Inside EPA's
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Novel EPA Ozone Standard Shows Greater Agency Focus On Ecological Risk

EPA's proposal to set a first-time, biologically relevant secondary air standard for ozone to protect sensitive vegetation and ecosystems is just one of several recent steps that show the growing importance the Obama EPA is placing on considering ecological risk in decisionmaking, sources say, which could spur stricter and more expensive regulations.

In addition to the ozone proposal, sources say there are a number of places EPA is increasingly looking at potential risks to ecosystems, including high-profile actions involving pesticides, such as a greater focus on adverse effects to birds and endangered species, and a new initiative to examine and quantify the role of ecosystems services. Climate change issues, including changes in the use patterns of pesticides, could also drive more movement toward ecological considerations in agency regulation, according to an academic source that tracks the issue.

But the approach is rife with complications, including insufficient data on how pollution can impact ecosystems, spurring some observers to raise concerns that greater ecological risk considerations could lead to more reliance on the precautionary principle of issuing regulations in the

continued on page 8

EPA Plans Broad TSCA Rulemaking To Regulate 'New' Nanomaterial Uses

EPA is launching a broad rulemaking under the Toxic Substances Control Act (TSCA) to regulate "new" uses of nanoscale chemical substances, a measure that together with another upcoming rule could provide the agency with an expansive regulatory architecture to gather data on the substances' risks and regulate them.

But the new rulemaking is prompting concern from industry officials, who fear the agency could be expanding the Bush-era definition of when nanomaterials are considered "new" substances subject to regulation.

The rulemaking is an "end run around the point that all nanomaterials should

continued on page 4

Activists Push EPA For Stricter Chemical CBI Rules Prior To TSCA Reform

EPA is taking steps to use authority under the Toxic Substances Control Act (TSCA) to tighten confidential business information (CBI) rules, a move long sought by activists who say it would boost disclosure of data such as health and safety studies on chemicals.

Lawmakers advocating toxics law reform are yet to introduce their legislation, but activists say there are steps EPA can already take before or in lieu of TSCA reform that would tighten CBI requirements and require companies to provide better justification for claiming data as confidential. EPA could also bar companies from claiming chemical names as CBI on health and safety

continued on page 10

EPA Faces Broad Opposition To Plan For Strict Risk Levels For Methanol

EPA is drawing broad opposition from industry and other federal agencies to its proposal to set strict risk levels for the synthetic fuel methanol, with industry warning it will undermine growing production of biodiesel and other commercial uses and federal agencies saying the agency has not made the case for strict cancer and risk protections.

EPA Jan. 13 unveiled its draft Integrated Risk Information System (IRIS) assessment of methanol which for the first time lists the chemical as a likely human carcinogen, and also sets a first-time safe daily dose for inhalation exposure, or reference concentration (RfC), of 2 milligrams per cubic meter of

continued on page 6

In This Issue . . .

Climate Change Considerations For Brownfields Site Could Set Precedent

First-time requirements for a California brownfields site to include contingency plans for the risk of sea-level rise due to climate change in its remedial plan could set a precedent for incorporating the effects of climate change into brownfields cleanups, possibly leading to more stringent requirements and increased cleanup costs, state and industry sources say.

Last year, California Department of Toxic Substances Control (DTSC) officials in a first-time action ordered an engineering firm preparing a feasibility study and remedial action plan for a San Francisco Bay-area brownfields site to evaluate the effects of sea-level rise and address them in their cleanup efforts.

State sources say DTSC in the near future will likely not only require consideration of climate change impacts in new cleanup plans but also during mandatory five-year reviews of existing remedial efforts under state and federal law. And one state source notes that Gov. Arnold Schwarzenneger's (R) California Climate Adaptation Strategy, released Dec. 3, makes recommendations for reducing climate risks in areas like public health and "could encompass ensuring that brownfields contamination is not disrupted by climate activities."

California officials have counted 130 EPA-regulated brownfields sites that are vulnerable to a 100-year flood event, according to a presentation DTSC Acting Assistant Deputy Director Barbara Cook made Nov. 18 at the National Brownfields Conference in New Orleans. A 1.4-meter sea-level rise would increase the number of fatalities from such a flood event by more than 250 percent, the slides say. *Relevant documents are available on InsideEPA.com.* *See page 2 for details.*

But any state push to require climate change considerations at brownfields sites is likely to raise concerns among developers, according to Michelle King of the engineering firm Erler & Kalinowski, who also spoke at the brownfields conference. Such requirements could increase costs, perhaps substantially, King told *Inside EPA* in an interview. "Especially if they review older remediation plans and make them go back and add measures that address things like sea level rise—that could become quite burdensome and costly for responsible parties," she says.

The state source says that addressing climate change will be more costly for everyone, but sea-level rise in brownfields is a "brand new issue" that "presents new challenges," and most stakeholders have not been informed on the issue. "It's probably several years before it becomes a routine concern," the source says.

At issue at the East Stege Marsh brownfields site in Richmond, CA, — a former pesticide production facility — is a projected 55-inch rise in sea level by 2100, as predicted by the San Francisco Bay Conservation Development Commission, according to King's slides. To mitigate these predicted effects, the site's cleanup plan includes building a biologically-active permeable barrier (BAPB) that could tolerate a sea level rise of 68-80 inches, King says. Contingency plans were also developed to replace or increase BAPB height if needed, based on water level monitoring.

In addition, engineers placed dolomite-treated cinder — aimed to reduce metals leaching — one foot above the site's current high groundwater levels.

King says the plan "sets a precedent to some degree" for including climate change in brownfields remediation plans, but adds that requirements for other sites will "obviously depend on the site and the nature of the contamination."

The East Stege Marsh plan was completed in early 2009, and will go out for public comment in early 2010, though "it is unlikely that there will be further changes," King says.

EPA Rejects Industry Call For Congress To Block Endocrine Test Program

EPA is rejecting industry's bid to block the agency's endocrine disruptor screening program (EDSP) until it sends the final rule establishing the program to Congress or the Government Accountability Office (GAO), countering industry's claim that the Congressional Review Act (CRA) mandates the submission before the rule can take effect.

