacy agreement between the state and EPA (*Risk Policy Report*, Dec. 16).

EPA Critics Float New Strategy To Challenge Agency Rules Using Data Law

Backed by former White House regulatory review officials, a free-market advocate is proposing a new legal theory to allow states and private companies to sue EPA based on alleged violations of the Information Quality Act (IQA) in the development of a host of rules, dodging the long-standing holding that IQA violations are immune from judicial review.

Federal courts have long held that private plaintiffs lack standing to challenge agency actions under the IQA, finding that the law lacks an explicit right of action and that suits brought under the Administrative Procedure Act (APA) are not reviewable because challenged agency actions are not "final."

Despite the current judicial limitations, industry has filed numerous IQA petitions challenging the science underpinning EPA's Integrated Risk Information System assessments, proposed revisions to worker protection standards for agricultural pesticides and other toxics and pesticides actions.

But in a February white paper published by the Washington Legal Foundation (WLF), Lawrence A. Kogan, a trade lawyer and free-market advocate, suggests that states and private plaintiffs could have standing to challenge EPA's greenhouse gas (GHG) endangerment finding on the theory that the plaintiffs have a right to be free from regulations that are founded on flawed science that contravenes the law's intent. *Relevant documents are available on InsideEPA.com.* *See page 2 for details. (Doc. ID: 179012)*

"The contemplated cause of action is based on the theory that Congress intended that the IQA . . . protect the *negative* right of a designated class of persons not to be burdened, financially or otherwise, by poor quality science that agencies disseminate in support of major regulations," Kogan says in the paper, "Revitalizing The Information Quality Act As A Procedural Cure For Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study."

He suggests that a challenge to EPA's 2009 finding that GHGs endanger public welfare — the basis for EPA's climate regulatory program — could provide a venue for plaintiffs to test the theory.

"EPA's 2009 GHG Endangerment Findings and the decision-making process that led to those Findings, offer an ideal case study in how the IQA applies in the rulemaking context and how agencies contravene the law. . . . Such final agency action potentially gives rise to legal challenges of EPA's failure to comply with the IQA's peer-review standards," the paper says.

If courts accept Kogan's reasoning it would open the door for EPA's opponents to allege IQA violations in challenges against a broad array of other rules, including still-pending actions and some recently finalized regulations. For example, Jim Tozzi — formerly a high-ranking official in the White House Office of Management and Budget (OMB) — says in an introduction to the paper that Kogan's theory could also be used to challenge EPA's controversial new source performance standards (NSPS) for GHG emissions limits from power plants when the final version of that rule is released later this year.

"Another possible target of the type of IQA challenge [Kogan] proposes would be against EPA's failure to conduct a peer review of 'highly influential scientific information' in its determination that carbon storage and sequestration is a viable technology — the central component of its proposed rule to control emissions from new gas-fired power plants," Tozzi writes in the introduction.

Later in the white paper, Kogan says that a successful climate IQA suit would pave the way for further challenges to EPA actions including the pending rule to define which waters are subject to the Clean Water Act; the social cost of carbon, which underlies many GHG standards; the proposed national ambient air quality standard for ozone; EPA's study on the human-health and environmental impacts of hydraulic fracturing; review of the Keystone XL pipeline's environmental impacts; joint EPA and National Oceanic and Atmospheric Administration disapproval of states' coastal nonpoint source pollution control programs; and the Fish and Wildlife Service's endangered species designations.

Tozzi in his introduction to the paper says that if courts reject Kogan's legal arguments, the executive branch — in particular OMB — could step in to conduct more robust oversight of agencies' research and response to petitions under the IQA. And he also suggests that if the effort fails, "then it is time for the Congress to pass legislation which declares . . . the [IQA] to be judicially reviewable."

The IQA — also known as the Data Quality Act — generally requires agencies to ensure that scientific and other data used to develop policy stances are objective, reproducible and peer-reviewed. While the law requires agencies to accept and respond to petitions to correct allegedly flawed data used in rulemakings and other decisions, key federal courts have so far held that agency responses to IQA petitions are not final actions and therefore not judicially reviewable, eliminating an enforcement mechanism for private parties to pursue challenges on the merits if agencies deny their petitions (*Risk Policy Report*, July 1).

Despite the legal hurdles, EPA critics have continued to file IQA petitions seeking corrections of agency determinations. For example, conservative groups have long alleged that EPA ignored IQA requirements in its 2009 endangerment finding — which was a prerequisite for EPA regulation of vehicle GHG emissions and other sources after the Supreme Court ruled in *Massachusetts v. EPA* that GHGs are "pollutants" and subject to Clean Air Act regulation.

The endangerment finding has already survived one major court challenge, *Coalition for Responsible Regulation v. EPA*, in which the U.S. Court of Appeals for the District of Columbia Circuit upheld the agency's determination and the

Supreme Court declined a petition for review.

But the WLF paper argues that the finding could be vulnerable to a second challenge, largely based on the IQA, even though courts do not allow suits directly challenging EPA's responses to IQA petitions.

Kogan says that even though the law does not allow direct suits, it can be read as creating a right "to be unburdened by improperly peer-reviewed information" — and that opponents of EPA rules could invoke that right when suing under the APA, which allows challenges to any "final agency action" that is allegedly "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law."

In prior rulings, courts have held that an agency's denial of an IQA petition is not a "final action" subject to APA suit, because it is not "an action by which rights or obligations have been determined, or from which legal consequences will flow," which is the test established by the Supreme Court in the 1997 ruling *Bennett v. Spear*.

While the *Bennett* standard bars suits over IQA petition responses, Kogan says EPA's endangerment finding, its denial of requests to reconsider that finding, and its forthcoming climate rules are all unquestionably final actions whose development involved scientific findings subject to IQA procedures — meaning underlying violations of the IQA could support a decision that EPA violated the APA in taking those steps.

Linking alleged IQA violations to EPA rulemakings could also help plaintiffs establish that they were directly injured by the agency's actions, Kogan continues. Litigants seeking to overturn a rule or other action must show that they suffered a negative impact from the agency's conduct, but courts have generally ruled that IQA violations do not in themselves satisfy that test.

The paper argues that without EPA's scientific findings, which were subject to IQA peer-review requirements, "it would not have been possible to issue [the determination], and consequently, it would have been neither necessary nor possible to promulgate the GHG emissions-control regulations they subsequently triggered."

Opponents of EPA's GHG rules already raised the alleged IQA violations involved in the endangerment finding in connection with its forthcoming GHG rules for existing power plants.

Most recently, the Institute for Trade, Standards and Sustainable Development (ITSSD), a free-market group that Kogan serves as executive director, raised those concerns in its Aug. 13 comments on the agency's GHG rules for existing power plants. The group, which says it advocates for "scientifically and economically benchmarked and justified, market-driven" regulations, says that EPA failed to ensure proper peer review of 28 "core reference documents" that supported EPA's conclusion that GHGs endanger public health and welfare.