"EPA officially submits all documents that contain binding legal requirements to Congress and GAO," according to a Jan. 13 agency statement. "These notices provide general guidance, not binding legal requirements; therefore they were not sent under" the CRA. The law not only requires some rules to be sent to Congress and GAO before they can take effect but also grants lawmakers the ability to pursue disapproval resolutions to revoke certain rules.

Industry says EPA never sent the rule establishing the EDSP to GAO and Congress, which it says is in violation of the CRA — representing a new argument by industry in its attempts to delay the screening program.

"Based on the clear statutory text of the CRA, the EDSP rule does not take effect prior to their submission, along with other specified material to each House of Congress and the Comptroller General" of GAO, according to a Jan. 8 letter from Jim Tozzi of the Center for Regulatory Effectiveness, a non-profit think tank linked to industry. EPA issued the final rule for its endocrine program April 15 but never sent the rule to Congress or GAO, Tozzi writes.

The letter was sent to Vice President Joe Biden and House Speaker Nancy Pelosi (D-CA) and asks them to advise EPA that its EDSP rule is not in effect until the agency sends it to Congress or GAO.

The letter cites a Dec. 29 Congressional Research Service (CRS) report, "Congressional Review Act: Rules not Submitted to GAO and Congress," that highlights the rule as one that violates CRA by not being submitted. Of 17 significant EPA rules reviewed by the White House Office of Management & Budget between October 2008 and June 2009, only the EDSP rule from April 2009 was not submitted to the GAO, according to the report.

In the report, CRS also says that when agencies do not submit their rules to Congress it denies lawmakers the ability to use CRA's "expedited disapproval authority" to overturn federal agency rules.

Environmentalists and others are also questioning why agencies did not follow up on the CRA requirements. "Agencies appear to be the most culpable for this potentially significant screw up," according to a Jan. 5 blog post by OMB Watch, a group that seeks greater transparency in governmental affairs. "The CRA is clear that agencies must send a copy of new rules to Congress and the GAO. There is no excuse for failing to do so."

Still, the group concludes there is a quick fix to the issue: The CRA "does not contain any apparent statute of limitations on the submission of rules, so, barring litigation, simply putting the rules in an envelope and sending them to GAO and Congress should do the trick," according to the blog post. — *Aaron Lovell*

FDA's Review Of BPA Clears Path For EPA's Pending Chemical Action Plan

The Food & Drug Administration (FDA) Jan. 15 released its long-awaited review of the plastic hardener bispehol-A (BPA) in food packaging, possibly clearing the way for EPA's own chemical action plan for the substance, which is currently undergoing review at the White House Office of Management & Budget (OMB).

The FDA study is also prompting new vows from Rep. Henry Waxman (D-CA), chairman of the House Energy & Commerce Committee, to strengthen EPA's authority under the Toxic Substances Control Act (TSCA). Waxman said in a statement following FDA's announcement that while he is "pleased" the Administration is taking necessary steps to protect public health, "We need to do a more effective job of preventing harmful chemicals from entering the marketplace, and for this reason, I look forward to considering reforms of the [TSCA] in the coming months."

In a notice announcing completion of its long-awaited review, FDA says studies employing standardized tests show the chemical is safe at low exposure levels but that it has "some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children" based on new studies that use novel methods to test for low-level effects.

FDA says it is now supporting a shift to a "more robust regulatory framework for oversight of BPA," and will consult with other agencies, including EPA, the National Institutes of Health, the National Toxicology Program, the Centers for Disease Control and Prevention and the Consumer Product Safety Commission (CPSC).

While the agency is carrying out in-depth studies "to answer key questions and clarify uncertainties," FDA is also supporting industry efforts to limit exposure, such as stopping production of bottles and cups with BPA, supporting efforts to replace BPA in other can linings and facilitating the development of alternatives of BPA for the lining of formula cans for infants, according to the notice. The notice adds that it will also take comment on recent studies and other material for 60 days.

The chemical — widely used in plastics and food packaging — has long raised concerns from environmentalists and public health advocates, who fear it can undermine development in male children and possibly create adverse heart effects.

The advocates have been urging FDA to quickly complete its study so that EPA and other agencies could proceed with new regulatory requirements. In a Jan. 14 letter to FDA Commissioner Margaret Hamburg, Ken Cook of the Envi-

ronmental Working Group urged FDA to complete its review and pointed out that other agencies including EPA have already singled BPA out as a chemical of concern.

"How much more does the FDA need to know to be convinced it must protect the national food supply from further contamination?" Cook said in the letter.

Completion of the FDA review appears likely to clear the way for EPA to issue later this year its own action plan. EPA late last year submitted to OMB a draft action plan on BPA that lists an array of actions the agency plans to take under its existing authority to limit risks posed by the chemical.

While EPA Dec. 30 unveiled action plans for four other chemicals, an EPA spokeswoman says the plan for BPA and another plan for benzidine dyes and pigments are still scheduled for release. "The remaining two are very much on our to-do list," the spokesperson said. "We committed to do four in December. We expect the remaining two to be done in early 2010."

But industry sources say the chemical is safe and are raising concerns about the effects of new regulatory requirements. The American Chemistry Council (ACC) said in a statement in response to the FDA study that they recognize that the health agencies are attempting to address public confusion about BPA but expressed disappointment that some of the regulatory recommendations "are likely to worry consumers and are not well-founded."

Industry sources say EPA efforts to regulate the chemical will also be difficult and will require significant coordination among the agencies. "EPA has stepped into a hornet's nest," with the BPA action plan, an industry source says. "There are jurisdictional and technical concerns, and legal authority issues." For example, another source notes that FDA is seen to have the lead on the issue, having worked on it for longer than EPA.

Industry sources are emphasizing the need for the administration to ensure that it coordinates any regulatory steps across several federal agencies. In a Nov. 3 letter to EPA toxics chief Steve Owens, ACC President Cal Dooley urged the agency to "identify and clearly articulate the jurisdictional boundaries existing among the various federal agencies, such as the [FDA and CPSC] when issuing [action plans]." *The letter is available on InsideEPA.com.* *See page 2 for details.*

Industry officials also presented the letter to OMB officials at a Dec. 22 meeting.

EPA has until April to issue their next set of chemical action plans, which "satisfies" Jackson's schedule for using existing TSCA authority to regulate chemicals of concern in lieu of broader TSCA reform, according to a legal source.

EPA Plans Nanomaterial TSCA Rule . . . begins on page one

be thought of as 'new'" under TSCA, which would allow the agency greater regulation of the materials, says a legal source.

EPA last month announced on its Action Initiation List that it is developing a "significant new use rule" (SNUR) to better manage nanoscale chemical substances. EPA says the rule will be promulgated under TSCA section 5, and sources say a notice of proposed rulemaking could appear as soon as late 2010.

"This action would require persons who intend to manufacture, import, or process this/these chemical substance(s) for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity," according to EPA's action list. "The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs to prevent unreasonable risk to human health or the environment."

A SNUR is the first step under TSCA to regulate materials, which EPA uses to require pre-manufacture notices (PMNs) for chemicals. Until now, EPA has only issued SNURs for individual carbon nanotubes, a broad class of nanomaterials. The agency requires protective face and body equipment for people working with certain carbon nanotubes in an effort to reduce the possible health impacts of the substances (*Risk Policy Report*, Aug. 25).

An EPA spokesperson said EPA "is still working on how the agency plans to proceed on nanoscale materials," but it anticipates "having an announcement on this issue in the not too distant future."

The SNUR comes as EPA also recently announced it would be pursuing new reporting requirements for existing nanoscale materials under section 8 of TSCA. Under the rule, slated to be published in June, EPA would "establish reporting requirements for certain nanoscale materials," according to the unified agenda, including information on "production volume, methods of manufacture and processing, exposure and release information, and available health and safety data" under the rule (*Risk Policy Report*, Dec. 22).

A former agency source says the SNUR, together with the new reporting rule, will provide the agency with a broad regulatory structure to oversee nanomaterials — especially after the Bush-era voluntary data reporting program provided the agency with lackluster data on the substances' risks.

A SNUR is "one way of getting regulatory oversight of nanomaterials," the source says, adding that the idea has been considered at EPA for some time. "A combination of a new chemicals [PMN process] plus the SNUR would give pretty good oversight," the source says.

The SNUR would also go a long way to closing the perceived gap in oversight of existing chemical nanoscale materials, according to a Jan. 7 memo from law firm Bergeson & Campbell discussing the move.

But industry sources are also raising concerns that the rulemaking plan is the latest indication from Obama EPA

officials that they plan to strengthen the oversight of both new and existing nanoscale materials.

Last year, toxics chief Steve Owens criticized the Bush EPA decision that granted broad latitude to regulators to exempt new nanoscale materials from oversight. The Bush era decision, supported by industry, determined that nanoscale versions of substances that have the same molecular structure of chemicals already appearing on the TSCA inventory are not considered "new" and are not required to go through the new chemicals review process, which can result in imposition of regulatory protections.

According to the 2008 EPA document, a nanoscale material is considered "existing" if the substance has the "same molecular identity as a substance already on the inventory," while "new" chemicals are somehow different in chemical structure from the bulk version already listed. "Although a nanoscale substance that has the same molecular identity as a non-nanoscale substance listed on the inventory differs in particle size and may differ in certain physical and/or chemical properties resulting from the difference in particle size, EPA considers the two forms to be the same chemical substance because they have the same molecular identity," the document states.

But in a key speech in London in September, Owens criticized this approach, saying an existing nanomaterial "is subject to much less scrutiny from EPA because of that designation, due to the different ways TSCA treats existing and new chemicals." Despite his criticisms, Owens said officials are not prejudging the outcome of their policy reassessment. "I cannot say what the outcome of that review will be, but I can tell you that we will be taking a fresh look at this issue and at the basis and reasoning for the decision made by EPA" in 2008 (*Risk Policy Report*, Sept. 22).

Industry sources, however, fear the rulemaking plan could open the door to the agency redefining when the materials are considered "new" or "existing."

The former agency source says there is some question of how to craft the trigger for capturing substances under the SNUR. The rule begs questions about "defining what subjects would meet the requirements. Anything in nanoscale?" Would there be an "intent component" where manufacturers would have to be "intentionally manufacturing at nanoscale," the source asks.

An industry source says the EPA approach seems like a "practical starting point," but cautions that "the devil is going to be in the details," particularly how EPA will define the limits of the SNUR. The source cautions that the novelty of nanomaterials and the potential differences from bulk substances do not necessarily require blanket regulation.

"Do the differences matter from a safety or environmental perspective?" the source says. "The risks are clearly not all the same," the source says, adding that "hopefully [EPA] will include that in their thinking" about the SNUR.

The legal source questions the broad approach of a general SNUR for nanomaterials, saying that just because the materials are small does not mean they are necessarily harmful. It's like "trying to regulate everything that is blue. The fact they have this one characteristic in common does not mean they are worthy of regulation."

The industry source also points out that the SNUR would only regulate new uses of the materials even though it is difficult to define what is a "new" use. "How they define a 'new use' will be critical." Further, because of the SNUR's focus on new uses, the agency will have to determine if the SNUR will "capture the information [EPA] wants to capture."

Sources say there is yet to be an accepted definition of a nanomaterial. For example, the legal source says, rubber tires would in no way be considered a nanoscale material, but they can release nano-sized particles through normal use. — *Aaron Lovell*

EPA Weighs Expanding Toxics Inventory To Include Key Carcinogens List

EPA is weighing a proposed rule to expand the list of chemicals companies must report under its Toxics Release Inventory (TRI) to include a key National Toxicology Program (NTP) list of substances thought to be carcinogens, which activists hope is a sign of future expansions of TRI to cover more unreported chemicals of concern.

Industry, however, says that while the move would be "defensible" because of the NTP's strict peer review policies, it would impose new reporting requirements that could require additional resources to meet.

EPA intends to propose by May a regulation to incorporate chemicals from NTP's Report On Carcinogens (ROC) into the TRI list, according to the agency's most recent Unified Agenda. The ROC, now in its 11th Edition, "identifies and discusses agents, substances, mixtures, or exposure circumstances that may pose a hazard to human health by virtue of their carcinogenicity" in a biennial report to Congress, according to NTP's Web site.

"EPA will propose to add to the TRI list, those NTP carcinogens that have sufficient production or use levels such that the agency expects that TRI reports will be filed," EPA's Unified Agenda says. TRI requires companies to annually report their releases of 581 individually listed chemicals and 30 chemical categories.