The group in its comments notes that EPA offers as the basis for the existing source performance standards' "major assessments" by the federal government, the United Nations and the National Academy of Sciences (NAS), a body outside of government but funded substantially with federal dollars. These same assessments, deemed "highly influential" under the IQA, formed part of the body of research supporting the endangerment finding.

Similarly, the Southeastern Legal Foundation, another free-market group that is still seeking to challenge the GHG endangerment finding, Feb. 9 filed a new suit under the Freedom of Information Act seeking documents related to the agency's development of its finding.

"The purportedly 'scientific' information on which the Agency relied was the subject of a number of systematic manipulations, including collusions to withhold scientific information, deletion of emails and raw data to prevent discovery of key facts, manipulation of data and computer code to create false impressions, and concerted efforts to boycott key journals to excluded disagreement," the complaint says. — *David LaRoss*

Senate TSCA Revisions Seek Preemption Compromise . . . begins on page one

revise a draft of the S. 1009 bill introduced in 2013 by Vitter and the late Sen. Frank Lautenberg (D-NJ), seen as a landmark compromise to reforming the decades-old chemical safety law.

But the bill drew opposition from then-Environment & Public Works Committee Chairman Sen. Barbara Boxer (D-CA) due to concerns about preempting state chemicals programs, and it failed to advance.

Similarly, divisions in the House over the preemption issue helped to kill the lower chamber's TSCA reform push last year. Rep. John Shimkus (R-IL), chair of the Energy & Commerce Committee's environment panel, says he will start anew on crafting a TSCA reform bill this year in a bid to win more Democratic support.

Some TSCA reform stakeholders have suggested the merits of crafting a TSCA reform bill first and punting a debate over the bill's preemption language until agreement is reached on all other aspects of the bill.

But Vitter says he is continuing to work closely with Udall on revising the legislation and is "optimistic that a revised compromise is on the horizon," according to a statement from Vitter's office. And a congressional source says the resulting changes are focusing on a bill that "will be more refined and attract more support from a broad variety of groups."

The original S. 1009 bill would have barred states from imposing new restrictions on chemicals identified as "high-priority" by EPA at the time the agency publishes a schedule for assessing safety of the substance and once the agency designates a chemical as "low-priority."

Vitter and Udall worked to revise the bill and added considerations for vulnerable subpopulations, deadlines for EPA

to take action on chemicals, and new preemption language that would only block state action on high-priority chemicals once EPA commences a safety assessment.

But gridlock on the bill escalated in September when Vitter criticized Boxer for what he said was a premature release of the revised bill.

Boxer released not only a revised S. 1009 bill but her revisions to the updated measure, which included dropping the provisions that she said would preempt state programs and tightening the bill's safety standard.

Sen. James Inhofe (R-OK), who took over as the panel's chairman for the 114th Congress, has vowed to pursue TSCA reform efforts this year but acknowledged in a brief Feb. 4 interview with *Inside EPA*, the "difference of opinion" with Boxer on preemption.

But a state source tracking the issue says "it sounds like the preemption issues are something they're looking at really closely," and that the planned revisions could be a "big step in that direction" toward narrowing how and when state authority would be preempted that could win a compromise with states.

That source adds that they would oppose any provisions that did not appear to preserve existing state labeling laws, which have a "proven track record" as being effective, and existing state restrictions on specific substances. Future chemical regulations are something that "states can partner with EPA on, but if a state has already taken" action, that action should be preserved, the source says.

Claudia Polsky, deputy attorney general with the California attorney general's office, said during a Jan. 27 Environmental Law Institute event on state preemption and TSCA reform that there are several "nonstarters" for California in the discussions, such as judicial oversight and "regulatory void preemption" that would "kick states out of the regulatory sphere before any final regulation" would take effect, which was a major criticism of early versions of the House and Senate bills.

She also indicated the state would oppose efforts to bar states from enacting parallel laws so they could function as "co-enforcers" of federal regulations, saying it is "unclear why they would want to have one cop on the beat when they can have 51."

EPA Eyes Staff Cuts At Many Program Offices In FY16 Budget Request

EPA is planning staff cuts in many program offices even as it asks Congress for a funding boost in fiscal year 2016, according to the agency's congressional justification for the FY16 budget request, signaling that agency employees could see another round of buyouts or other staff reduction measures in the coming year even if appropriators in Congress do not cut EPA's total budget.

While the agency is seeking an overall increase for FY16 of 38 full-time equivalents (FTEs), the budget justification, released Feb. 2 alongside EPA's overall FY16 funding request, says program areas including the waste, toxics and water offices would be targeted for reductions under EPA's plan, despite many of the same offices being slated for larger budgets. *Relevant documents are available on InsideEPA.com. See page 2 for details. (Doc. ID: 178044)*

The FY16 budget request includes 15,373.3 FTEs, which would be up from the current enacted level of 15,335. But that increase is due almost entirely to a proposed increase of 105 FTEs in the air and radiation program, which the agency says is needed to implement the Obama administration's climate change agenda and to move forward on an array of air actions such as rulemakings that are subject to court-ordered or statutory deadlines.

Meanwhile, the budget proposal says the agency's cleanup programs are set to cut 51 FTEs, from the current level of 3,871.4 down to 3,820.4; the water program plans to cut four FTEs, from 3,160 to 3,156; and the chemicals program 21, from 2,410 down to 2,389.

The cuts could be implemented through simple attrition, by choosing not to replace staff who voluntarily leave EPA; by transferring employees from one program area to another; or through a new round of buyouts mirroring offers made to many career staff in 2014 and 2013 in order to achieve payroll reduction goals in those years.

It is uncertain how new buyouts would be received by the EPA workforce, however, after staff unions threatened to file a labor complaint against the agency over its handling of "impact and implementation" procedures for reassigning duties after staff who accept buyouts depart.

The proposed staff reductions at the affected offices are being spread out across a variety of individual program areas. For instance, the Resource Conservation & Recovery Act (RCRA) program would lose five FTEs from its corrective action office, and 9.3 from the waste management area, while gaining 4.2 in the waste minimization and recycling program.

EPA acknowledges in the justification that the staff moves could lead to lower performance in the affected offices. In the waste management section of the request, it says the proposed reduction "may delay activities such as conducting additional analysis to support non-hazardous secondary materials categorical rulemakings and responding to regulatory backlog petitions."

Meanwhile, addressing the boost to staffing in the air office, the request says that "[a]t a national level, the agency is requesting additional FTE to provide support in targeted areas" including rulemakings and regulatory reviews subject to

statutory deadlines, guidance on federal planning and permitting requirements and implementation of motor vehicle engine standards.

Enforcement is the only other major program area slated for an increase in staff, from 3,390.7 to 3,401.9 FTEs. However, the agency says in the justification that it will continue with its "next generation compliance" strategy — EPA's plan to cut enforcement costs through innovative measures that will rely more on data than inspections for enforcement. The strategy has prompted outcry from environmentalists and others who warn it will reduce EPA's ability to identify and prosecute violators of environmental laws.

"The FY 2016 [enforcement] request maintains FTE at a reduction from pre-FY 2010 levels, but includes funding that allows EPA to support those staff so they can identify and address noncompliance, through investments in data analysis and systems, lab support, equipment for front line enforcement personnel, inspector training, and case support such as expert witnesses and document management service," the request says.

EPA's Inspector General (IG) Arthur Elkins Jr has already urged Congress to reject a proposed cut to the Office of Inspector General (OIG) payroll, warning that existing funding is hindering investigations of fraud, waste and abuse.

"The budget levels made available to me are impeding our ability to do our work. . . . When the OIG is not able to carry out its responsibilities because of inadequate funding, it is a net loss to the federal government and American taxpayers," Elkins said in testimony to a Feb. 3 House Oversight & Government Reform Committee hearing on agency IGs' access to documents, which also included testimony from IGs at two other agencies.

The agency's proposed staffing hike is part of a general funding increase sought in President Obama's proposed FY16 budget for EPA, which would increase appropriations for the agency by $452 million — up to $8.591 billion from its current $8.139 billion funding.

But lawmakers are expected to largely ignore the president's budget proposal when they craft FY16 spending bills later this year, and Republicans are likely to use the appropriations process for EPA's FY16 budget to push significant cuts in EPA's overall budget and its Environmental Programs & Management account in particular, which funds most agency rulemaking and regulatory efforts and is currently set at $2.613 billion.

While the Senate has in recent years blocked House proposals for sharp EPA funding cuts, this year the interior panel that oversees the agency's budget and other environmental spending includes many prominent EPA critics, including Majority Leader Mitch McConnell (R-KY) and Roy Blunt (R-MO). — *David LaRoss*

Advisors Urge EPA, FDA To Change Tuna Advice . . . begins on page one

can be purchased with Women, Infant and Children (WIC) checks by low-income mothers and their children, and which foods are included in public school lunches. Tuna has long been included in both programs because it is a low-cost source of protein.

Environmentalists and public health advocates are already protesting the report's tuna recommendations, citing high levels of mercury in the fish compared to other types of seafood, and vowing to fight any efforts to change EPA and FDA's advice.

Since 2004, EPA and FDA have provided joint advice on fish consumption for pregnant women, or those women who may become pregnant. The agencies' advice is intended to educate the public about the risks that methylmercury poses, particularly to fetuses and young children, as well as the cardiovascular and developmental benefits of fish oils and proteins.

The agencies last year released a draft update to their advisory, one that for the first time recommends a minimum amount of fish consumption as well as a maximum. The recommendation that pregnant women should eat a minimum of eight ounces of fish per week was highly controversial. Earlier versions of the advice recommended only that pregnant women eat no more than 12 ounces of fish per week overall and limit albacore tuna consumption to no more than six ounces per week, recommendations continued in the latest draft.

The draft is controversial in part because it was based on an FDA risk-benefit model that EPA and others harshly criticized when the draft version of the model was released for public comment in 2009. The FDA model attempts to weigh the developmental risks against the cardiovascular benefits of eating fish, but environmentalists and public health advocates continue to argue that the model underestimates the risks of mercury.

FDA announced Feb. 23 that the agencies set a March 25 deadline for comments on the agencies' draft update.

The Dietary Guidelines Advisory Committee (DGAC), a group of scientists charged with providing recommendations to HHS and USDA on what should be included in each update to the Dietary Guidelines, released Feb. 19 its report. The committee's report urges EPA and FDA to re-consider their advice that pregnant women or those that may become pregnant eat no more than six ounces of albacore tuna per week.

The committee concludes that "for the majority of commercial wild and farmed species, neither the risks of mercury nor organic pollutants outweigh the health benefits of seafood consumption, such as decreased cardiovascular disease risk and improved infant neurodevelopment," according to their report. *The relevant section of the report is available on InsideEPA.com. See page 2 for details. (Doc. ID: 179113)*

"Based on the most current evidence on mercury levels in albacore tuna provided in the 'Report of the Joint United

Nations Food and Agriculture Organization/World Health Organization Expert Consultation on the Risks and Benefits of Fish Consumption,' 2010, the DGAC recommends that the EPA and FDA re-evaluate their current recommendations for women who are pregnant (or for women who may become pregnant) or breastfeeding to limit white albacore tuna to not more than 6 ounces a week." The recommendation footnotes the agencies' draft update.

Asked about the recommendation, an EPA spokesman replies that FDA is announcing "that in 30 days, the FDA and EPA will close the public comment period on their draft advice on fish consumption for certain population groups. Following the close of the comment period, the agencies will review the public comments and determine whether to further revise the advice for fish consumption for these population groups."

DGAC's report adds that "Albacore tuna, produced only from wild marine fisheries, is a special case of a popular fish highlighted by the 2004 FDA and EPA advisory. For all levels of intake including more than double the 12 ounces per week recommendation, all evidence was in favor of net benefits for infant development and [cardiovascular] risk reduction."

The National Fisheries Institute (NFI), which represents the fishing industry, praised the DGAC's report, saying it "strongly reaffirms seafood's position as one of the healthiest options in the American diet," in a Feb. 20 statement.

Regarding DGAC's recommendations to EPA and FDA, an NFI spokesman writes, "This is an important recommendation as the FDA's own Net Effect report clearly illustrates that the 6 ounce limit on Albacore [is] out of step with current science." The spokesman points to a conclusion in the FDA model indicating that albacore tuna consumption greater than that amount would not be harmful, information that the agencies did not use in the latest draft update, choosing instead to retain their earlier recommendation for pregnant women to eat no more than six ounces of albacore tuna per week.

But environmentalists and public health advocates are already protesting the DGAC's recommendation. In a Feb. 23 press release, the Environmental Working Group and Mercury Policy Project refer to the DGAC's comments on fish consumption as "shocking."

"There's confusion about how this affects the other agencies. It's not clear that revising the advisory will happen. But that's a very clear and specific mandate," an EWG source adds, calling such a mandate unusual. Changing the albacore tuna recommendation in the latest draft advisory "wasn't even on the agenda of either of the two agencies. It's not going to happen without a fight . . . This isn't merely an academic exercise. It's about what women buy [to eat] with WIC checks."