The ROC is seen as an accepted authority on the risks of chemicals, much like data produced by the International Agency for Research on Cancer and the Occupational Safety and Health Administration's Carcinogen Listing, a legal source says. NTP — part of the Department of Health & Human Services — reviews peer-reviewed data to determine whether a chemical is "known to be human carcinogen" or "reasonably anticipated to be human carcinogen." The ROC review process includes external peer review and several opportunities for public comment.

To add a chemical to TRI, EPA must demonstrate that a chemical meets a listing criteria, for example known to cause

cancer. An EPA spokeswoman says that a benefit of adding the NTP list to TRI is an "efficiency" because the NTP review process uses data consistent with that used by EPA to evaluate chemicals for their potential to cause cancer and classify them as either "carcinogenic to humans" or "likely to be carcinogenic to humans."

In reviewing the ROC list for possible carcinogens to add to TRI, EPA focused on "ensuring that there no inconsistencies with how the agency would consider the available data. EPA also reviewed available production and use information for each chemical to determine whether it is expected to be manufactured, processed, or otherwise used in quantities that would exceed TRI reporting thresholds, according to the spokeswoman.

Among the chemicals that EPA could add to TRI reporting requirements by adopting the ROC list are vinyl fluoride, which is used in coatings, and the chemical stabilizer glycidol, the spokeswoman adds. Both substances are found on the ROC list under the category of "reasonably expected to be a human carcinogen."

Environmentalists welcome any expansion of TRI and one activist hopes that EPA's pending proposal is a "harbinger" for even further expansion of the inventory. During the Bush administration, the source argues, many chemicals that are not required to be reported under TRI were introduced into commerce while health professionals have become increasingly concerned about the chemicals found in humans and the environment.

Environmentalists would also like to see the TRI list brought into harmonization with similar lists to the ROC that are in place in Canada and Mexico, and possibly also similar lists in the European Union, the activist says. The move is important because it is likely that a chemical being used in the other countries on the continent is also being used in the United States, the source says. "Many companies are obviously operating in all these jurisdictions."

Some activists would also like EPA to expand on the sort of data it is receiving from TRI respondents, suggesting the agency collect more data on chemical substitutes and pollution prevention.

Advocates of stricter TRI rules would like to see the program expanded from its focus on land, air and water releases to also look at the chemicals present in products, which is also an important vector for chemical releases, the source says. It would be "very simple for EPA to expand TRI by designating products as another media," the source says, adding that the change could be made via regulation, rather than legislation. Expanding the list could provide the agency with information on environmental releases like mercury from batteries and light-bulbs.

The Obama EPA has already taken steps in this direction, proposing to adopt a Bush-era policy that wood treatment facilities must include finished products stored on site in their TRI reports, though industry has raised concerns with the rulemaking. One industry source has said that the proposal fails to resolve the question of when reporting requirements apply to products even though there is no active or ongoing process occurring.

An industry source says EPA's proposal would be "defensible" because of the ROC's strong peer review policies. The addition of a chemical included in the ROC to TRI would be "tough to oppose" because the list is "well established and very defensible," according to the source. Once a chemical appears in the ROC, "it has been the subject of multiple peer reviews," the source says. *— Aaron Lovell*

EPA Faces Resistance To Draft Methanol Assessment . . . begins on page one

air. *Relevant documents are available on InsideEPA.com. See page 2 for details.*

The agency's prior assessment, published in 1993, included a safe daily oral dose, or reference dose (RfD) of 0.5 milligrams per kilogram per day (mg/kg-day) but concluded there was insufficient data to perform a cancer assessment or calculate an RfC. EPA's new draft includes a nearly identical RfD of 0.4 mg/kg-day.

EPA's draft says notes that methanol is "among the highest production volume chemicals reported in the U.S. EPA's Toxic Release Inventory," in 2008. EPA notes that it anticipates increased demand for methanol, which it says is "growing steadily in almost all end uses," but is largely linked to increased biodiesel production.

But the Methanol Institute, the industry's global trade association, says in a Jan. 12 statement that EPA's pending risk assessment could result in harmful economic impacts. "The stakes of this scientific review of the EPA health assessment are high," says Institute spokesman Greg Dolan.

According to the Institute's statement, methanol is used to make products including paints, plastics, solvents, and textiles. Global methanol consumption in 2008 was approximately 14 billion gallons, and is expected to reach more than 17 billion gallons by 2012, according to the statement. "Methanol is an essential chemical building block for hundreds of products that touch our daily lives. It is also a re-emerging energy fuel," he says.

Methanol also occurs naturally in fruits and vegetables.

But industry and the White House Office of Management and Budget (OMB) argue that EPA's proposed risk levels are stricter than background levels. "Does EPA recognize, based on the [World Health Organization's International Programme on Chemical Safety] findings, that they are proposing standards that would be below background levels? ... How has EPA taken consideration of background levels into account?" OMB writes.

The Methanol Institute' s Dolan says that EPA's proposed reference dose could be equaled by drinking an eight-ounce glass of orange juice.

The agency critics also raises numerous questions with EPA's assessment of methanol's carcinogenicity. The Defense

Department, for example, says it is "premature" for EPA to identify the fuel as a "likely" human carcinogen, due to stated differences between human and rodent metabolic processes, the limitations of the animal studies discussed in EPA's draft assessment, and lack of human data to support the carcinogenic potential of methanol, according to the Pentagon's February 2009 comments released alongside the draft assessment.

The comments suggest that EPA's assessment is on shaky ground because there has not been an increase in the incidences of lymphoma suggested by EPA's risk findings. "Since food represents the greatest source of exposure, one would anticipate a large increase in incidence of lymphoma in humans as methanol is a naturally occurring chemical produced in the human body and readily found in air and body fluids."

Similarly, OMB points out that the National Institutes of Health's Hazardous Substances Data Bank, which is frequently updated, states that there is no evidence from animal studies to suggest that methanol is carcinogenic.

OMB and the Methanol Institute raise special concern about the scientific studies EPA uses to justify its findings. Dolan, for example, says EPA considered three studies of lab animals dosed with methanol, but only one of these — conducted by the Japanese New Energy Development Organization (NEDO) — was peer-reviewed. "We think that peer review process is very important," Dolan says.