Environmentalists are particularly concerned about the DGAC's tuna recommendation because of the outsized impact that one species has on Americans' exposure to mercury — and because of the impact they believe the Dietary Guidelines can have on other agencies' dietary recommendations.

"In the scheme of things, when Congress ordered [the Department of Health and Human Services] and USDA to come up with these guidelines, they said [other agencies' advice] has to conform with the Dietary Guidelines. They're the most important game in town," said Edward Groth III, a scientist retired from Consumers Union, in a Feb. 23 interview.

Groth has reviewed the FDA benefit-risk report underlying the agencies' draft fish consumption advice. In comments recently submitted to FDA, Groth argued that "canned tuna (both types combined) is the largest source of US methylmercury exposure, by a very wide margin," citing market share data and average mercury levels in seafood types. "All forms of tuna (including fresh and frozen steaks and sushi in addition to canned varieties) together account for 45 percent of total mercury [exposure]."

Groth in the interview questioned the DGAC's decision to cite only the United Nations/World Health Organization's (UN/WHO) expert consultants' report as the basis for its conclusions. Groth argued that report is five years old, and important new epidemiology research, indicating even greater risks from mercury exposure, has been published since. Groth also questioned the conclusions in the FAO/WHO report, arguing that it was not peer-reviewed, and did not conduct a literature search or weight of the evidence analysis. Instead, he said, is was largely based on FDA's modeling exercise. "A model is not evidence. It's an expert guess. It's not facts," he said.

From this modeling exercise, the group concluded that "the benefits [of eating fish] outweigh the risks for most people most of the time. That's true. But they didn't look at the margins," Groth said. "Whether the benefits outweigh the risks is not the right [policy] decision. It's maximizing the benefits and minimizing the risks." — *Maria Hegstad*

SUBSCRIPTIONS:
703-416-8500 or
800-424-9068
custsvc@iwpnews.com

NEWS OFFICE:
703-416-8541
Fax: 703-416-8543
riskpolicy@iwpnews.com

Publisher: Jeremy Bernstein (jbernstein@iwpnews.com)
Managing Editor: Maria Hegstad (mhegstad@iwpnews.com)
Associate Editor: Dave Reynolds (dreynolds@iwpnews.com)

Production Manager: Lori Nicholson (lori.nicholson@iwpnews.com)
Production Specialists: Daniel Arrieta, Michelle Moodhe

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pesticides and other stressors contribute to their declines; and acting where appropriate.

Observers say the strategy will likely include strict default pesticide label requirements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for products that are toxic to bees, but that those federal restrictions will defer to state pollinator protection plans, which generally seek to mitigate risks to bees through improved cooperation between beekeepers and pesticide applicators.

A half dozen states currently have pollinator protection plans, though sources say roughly 25 to 30 other states have begun the process of developing one. Exactly how the pesticide labels will reference or defer to state plans has been a subject of concern for industry and state regulators in recent weeks.

During the National Cotton Council's annual meeting in Memphis, TN, Feb. 6, growers told EPA toxics chief Jim Jones that federal officials should hold off on imposing new regulatory requirements on pesticide applicators in states that are currently crafting plans to protect bees, according to an industry source.

The source says growers noted that developing a state plan is a lengthy process and that the federal strategy could potentially preempt those efforts.

"States are working on these plans, but whenever you bring multiple stakeholder groups together," agreeing on an approach can be a time-consuming process, the source says, describing the concern growers addressed to Jones during his remarks at the conference.

The industry source says Jones did not detail how federal officials might accommodate the growers' concern, but said Jones reiterated past statements from other EPA officials that the agency is backing the state pollinator protection efforts as a means of mitigating pesticides' risks to bees while accounting for the different needs of agriculture around the country.

EPA declined a request to provide *Inside EPA* with Jones' comments to the National Cotton Council, saying he did not speak from prepared remarks.

EPA and USDA are leading a federal task force in working to stem declines in bee populations, and the agencies have named pesticides, namely neonicotinoids, as one of several factors in the decline, with others including decreasing habitat as well as pests and pathogens like the varroa mite.

While federal officials are expected to soon announce plans for implementing Obama's memo, EPA is also weighing the risks and benefits of neonicotinoids as part of its registration review process, which is ongoing and expected to last several more years.

Industry officials have recently met with EPA pesticide officials, urging them to reconsider the agency's Oct. 15 analysis, conducted as part of registration review of several neonicotinoids, which concluded seeds treated with the pesticides bring negligible benefit to soybean yields over no pesticide use at all.

The growers' request during the Feb. 6 conference for EPA to withhold pesticide labeling restrictions in states where pollinator protection plans are in the works backs similar concerns that industry officials and regulators from some Midwestern states have raised about the implementation of the forthcoming federal strategy.

During the National Association of State Departments of Agriculture's winter policy conference in Washington, DC, Feb. 3, the North Dakota Commissioner of Agriculture said the federal strategy should back state efforts to improve collaboration between beekeepers and growers and not restrict pesticides, adding that risks from pesticides to bees have been overstated.

Industry sources tell *Inside EPA* that the state plans are better able to accommodate various farming and pesticide application processes around the country than any federal policy.

"For EPA to try to write a management plan that covers all crops in all regions" would be almost impossible, a second industry source says. The source added that EPA, in implementing the president's memo, is expected to establish a framework for state plans, which states may implement in a way that is suitable for local agriculture.

EPA signaled it was moving in that direction with an August letter to the State FIFRA Issues Research and Evaluation Group (SFIREG). In the letter, agency pesticide officials called state pollinator protection plans a first step in mitigating acute risks from neonicotinoids and other pesticides to bees, and said the plans are consistent with the agency's pollinator protection efforts.

In December, SFIREG circulated draft guidance aimed at helping states craft pollinator protection plans, and took comment from its members through Feb. 1. The draft guide says growers and beekeepers can mitigate unreasonable risks to bees through communication and collaboration prior to pesticide applications on topics including choosing a pesticide product and application time, as well as by allowing beekeepers time to move or cover their hives.

The document also calls for states to accept stakeholder input before crafting a plan and to establish mechanisms to facilitate communication between beekeepers and growers. SFIREG is currently reviewing comments from its members, an official with the group says, adding that the group hopes to soon finalize the guidance.

Environmentalists have opposed relying on the state plans to protect bees, arguing the strategy shows EPA shifting responsibility for pesticide risks to bees to state regulators, creating a patchwork of approaches that are inadequate to

address the risks that systemic pesticides, which are taken up into plants' pollen and nectar, pose to bees.

"Honey bees are going to be affected everywhere in the same way from these chemicals so the best way to address this pollinator crisis is with action at the federal level," a source with the Center for Food Safety says.