The other two studies were conducted by a controversial Italian laboratory, the European Ramazzini Foundation (ERF) Laboratories, while the third appears to be a Finnish graduate student's dissertation, Dolan says.

Of particular concern is EPA's use of a study from the ERF lab, which industry has previously argued produces biased studies, in part because its animals are not properly cared for and as a result present health effects unrelated to the chemicals they are exposed to (*Risk Policy Report*, Nov. 10).

The lab has also released studies on aspertame, methanol and the fuel additives methyl tertiary butyl ether (MTBE) and ethyl tertiary butyl ether (ETBE). EPA cited the lab's ETBE study in its draft assessment of ETBE, which was attacked by the petrochemical industry last fall.

"EPA seems to limit discussion of cancer studies related to ethanol, aspartame, MTBE and formaldehyde, to the ERF data. Are there any other cancer studies that could be informative here?," according to OMB's undated comments.

OMB also urged EPA to strengthen and clarify the charge questions on the carcinogenicity assessment that the agency will pose to the group of experts who peer review the assessment. OMB suggested the agency ask the reviewers how it should treat the ERF data. OMB suggested that EPA ask the reviewers to "comment on the cancer weight of evidence characterization taking into consideration the uncertainty created by EPA's reliance on tumors in one species, the uncertainty associated with the ERF use of historical control data which is unpublished, and the support provided by other ERF studies that look at chemicals which have formaldehyde metabolites."

OMB continued by encouraging EPA to ask the reviewers if "another classification for the weight of evidence characterization be more scientifically defensible?" and if "EPA should not be quantifying the risks based on these [ERF] data due to the limitations." OMB explained that asking the reviewers these questions is "very important considering the contentiousness of ERF data … and the fact that the EPA has not clearly identified MTBE and formaldehyde as carcinogens yet the implications here imply that because they are, methanol should be."

The draft study EPA released appeared to drop references in an earlier version stating that formaldehyde, a metabolite of methanol, is a carcinogen. The reference drew criticism from OMB which argued that EPA has yet to release its draft study on formaldehyde and does not currently classify the chemical as a carcinogen.

The agency is holding a public listening session for stakeholders on the document Feb. 23, and will accept comments on the draft through March 15. — *Maria Hegstad*

EPA Provides Key Flexibility In Landmark Florida Numeric Nutrient Limit

EPA Jan. 15 unveiled a potentially precedent-setting proposed rule to set risk-based numeric nutrient criteria for lakes and streams in Florida that includes flexibility for industry by recognizing differences between eco-regions in the state, which allows for the development of site-specific criteria and creates an additional enforcement tool to give good actors incremental milestones for reducing nitrogen and phosphorus discharges.

The numeric criteria are the first in a hotly-contested environmentalist push to force EPA to, for the first time, implement stringent numeric criteria where states have failed to do so. Under the Clean Water Act, states draft and EPA approves water quality criteria — risk-based limits that regulators use, along with waterbodies' designated uses and antidegradation policy to set water quality standards and permit limits.

Florida, like most states, has long opted for a "narrative standard," which allows discharges to continue so long as there is no discernible effect on the waterbody. In July 2008, activists sued EPA, claiming the agency had failed in its nondiscretionary duty to protect Florida's waters by failing to require the state to develop a numeric standard. EPA agreed in January 2009 to issue proposed numeric criteria for the state's lakes and flowing waters by Jan. 14, 2010, and for coastal and estuarine waters by Jan. 14, 2011.

The agency's method for setting numeric criteria for flowing waters has been controversial, with EPA's Science Advisory Board (SAB) saying late last year that EPA's currently used guidance on how to develop nutrient criteria for

water pollution limits is neither defensible nor adequate (*Risk Policy Report, Nov*. 24).

Nevertheless, the White House Office of Management & Budget Jan. 14 approved a proposed rule to set numeric criteria for lakes, streams, springs and clear streams, and canals. *The proposed rule is available on InsideEPA.com. See page 2 for details.*

The proposed Florida rule divides the state into four watershed-based regions for streams and develops different nitrogen and phosphorus criteria for each region, responding to criticism that the wide-ranging geographic differences in Florida make setting one standard unreasonable. To set the criteria, "EPA evaluated a combination of biological information and data on the distribution of nutrients in a substantial number of healthy streams measured by Florida's stream condition index," an EPA fact sheet says.

The rule also includes an alternative approach for deriving site-specific criteria "based on State submissions of scientifically defensible recalculations that meet the requirements" of the water act, the fact sheet says.

Industry is likely to push for the use of the alternative method, with one industry source saying, "There is not a good technical approach you can use on streams without looking at case specific-information."

But an activist disagrees, saying there is not enough variation in streams to provide a legitimate argument for the widespread use of site-specific criteria. The source says the proposal's criteria are less stringent than environmentalists wanted to see, and therefore there is room to get past arguments that a site-specific analysis is needed.

"They're already making it so lenient . . . the speed limit ought to be 45, and they're going to set it at 60, so don't tell me you need a high speed area," the activist says.

EPA notes the criteria "may not be stringent enough to ensure protection of aquatic life in certain downstream lakes and estuaries" so the agency is also proposing an equation that would would be used to adjust instream total phosphorus criteria to protect downstream lakes and a separate methodology to adjust total nitrogen criteria for streams to ensure protection of downstream estuaries, the fact sheet says.

For lakes, EPA is proposing to create different criteria based on the waterbodies' clarity — colored, clear and alkaline, and clear and acidic — rather than the watershed in which it is located. Each lake group will have a separate total nitrogen and total phosphorus criteria, based on biological response in chlorophyll a production.

The agency is also allowing for upwards adjustment of standards in lakes where it can be shown that appropriate chlorophyll a criteria will still be met. Industry opponents to numeric standards often argue that some waters could have nutrient content above traditional standards without showing negative effects, such as algae blooms.

Finally the proposed rule includes a new water quality regulatory tool, which the fact sheet refers to as "restoration standards." The approach provides milestones for reducing nutrient discharges over time, but if a discharger misses a milestone, regulators would require the discharger to immediately meet the most stringent discharge limit. "This will enable Florida to set enforceable incremental water quality targets (designated uses and criteria) for nutrients, while at the same time retaining protective criteria for all other parameters, to meet the full aquatic life use," the fact sheet says.