Industry officials, meanwhile, are continuing their pushback against an EPA Oct. 15 analysis that found neonicotinoids provide negligible benefits for soybean yields over no pesticide use at all, a boon for environmentalists who argue neonicotinoids pose unreasonable environmental risks while bringing little, if any, benefit.

EPA sought comment on the efficacy study through Jan. 23 and has indicated it will consider those comments as part of its registration review of the neonicotinoids clothianidin, imidacloprid, and thiamethoxam.

According to documents posted to a federal website Feb. 10, EPA staff has met twice in recent months with industry officials who offered research showing neonicotinoid seed treatments provide a host of benefits for agriculture and the economy, including increased crop yields and quality, as well as lower food prices.

During a Jan. 22 meeting, industry contractor AgInfomatics told EPA staff that neonicotinoids add billions to the North American economy, including between 4 billion and 4.3 billion annually to U.S. agriculture, primarily through corn farming, and between $150 million and $275 million for agriculture in Canada, primarily for canola, according to a presentation from the industry contractor. *The presentation is available on InsideEPA.com. See page 2 for details. (Doc. ID: 179084)*

AgInfomatics also reiterated arguments that without neonicotinoids farmers would revert to fewer but more toxic pesticides leading to increased pesticide spraying and increased resistance in target pests.

More than 15 EPA officials and two USDA officials attended the Jan. 22 meeting with industry officials from AgInfomatics, as well as Bayer CropScience, Syngenta and Valent U.S.A. Corporation, according to public documents. A smaller group of EPA staff met Dec. 2 with Dupont/Pioneer where industry presented results from a decade of research showing the efficacy of neonicotinoid-treated seeds in soybean and corn production, according to documents recently posted online.

Environmentalists have said they met with EPA staff Dec. 12, and that agency officials said they intended to analyze the efficacy of neonicotinoid-treated seeds in corn production, and that the review would follow a similar approach as the agency's analysis of the efficacy of treated seeds in soybean production.

One of the sources says industry officials are urging EPA to reconsider its conclusion in the Oct. 15 efficacy analysis during its ongoing registration review of neonicotinoids. The source also says EPA has not requested efficacy data to support an analysis of the efficacy of treated seeds in the production of other crops besides soybeans. — *Dave Reynolds*

EPA Regulation Of Ultrafine PM Still Distant . . . begins on page one

officer with the California Resources Board (CARB), at the recent conference. EPA hosted the UFP workshop from Feb. 11-13 in Research Triangle Park, NC.

Ayala said "we don't have an ambient air standard, and we are probably not going to have one in the near term" for UFP, and also noted that CARB is unlikely to pursue UFP rules in the near-term.

The Clean Air Act gives California authority to set air regulations for mobile sources — one of several sources of PM pollution — stricter than the federal government. But Ayala said that without more data on UFP, it would be hard to craft the right state or federal rules to reduce those risks. Nevertheless, he said there is sufficient proof of UFP's harm to humans that the state will still seek to mitigate emissions without rules in place.

EPA and state air regulators have for some years been studying the adverse health effects of ultrafine particles, which are much smaller even than PM2.5, which is blamed for a variety of ailments including cardiovascular disease and pulmonary effects such as asthma. The agency is currently pursuing a review of its PM2.5 NAAQS of 12 micrograms per cubic meter last updated in 2012, and could potentially alter that standard.

However, the agency is not expected to include direct or distinct regulation of UFP in the upcoming revision to its PM2.5 NAAQS given the various scientific doubts about how to define and control it.

UFP is conventionally defined as particles 100 nanometers (nm) or less in diameter, but not all experts agree that this is necessarily the most useful threshold for the purposes of regulation.

Some experts at the workshop suggested that more than one size category smaller than PM2.5 may be required — for example, a "very fine particles" category smaller than PM2.5 but larger than 100 nm.

In its last review of PM NAAQS standards, EPA found the available scientific evidence was "suggestive" of a causal relationship between UFP and short-term health effects, such as cardiovascular effects and mortality, said Scott Jenkins, of EPA's Office of Air Quality Planning and Standards, during the workshop. The agency, however, found the evidence inadequate to suggest a causal relationship for other health effects.

The agency also noted the ongoing difficulty in measuring the ambient concentration of UFP, due to a lack of air quality monitoring networks aimed specifically at the class of tiny particles.

In a 2013 survey of scientific studies on UFP, the Health Effects Institute (HEI) found that "Several factors — the

unique physical properties of UFPs, their interactions with tissues and cells, their potential for translocation beyond the lung — have led scientists to expect that UFPs may have specific or enhanced toxicity relative to other particle size fractions and may contribute to effects beyond the respiratory system. However, the considerable body of research that has been conducted has not provided a definitive answer to this question."

HEI concluded that, "The current evidence does not support a conclusion that exposures to UFPs alone can account in substantial ways for the adverse effects that have been associated with other ambient pollutants such as PM2.5," but cautioned that more research is required and that unique health effects caused by UFP cannot be ruled out.

HEI, a research organization funded half by EPA and half by the auto and other industries, found a striking absence of long-term studies from which to draw conclusions about possible long-term health effects.

During EPA's workshop and a related event, experts' comments highlighted there is no consensus about the size of particles that EPA should regulate if it chooses to eventually set a NAAQS for UFP.

For example, Professor Michael Kleeman, a clean air expert with the University of California, Davis, said in a Feb. 11 presentation at an earlier "kick-off" conference hosted by EPA in Research Triangle Park to inform the current PM2.5 NAAQS review, that it is "not clear" that the 100 nm threshold is the correct one.

Participants at the Feb. 13 UFP event also discussed the arbitrary nature of the 100 nm cutoff, and discussed whether EPA should perhaps consider other thresholds and maybe more than one additional size class of particles, such as PM0.5 or PM1. Particles smaller than PM2.5 but larger than 100 nm could quite plausibly be responsible for specific health effects, participants noted.

Another ongoing debate is how to measure UFP concentrations. Because of its small size, UFP typically makes up a very small portion by mass of larger PM classes of which it is a constituent, but accounts for a large number of particles in any given air sample. However, counting the number of ultrafine particles may not be the best way of determining the health risk of UFP, participants agreed, as the number of particles does not necessary equate to their toxicity.

CARB's Ayala noted that California recently considered determining compliance with its Low-Emission Vehicle III standards using particulate-count, but reverted to a mass-based system when faced with public criticism over the approach's drawbacks.

Participants in the Feb. 13 meeting broadly agreed with the findings of HEI's 2013 study, however, that a variety of existing regulations aimed at reducing PM2.5 will also curb UFP. Ultrafine particles from vehicles, in particular, should be relatively easy to mitigate using existing technology, meeting participants said.