The agency will hold three public hearings on the rule in February, and collect comments for 60 days.

Novel Ozone Standard Shows Eco Risk Focus . . . begins on page one

absence of evidence showing no risks.

EPA issued Jan. 7 a proposal to tighten the primary ozone national ambient air quality standard to protect human health and for the first time proposed a "biologically relevant" secondary standard designed to protect sensitive vegetation and ecosystems. EPA is proposing to set the level of the secondary standard within the range of 7-15 parts per million hours, consistent with recommendations from its Clean Air Scientific Advisory Committee.

Previous secondary NAAQS have largely been based on the primary standards, though the new distinct secondary standard for ozone was designed to be more protective of ecosystems and biologically relevant.

The move illustrates the agency's growing focus on the ecological risks of air pollution and other pollutants, sources say. In addition to curbing the ecological effects from air pollution, much of EPA's increased focus on ecological risk "ties back to the Endangered Species Act" and the Obama administration's efforts to preserve more land in an attempt to use trees to reduce levels of carbon dioxide (CO2) and CO2 equivalents, a legal source says.

Regulating indirect effects of a pollutant such as CO2 illustrate the trend because, while pollutants like nitrous oxides have direct effects on human health and have long been regulated, CO2 poses indirect effects to ecosystems, including risks to polar bears and adverse impacts on the migration patterns of birds, the legal source says.

EPA is also analyzing ecosystem impacts in non-air regulatory decisions, including pesticide registrations. For example, Debbie Edwards, former head of pesticide program at EPA, told a Nov. 12 meeting hosted by the American Bird Conservancy in Washington, DC, that ecological considerations would be playing a key role as EPA ramps up plans to complete 70 pesticide re-registrations annually. Over the past 10 to 20 years reviews have focused largely on human health risks, but they are increasingly looking at ecological risk and endangered species issues, among other issues, Edwards said.

Ecological risk assessment is "a very different way of looking at the world," because human health assessments that EPA traditionally conducts for rulemakings focus on one organism, while ecological assessments are considering numerous factors in an ecosystem, according to the academic source.

The complexity of considering ecological risk, coupled with the fact many statutes are vague about what they are

protecting, have made ecological assessments slow to gain acceptance, but tools have been developed in the past 10 years to help make the assessments more commonplace, the source says. For example, the use of probabilistic risk assessment has become increasingly commonplace over the last 10 years. It is used to estimate the likely extent of damage from a substance to an ecosystem, the source says.

EPA's pursuit of a greater role for ecological risk assessments in rulemakings, however, faces several hurdles including the fact that such assessments are more complex than traditional human health studies.

The academic source says that traditional ecological risk assessment models are based on those used for human health risk assessment, despite the former considering a multitude of factors interacting with one another. There may be little to no data on the effects of certain chemicals on many species of wildlife, which means agency scientists must perform extrapolation to estimate the effects through a system, according to the source.

It is also important to consider how the ecosystem risk assessment interacts with the human health risk assessment, the source says, because EPA will want to make sure, for example, that an action to protect an endangered species will not have an adverse health effect for human. "How do you manage that system to get all of its benefits?" the source says. "You need to manage systems as an entire entity — not just human, not just ecological."

While the tools and methods to achieve these ecological risk assessment goals are increasingly available, it can take time to get the tools out to regional offices and through the department in the agency, and agency scientists with human health or engineering backgrounds may need additional training, according to the source.

Some observers also worry about the precedent being set with the greater consideration of ecological risk in EPA decisionmaking. In particular, sources have concerns about a greater reliance on ecosystem-based management leading to increased reliance on the precautionary principle in environmental regulation.

The legal source says it is expensive for industry to prove that there is not environmental damage when trying to respond to, for example, the potential secondary impact of pollution on an ecosystem. Further, regulators can use the argument of protecting plants and animals to impose stricter regulation, which resonates with the public who may favor strict rules if they are pitched as protecting wildlife, the source says.

The focus on ecosystems also represents a "nuanced shift from a focus on risk to a focus on hazard," which opens up a "broad universe of harms that need to be regulated" by EPA, says Lawrence Kogan, an attorney with Boston-based Exemplar Law Partners and head of the New Jersey-based non-profit Institute for Trade, Standards and Sustainable Development. These "health and environmental harms are not evaluated on the basis of probability, but possibility," Kaplan said in an interview, meaning EPA could give greater consideration to the potential risk on ecosystems of a given pollutant, rather than a proven link between a pollutant and, for example, health effects.

Kogan says the use of a cumulative risk assessment, which combines reviews of both health impacts and ecological impacts at EPA, could address concerns with ecosystem-based management, because the assessment would require the need to prove the link between cause and environmental harms. Such a risk assessment could be made even "more robust" with the addition of variables, he says. — *Aaron Lovell*

New Traffic Emissions Study Highlights Asthma Risk But Notes Data Gaps

A new study from an influential clean air research group underscores the serious impact of traffic pollution on asthmatics, but also draws attention to the urgent need for better monitoring and analysis of pollution close to major roads, a source with the group says.

The Health Effects Institute (HEI) in its Jan. 13 study, *Traffic-Related Air Pollution: A Critical Review of the Literature on Emissions, Exposure, and Health Effects*, builds on an earlier draft version released last May, which found hard evidence of a link between vehicle emissions and worsened symptoms in existing childhood asthma sufferers.

The final report reiterates the conclusions of the May draft regarding health effects, finding that there is a definite link between exposure to traffic pollution and exacerbated asthma. "The Panel concluded that the evidence is sufficient to support a causal relationship between exposure to traffic-related air pollution and exacerbation of asthma among children" HEI says in a statement issued Jan. 13. *Relevant documents are available on InsideEPA.com. See page 2 for details.*

HEI also found in both the draft and final study evidence that is "suggestive but not sufficient" for a causal link to other key health effects, such as the onset of childhood asthma and cardiovascular mortality (*Risk Policy Report,* May 26).

At the same time, researchers in a new report are suggesting that exposure to traffic-related particulate matter (PM) may play a role in the development of Alzheimer's disease.

An HEI source says the group's final report also shows major data gaps, including the need for better exposure models and the need for more concentrated research in a critical zone close to major roadways, where an increasing proportion of the North American population now lives.

In its statement, HEI says, "In light of the large number of people residing within 300 to 500 meters of major roads, the panel concluded that the sufficient and suggestive evidence for these health outcomes indicates that exposures to traffic-related pollution are likely to be of public health concern and deserve public attention." HEI, a Boston-based nonprofit corporation jointly funded by EPA and the motor vehicle industry, does not issue policy advice, but the group's

research serves as a key reference for air regulators.

The HEI source notes that much of the country's air monitoring network is concentrated away from major roadways in an effort to produce measurements representative of where people live, but this may no longer be appropriate, given that so many exposures now happen close to highways.

Environmental groups are urging similar monitoring needs and are pressing EPA to focus on near-road environments as the agency reviews national ambient air quality standards for nitrogen dioxide — a move EPA officials said they are considering, especially for particulate matter (PM).

In addition to establishing sufficient emissions monitors close to major roads, better analysis of near-road exposures is also needed, the HEI source says. For example, estimating exposure using the number of people living within 500 meters of a roadway may be simplistic and misleading if there are barriers to emissions, such as large hills, between the road and the buildings where people are located.

However, a source with the American Petroleum Institute seeks to downplay the report, noting that because it is a synthesis of available studies, it does not include any new evidence of adverse health effects and fails to support more stringent air quality regulation, the source says.

Meanwhile, a fresh study not included in HEI's review, published in the journal *Environmental Research* in November, suggests a link between PM exposure from traffic and the onset of Alzheimer's disease. The study looked at the PM exposure among women living near major roads and their likelihood of developing mild cognitive impairment (MCI), a precursor condition to Alzeimer's.

"Consistent effects of traffic-related air pollution exposure on test performances [for MCI symptoms] including a dose-response relation were found," the researchers say. "These results indicate that chronic exposure to traffic-related PM may be involved in the pathogenesis of [Alzheimer's]."

A source with the American Lung Association notes that EPA also acknowledged a possible link between PM and Alzheimer's in its final Integrated Science Assessment (ISA) for PM released in December, based on prior studies conducted in 2003, 2008 and last year. EPA concludes, however, that the evidence is insufficient to prove a causal link between PM and the disease at this point.

Activists Push For Stricter CBI Rules . . . begins on page one

studies, and revise existing older CBI claims to require greater justification.

EPA says it is looking at ways to tighten the rules. "The agency is currently looking at the available options for tightening CBI controls and making more useful data available to the public," an agency spokesperson says. The agency is also planning to consider changes to CBI rules as part of its TSCA Inventory Update Reporting (IUR) rule due out later this year, according to the unified agenda.

Industry officials also say they are open to discussing a more "disciplined" CBI process as part of talks on TSCA reform legislation, but are wary of an activist push to eliminate CBI, which they say is key to ensuring innovation. In its principles for TSCA reform released last fall, EPA also asked for greater statutory authority to allow for stricter CBI requirements.

The Environmental Working Group (EWG) released a report Jan. 4 that claims existing CBI rules mean "[t]he public has no access to any information about approximately 17,000 of the more than 83,000 chemicals" on the TSCA inventory of chemicals in commerce. Of the 20,403 chemicals added since TSCA was enacted in 1976, industry has placed CBI claims on 13,596 — nearly two-thirds — of these new chemicals, the report claims.

EWG's analysis indicates that "the number of confidential chemicals more than quadrupled" on the sub-list of chemicals produced in amounts greater than 25,000 pounds annually between 1990 and 2005.

The study also says industry has concealed "the identity of the chemicals in more than half the studies" submitted to EPA in the first eight months of 2009 that indicated a substantial risk of injury to health or the environment. TSCA section 8(e) requires industry to provide EPA the results of studies indicating their chemicals show this substantial risk. "By definition, compounds with 8(e) filings are the chemicals of the greatest health concern," EWG writes.

Environmentalists say they want greater disclosure of chemicals' health and safety impacts and other data to help the public better understand the possible risks of exposure from industrial chemicals used in commerce.

A source with the Environmental Defense Fund (EDF) says that existing federal toxics law indicates "EPA ought to be able to insist that chemical identity not be claimed as CBI" in the studies, adding that allowing the CBI could be linked to the fact that the chemicals are new.

An agency spokesperson confirms that the agency has the authority to require justification of CBI claims in conjunction with the studies. "EPA uses this authority to require substantiation of CBI claims made in TSCA section 8(e) filings," the spokesperson says.

Activists and legal sources say EPA should also use its existing authority under TSCA to reform CBI rules to impose stricter requirements on claiming data as confidential. For example, sources say EPA could require greater "up-front justification" of CBI claims by industry, something the legal source says could lead to a "speed-bump" for industry in filing the claims, which may act as a disincentive for companies to file such claims.

The EPA spokesperson says the agency has the authority to require justification and does so in some instances,

including when dealing with the IUR and new chemical submissions. "Additionally the agency has the authority to review and require substantiation of CBI claims on materials already received," the spokesperson says.

Sources also point to a need to review and revise CBI, something EPA is currently doing. "From 1990 to 2005, the number of confidential chemicals more than quadrupled — from 261 to 1,105 — on the sub-inventory of substances produced or imported in significant amounts (more than 25,000 pounds a year in at least one facility)," according to the EWG report. "In July 2009 the EPA released the identity of 530 of these chemicals, lowering the number of these moderate- and high-production volume secret chemicals to 575."

The EWG source says, "That act opens up the question, 'How much more can be done in this area?'" The source also points to a 2005 Government Accountability Office report that advocated periodic reassertion of CBI claims, something the source says "seems possible" under current chemicals law and could be amenable to industry.

The EDF source also says TSCA does not preclude changing the training regime for CBI, affording more agency scientists access to the information. TSCA imposes criminal penalties for leaking the data, the source says.

Any changes to CBI requirements would require political will, in addition to greater resources, the legal source says. But some actions, like requiring more justification for CBI claims, could cut down on the amount of claims without requiring additional resources on behalf of the agency, sources say.

While activists say that EPA may have existing authority under TSCA to achieve many of their goals for tightening CBI requirements, other changes to CBI rules would require legislative fixes.

The EWG report concludes that EPA's CBI rules have allowed industry to keep much of the information on their chemicals secret, largely because TSCA "is an extraordinarily ineffective law." Sources also say it is important to put the suggested changes explicitly into the statute, or even pursue stricter rules.