Diesel particulate filters are already in widespread use and are very efficient at reducing UFP if correctly maintained, participants said, while similar filters could be introduced for gasoline-powered vehicles. Should filters for gasoline vehicles prove too costly, improving the efficiency of combustion systems offers similar benefits, various speakers said. — *Stuart Parker*

Experts Outline Key Scientific Issues For EPA's Particulate NAAQS Review

EPA officials, university researchers and others say that key scientific and policy issues for the agency's latest review of its particulate matter (PM) national ambient air quality standards (NAAQS) include how to respond to new science on shorter-term exposures to the pollutant and better information on identifying the sources of PM.

Whatever the agency decides in response to those issues could be central to its eventual decision on whether to revise or retain the existing fine particulate matter (PM2.5) NAAQS of 12 micrograms per cubic meter (ug/m3) set in 2012, which is stricter than the previous 15 ug/m3 standard issued in 1997. EPA in its 2012 rulemaking retained its prior separate NAAQS for larger coarse PM (PM10) of 150 ug/m3 over a 24-hour period.

The Clean Air Act mandates that EPA review its various NAAQS every five years, and the agency Feb. 9-11 held a workshop in Research Triangle Park, NC, to help inform its review of the PM standard. Immediately after that event, the agency also held a Feb. 11-13 workshop to discuss the science on smaller "ultrafine" particles (UFP).

EPA staff announced during the PM NAAQS workshop that it expects a draft integrated review plan outlining how the agency will conduct the review will be ready by fall or winter of 2015. The agency will then craft an integrated science assessment (ISA) outlining the most policy-relevant science on PM pollution and its impacts on public health and the environment, and plans to have a first draft review by its air advisors in late 2016.

Scott Jenkins of EPA's Office of Air Quality Planning & Standards said in a Feb. 9 presentation to the workshop that some key considerations in the current review include the extent to which new scientific evidence reinforces, extends or calls into question the data EPA assessed in previous PM NAAQS reviews; and the extent to which uncertainties in data from the last review of the standard have been reduced and/or whether new uncertainties have emerged. *Relevant documents are available on InsideEPA.com. See page 2 for details. (Doc. ID: 179004)*

These uncertainties include EPA's understanding of PM-attributable health effects, particularly at low ambient concentrations, and at-risk populations; uncertainties in the agency's characterization of PM emissions, ambient concentrations and exposures (i.e., monitoring and modeling); and uncertainties in the public welfare implications of visibility

and non-visibility effects, and uncertainties in monitoring for welfare effects.

During a recap of a session on broad scientific issues of atmospheric science, modeling and monitoring of PM, panelist Mike Kleeman with the University of California, Davis, said there is an extensive amount of new data on PM from modeling and monitoring, but a question is how the "power of data can be harnessed."

Kleeman also said that studies that identify PM sources that are harmful to human health and ecosystems exist but their results are "unsatisfactory," and that the panel "articulated a wish to continue studying that."

Regulators have long debated speciation, or the ability to define the individual components of PM and their sources. Speciation could potentially allow for more-targeted regulation of PM than setting an overall NAAQS, because it might allow officials to regulate those sources of PM that contribute the most harmful or largest components of particles. PM is emitted from a host of mobile and stationary sources, including cars and power plants.

One panelist said during a Feb. 9 discussion that since the last NAAQS review there have been a number of field studies done on the characterization of secondary aerosol emissions, and "a lot of new instrumentation" used, such as maps and the online measure of organic PM, to better characterize the pollutant.

Panelists also talked about the emergence of new findings related to local-scale efforts of near-road monitoring and being able to get more "complex" gradations of PM size distribution and particle composition, and learning what sources are large contributors of PM — which could potentially help speciation efforts.

Near-road monitoring is crucial given mobile source emissions of PM, and the need to better understand their impacts on human health. EPA's Gayle Hagler said that the upcoming ISA will need to include a "significant" new volume of literature on near-road trends using a "wide variety" of measurement techniques.

Discussing key messages from a workshop session on linkages from atmospheric science, exposure characterization and interpretation of results from health studies, EPA's Tom Long summarized panelists' comments on a need to start thinking about PM exposures, efforts to characterize exposures in health studies, and options for improving ways to model exposure. The "gap for personal exposures" is "huge and complex," he said.

Exposure plays an important role in the NAAQS review process, because EPA sets the standards for PM, ozone, carbon monoxide, and other criteria pollutants based on the level it believes is necessary to provide an adequate level of protection to public health based on the level of exposure humans face from a pollutant. Long said that there is better data available now that can help to refine exposure and clarify the interpretation of study results.

Some uncertainties from the 2009 ISA that informed the last PM standard review included spatial and temporal variability of UFP, PM components and PM sized between PM2.5 and PM10, and how exposure measurement error changes across PM size and composition influence health effect estimates; and characterization of how ambient exposure is influenced by climate, season, housing stock, and proximity to roads or other sources.

Scientific advances could help to address some of those questions in the upcoming NAAQS review, panelists suggested, for example increasing use of satellite data that provides better information on PM.

Within the last five years, the use of satellite information has been "finding its way into a wide range of health applications" and its use is "ready to be thought about in the ISA." Satellites have enabled the "ability to characterize exposures to many more people and a wider exposure range," Long said, which is "useful."

Panelists suggested that EPA in the review should increase its research on assessing PM emissions and exposures in different areas, for example better comparisons of rural and urban or eastern and western locations.

This approach "may provide insights specifically to coarse particles" that are regulated under the PM10 NAAQS and different compositions of coarse particles, another panelist said. Monitoring low-density populations in agricultural areas "may provide additional insights" on particle size differences, the panelist suggested.

Research studies on PM in the United States have advanced to assessing "lower and lower concentrations" of PM, which is helping to provide "more and more precision" in ambient concentrations and estimates at lower concentrations, putting "pressure" on thinking about health effects at even lower concentrations of PM, said another panelist, which could be important in EPA's decision on whether to tighten the NAAQS.

During a wrap-up discussion of all of the key messages from the various sessions, some panelists emphasized a need for EPA in the upcoming NAAQS review to focus on predicting how PM exposures will change over time — by the year 2030, for example — while others emphasized focusing on current PM exposures.

One panelist pointed out that while "big changes are hard to predict," small changes are occurring with respect to vehicle technology and gas mileage, which could impact mobile sources' contribution to PM formation. — *Lea Radick*

NAS Calls For Climate 'Intervention' Debate But Stresses Need For GHG Cuts

The National Academies' National Research Council (NRC) in a new two volume report is calling for policymakers and others to discuss possible new governance structures to monitor research on the riskiest climate "intervention" options but concludes that such engineering is no substitute for dramatic greenhouse gas (GHG) emissions cuts.