And EPA has asked for greater statutory authority for stricter CBI rules in its principles for TSCA reform, which were unveiled by Administrator Lisa Jackson last September. "Manufacturers should be required to substantiate their claims of confidentiality," the principles say. "Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety."

Some such fixes could be included in TSCA reform legislation that Sen. Frank Lautenberg (D-NJ) plans to introduce early this year. Previous versions of the Lautenberg bill, for example, included language requiring up-front justification of CBI claims submitted by companies and shifting more burden to industry to prove chemicals are safe. The EWG source says there could be a fee system for CBI claims, similar to that recently enacted in the European Union, while the legal source says administrative penalties could also be pursued under a revamped TSCA.

Industry has identified CBI as a place where it is willing to talk to activists in the burgeoning TSCA reform debate to try and reach a possible consensus. But while one industry source says industry stakeholders "should be able to come to an agreement about a more disciplined process," they "won't come to the agreement that you can't have CBI." The source stresses the role of CBI in innovation, "which allows products to be improved."

Activists are also raising questions about CBI in EPA's pesticide programs. For example, groups seeking stricter regulation of the pesticide atrazine are urging EPA to primarily use "publicly funded and peer reviewed science" in the upcoming review, according to a Jan. 5 letter to EPA Administrator Lisa Jackson from a coalition of pesticides and farm groups, including Pesticide Action Network North America (PANNA) and the Land Stewardship Project.

"All scientific studies supporting the continued registration of atrazine should be made available for public scrutiny or removed from consideration," the letter says. "Syngenta and other atrazine registrants should not be permitted to hide critical data from independent scientific examination" via CBI claims, the letter continues, though under the Federal Insecticide, Fungicide & Rodenticide Act, scientific studies must be publicly available.

"We don't believe critical data should be hidden, claimed as proprietary business information," Kathryn Gilje, executive director of PANNA, said on a Jan. 5 call discussing the report. Still, a Syngenta source says the studies done by the company and submitted to EPA conform to agency standards and are part of the public record. — *Aaron Lovell*

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DOD Eyes Earlier Risk Reviews In Chemical Acquisitions To Reduce Hazards

The Defense Department's (DOD) chemical risk management office is eying potential changes to its acquisition program, including analyzing earlier the human health and environmental risks of chemicals and substances used in weapons systems, weighing alternative chemicals and incorporating lifecycle costs related to those risks as a way to reduce hazards and make DOD more sustainable.

"The idea is to make better informed, more sustainable choices in chemicals and materials early in the process," according to DOD environment official Paul Yaroschak in an abstract of a presentation he made last month at a defense environmental technology forum. "Hazards, and thus mitigation of hazards, can be reduced by wise choices that still meet performance requirements."

Yaroshak suggested the three areas of making DOD systems sustainable are performance, lifecycle costs, and human health and environmental impacts. While performance can be tested and measured, and lifecycle costs can be calculated, criteria are still needed to weigh alternatives to chemicals currently used in terms of human health and environmental risks, according to Yaroschak.

"We don't have a good way yet of analyzing those alternatives and looking at the long-term implications," Yaroschak said during his presentation Dec. 1 before the Strategic Environmental Research & Development Program's Partners in Environmental Technology Technical Symposium in Washington, DC. Yaroschak is deputy director of DOD's Chemical & Material Risk Management Directorate, which falls under the department's Installations & Environment Office.

DOD lacks detailed criteria "for what chemical, physical, and toxicity data should be obtained for chemicals and materials being developed and specified in DoD acquisition programs," the abstract says.

"I don't think we have the detailed guidance we need. Some [weapon systems] program managers are very good at assessing the risks and getting them out, some are not. And that's a problem," Yaroschak said. For instance, he said in a follow-up interview, the Army in the munitions and energetics area has guidance on this, but across DOD there is none.

While it is unclear at this time what policy changes may occur, Yaroschak is suggesting new requirements be incorporated into DOD acquisition series policies to assess risks earlier, and that detailed guidance or military standards be developed for technology developers and weapons program managers. While DOD has lots of policies, "they're rather general so far," he noted.

Current acquisition policies focus on identifying environmental and health hazards and mitigating the high risks, primarily just before moving into design and production, Yaroshak explained in the interview. Instead, he would like to see an earlier look at the chemicals and substances used, and an analysis of alternatives to chemicals and materials being used so that the lifecycle implications of a chemical or material are analyzed. As an example, he said the cost of maintainers having to wear personal protective equipment when working on a system, as well as the disposal costs of that system due to hazardous chemicals, is not necessarily considered currently.

Yaroschak said early design decisions matter because 95 percent of the cost of a weapon system is locked in very early in the technology development and engineering phases when DOD makes critical choices on chemicals and materials it will use for a system's lifecycle.

"These choices can affect human health and the environment for many years," he says in the abstract. "Too often, these choices are made without a robust analysis of alternatives, life-cycle costs, and sustainability factors."

In an effort to move forward on this issue, DOD benchmarked public and private practices and policies worldwide, such as EPA's Pollution Prevention Framework and the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations, and took the best practices from them.

"We're trying to identify right now the critical points in the acquisition process, in other words what do you need to know [to assess and manage risks] and when do you need to know it," Yaroschak said in his speech.

To address this, DOD developed a standard set of physical, chemical and toxicological data needs, laid out in five tables. Among these tables, staff will pick and choose the kinds of information needed, he said in the interview, noting that no one will need to collect information responding to all of the data elements outlined in the five tables.

"The idea here is, depending on how you're going to use a chemical or material, you look at this and you determine what you need to know," he said during his presentation. For instance, "what are the exposures going to be of that chemical and material? Is this something that is going to be embedded in another material and never released? Or is it something that you're going to actually release and disperse?"

The five tables are: general chemical, production, and use information; physical-chemical information; environmental fate and transport characteristics; environmental and non-mammalian toxicity; and mammalian toxicity/carcinogenicity. For instance, under environmental fate and transport, possible data needs of a chemical are to determine its solubility and degradation/stability, the slides say.

The data will be "a useful tool for developers and program managers," he said in the interview.

Yaroschak said implementing such requirements would drive the need for more studies and research and development, adding, "I think it's a good thing because we're going to know more about the chemicals and material before we use them."