"Efforts to address climate change should continue to focus most heavily on mitigating greenhouse gas emissions in combination with adapting to the impacts of climate change," NRC says in its report, "because these approaches do not present poorly defined and poorly quantified risks and are at a greater state of technological readiness."

The report elevates discussion of such intervention technologies by endorsing the need for more research on multiple possible options.

But it also makes clear limitations of the intervention technologies to address global warming and concludes that "albedo modification," a group of techniques which seeks to limit climate change effects by increasing reflectivity of clouds, is not ready for large-scale deployment and requires research and oversight to understand and manage its risks.

"It may be prudent to examine additional options for limiting risks from climate change," including the options of carbon dioxide (CO2) 'removal' (CDR) and albedo modification.

Marcia McNutt, the former director of the U.S. Geological Survey who chaired the NRC panel, told a Feb. 10 briefing that the group's number one recommendation is "there is no silver bullet here" from climate intervention techniques . . . we cannot continue to release [CO2] and hope to clean it up later."

McNutt and others at the briefing delivered a cautionary note against over reliance on such intervention technologies, in part by noting that the title and text of both reports report spurn use of the terms "geoengineering" and solar radiation management (SRM) in favor of references to climate intervention and albedo modification.

McNutt said panel members felt "engineering" exaggerates the possibility of climate control and reached similar conclusions on the reference to "management" in the often used moniker SRM. She also noted that climate intervention is "riskier, more expensive and slower" than GHG cuts and cautioned that gains from CDR would happen slowly but also be less risky than solar strategies.

The new reports released by NRC Feb. 10 — Climate Intervention: Carbon Dioxide Removal, and Climate Intervention: Reflecting Sunlight to Cool Earth, are the culmination of a multi-year effort to examine climate control options at the request of the intelligence community, National Aeronautics and Space Administration (NASA), National Oceanic and Atmospheric Administration (NOAA) and the Department of Energy (DOE).

Many environmentalists remain skeptical of the technologies — particularly cloud manipulation — fearing it will divert from GHG reduction efforts and could result in significant unintended consequences. For example, addition of aerosol sulfates to reflect sunlight could have adverse environmental and health impacts.

But some industry officials and conservatives have touted use of the technologies as an alternative to emissions cuts and even some environmentalists say debates need to happen in part to create new governance mechanisms for risky research and to better understand the consequences of such actions by "rogue" actors.

"It's prudent to do research into geoengineering because, for instance, improved [CDR] techniques could help reduce such dangerous pollution," the Natural Resources Defense Council (NRDC) said in a statement.

Several former government officials recently called for a more organized and regulated approach for new climate intervention research, including picking low-risk research that can help establish a track record, explicitly identify the research as climate engineering, seek broad advice to identify potential risks and benefits, acknowledge that geoengineering is not a substitute for GHG controls and adaptation and assess results early and decide how to proceed.

The first report on CDR evaluates options for enhancing natural carbon sinks — through mechanisms including land management, increased "mineral weathering" to boost ocean or land uptake of CO2 and ocean fertilization — as well as industrial approaches such as biomass burning with carbon capture and sequestration (CCS) to remove CO2 from the atmosphere and use of machines to directly scrub the air.

NRC characterizes such efforts as complementary to CCS at power plants or other industrial facilities.

"It is increasingly likely that, as a society, we will need to deploy some forms of CDR to avoid the worst impacts of climate change, but without research investment now such attempts to climate mitigation are likely to fall well short of needed targets," the report says.

The report concludes that possible ocean fertilization as a CDR technique is a non-starter, but generally finds that CDR options, in contrast to albedo modification, do not create "novel global risks" and raise fewer governance challenges. The report suggests that such efforts will ultimately be judged on cost considerations, may require decades to produce only "modest" effects on climate, and will require international cooperation by major emitters.

The second report on mitigating the effects of sunlight examines a category of strategies often referred to as SRM, which have been touted as potential ways to mask effects of greenhouse warming though methods including sulfur dioxide injection into the stratosphere, while not reducing GHG concentrations.

NRC in the report on solar strategies outlines numerous "domestic and international legal questions" that would arise from research or deployment of albedo modification, and cites several U.S. laws and international treaties that are

potentially relevant to such research. They include the Clean Air Act and National Environmental Policy Act, as well as the 1972 Weather Modification Reporting Act and the 1976 National Weather Modification Policy Act.

NRC says the two weather modification statutes give NOAA the authority to require reporting of all weather modification activities in the U.S.

The report suggests that the main relevance of the CAA comes from concerns that sunlight management through such strategies as injection of sulfur dioxide into the stratosphere could deplete stratospheric ozone, which is protected by Title VI of the 1990 air act amendments granting EPA the authority to phase out ozone destroying substances as part of U.S. compliance with the Montréal Protocol.

NRC calls for some research into both CDR and albedo modification, but generally touts CDR as a potentially important if slow-moving climate strategy. By contrast, the report characterizes risks from efforts to manipulate clouds as "dramatically different" and greater and unable to solve issues such as ocean acidification from increased CO2.

It also notes risks of the latter could include centuries-long dependence on SRM type strategies that would be hard to stop without creating a shock to the climate from elevated GHG levels.

NRC in the reports characterizes risks from albedo modification techniques as "dramatically different" and greater than potential CDR techniques. NRC in its press statement says more generally, "If society ultimately decides to intervene in Earth's climate, any action should be informed by a far more substantive body of scientific research, including ethical and social dimensions, that is presently available, the committee said", NRC states in the press statement.

The NRC reports include six broad recommendations, including that GHG mitigation coupled with adaption should continue to be the main focus of climate efforts; more research and development investment is needed to improve CDR methods "at scales that would have an impact on reducing greenhouse warming; and large scale albedo modification "should not be deployed" at this time.

The report did endorse smaller scale albedo modification research based on "multiple benefit research" that furthers basic understanding of the climate system and human dimensions. It also calls on the United States to improve its capacity to detect and measure changes in "radiative forcing" of the climate.

And NRC called for the initiation of "a serious deliberative process" to examine the type of research governance, beyond existing mechanisms, that is needed to address research on albedo modification, citing concerns that included potential for "detrimental direct and indirect effects."

"Such a governance structure should consider setting clear and quantitative guidelines for experimentation and be responsive to domestic and international laws and treaties," the report says. It added that the process should focus on research that involves injecting material into the atmosphere, should provide for a sufficiently specific governance regime to at least define the scale of experiments at which oversight begins, and should consider the need for increasing supervision as the scope and scale of the research and its potential implications increase.

It is not immediately clear how federal agencies will follow up with the recommendations in the report, but panelists at the briefing suggested recommendations for more research may be most immediately relevant to the United States Global Change Research Program, DOE and NASA.

McNutt cited ongoing research on industrial carbon sequestration or similar efforts at DOE, and panel member Waleed Abdalati of the University of Colorado suggested the recommendations could also play into a NASA review of research needs that occurs once ever decade. — *Doug Obey*

EtO Report Suggests EPA Consider Objective Models . . . begins on page 14

selection," and he urged SAB to establish or recommend that EPA establish "clear criteria to benchmark each study" cited in the IRIS assessment. Gulledge also questioned the quality of the Swedish study, arguing that "probably a good, new, independent review of this study should be conducted before" it is included in the IRIS assessment.

But the panel did not appear concerned with the industry concerns about the two studies, instead focusing on changes recommended by panel members and clarifying questions from the agency.

Once the panel completes editing the report, it will be reviewed by the chartered SAB before it is transmitted to EPA. The chartered SAB will also accept public comments regarding the report.

Since 1999, EPA has sought to update its published 1985 IRIS assessment of the chemical's carcinogenicity. EPA first released a draft assessment in 2006 and sought peer review from SAB. After struggling to respond to that panel's recommendations, EPA released a second draft in 2013, and then a third draft responding to public comments.
The panel concluded at the recent meeting that EPA faithfully responded to the recommendations of the 2007 peer review, and fully responded to public comments on the latest draft assessment.

This unusual third draft IRIS assessment includes the same overall cancer risk estimate as the 2013 draft, a "full lifetime total cancer unit risk estimate" of 1.8×10^-3 per microgram per cubic meter of air (per ug/m^3), or 3.3×10^-3 per part per billion (ppb). The new draft cancer risk estimate is slightly stricter than the estimate of 1.5 x 10^-3 per ug/m^3 that appeared in the first draft released in 2006 and peer-reviewed by SAB. Both draft numbers are significantly stricter than the number EPA calculated for EtO in a previous analysis of the chemical in 1985, of 1 x 10^-4 per ug/m^3. — *Maria Hegstad*

Draft SAB Report Suggests EPA Consider 'More Balanced' EtO Risk Modeling

Science advisors reviewing EPA's draft assessment of the human health risks of the sterilizing chemical ethylene oxide (EtO) are indicating in a first public draft of their review report that EPA should consider a "much more balanced and objective" approach to modeling the chemical's cancer risks, and urge the agency to present analysis showing unit risk estimates calculated from multiple models.

This is the second time peer reviewers have urged the agency to modify its modeling approach in the long-ongoing assessment of EtO. A Scientific Advisory Board (SAB) panel in 2007 recommended numerous changes to an earlier draft assessment, calling on the agency to assess the chemical's lymphoid and breast cancer risks with both linear and non-linear approaches. EPA, however, chose to present just the linear approach in its 2014 draft assessment, which is now under the review of a new SAB panel, under the auspices of its Chemical Assessment Advisory Committee.

EtO, commonly used as an intermediate to make other chemical products like detergent, antifreeze and polyester and to sterilize medical equipment, has long been suspected of causing breast and lymph cancers.

Arguments over whether to use linear modeling, which assumes there is no safe level of exposure to a chemical, or non-linear approaches, which assume a threshold exposure level is without harm, in risk assessments occur frequently.

But presenting multiple risk estimates would be unusual for EPA since the agency's Integrated Risk Information System (IRIS) program has historically provided single point estimates in its influential toxicological hazard assessments of environmental pollutants. Such an approach would be unusual, since EPA's Integrated Risk Information System (IRIS) program has historically provided single point estimates in its influential toxicological hazard assessments of environmental pollutants. SAB's recommendation, should it be finalized, would be the latest recommendation for EPA to provide more that a single point estimates.

Last spring, the National Academy of Sciences in its review of the IRIS program recommended that the IRIS assessments should provide a range of risk estimates to better characterize the uncertainty and variability inherent in risk analyses. Such recommendations have traditionally met with resistance within the program, as when the former research chief during the George W. Bush administration, George Gray, sought similar changes to IRIS assessments.

SAB's Jan. 7 draft version of the report says, "The SAB does not insist that a non-linear approach be included in the assessment. The SAB agrees with the agency that EtO has a genotoxic mode of action . . . and finds that conditions for including a non-linear assessment per EPA Guidelines for Carcinogen Risk Assessment . . . are not met in the case of EtO. However, the SAB recommends that the issue be treated in a manner that is much more balanced and objective." *Relevant documents are available on InsideEPA.com. See page 2 for details. (Doc. ID: 179114)*

The EtO assessment includes reviews of both breast and lymphoid cancer risks. With regard to modeling the lymphoid cancer risk, the SAB panel's draft report states, "The SAB recommends inclusion of multiple estimates of the unit risk in sensitivity analyses and an updated justification of model selection."

Lianne Sheppard, one of the panelists who met by conference call Feb. 20 to discuss the draft report, and a biostatistics profesor at the University of Washington explained, "We requested sensitivity analysis and a range of unit risk estimates and then … if somebody comes down differently, they have that [range] in front of them."

Despite these and other recommendations for altering how EPA models cancer risks, several members of the SAB panel again urged EPA to hasten the completion of the EtO assessment during the conference call, reiterating similar calls from several members at the panel's November meeting. Perhaps because of these concerns, the panel chose not to address industry pleas that the report should again urge EPA to present linear cancer risk modeling and also urge EPA to use a different study for its risk calculations. Industry representatives have for years urged EPA to use instead an industry epidemiology study, known as the Union Carbide study, or use both the Union Carbide study and the NIOSH study EPA prefers.

In public comments at the meeting, Nancy Beck, a toxicologist with the chemical industry association American Chemistry Council (ACC), sought a better explanation of why the panel concurred with EPA that its cancer guidelines did not require presenting both linear and non-linear EtO cancer risk models.

Stephen Roberts, one of the panelists and a toxicology professor at the University of Florida, agreed with Beck that the report was lacking in its explanation. Roberts said he would review the cancer guidelines and add additional language explaining the panel's decision.

Beck also pressed the panel to explain why it agrees with EPA that the NIOSH data is the best basis for the cancer risk calculations, and that the Union Carbide study shouldn't be considered. "There was not much discussion [about this] at the meeting, and even some discussion of not using [the Union Carbide study] because it was industry funded," Beck said. She reminded the panel that the Society of Toxicology has a position paper stating that study funding source should not be a factor in evaluating study quality.

Beck's colleague, Bill Gulledge, manager of ACC's EtO Panel, also spoke on the Feb. 20 conference call, where he urged the panelists to reconsider their recommendation that EPA bolster its breast cancer risk findings by adding data from a newer epidemiology study of Swedish medical sterilization workers. The study indicates strong breast cancer risk at exposure levels even lower than those included in the NIOSH study.

Gulledge argued that adding the Swedish study "and excluding the Union Carbide Study adds a bit of bias in study

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