Inside EPA's
Risk Policy Report
An exclusive weekly report for scientists interested in environmental policymaking and policymakers interested in science

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EPA Grapples With Major Questions In New 'Cost-Benefit' White Paper

As EPA completes a white paper on its method for estimating the economic benefits of its regulations, experts say the agency will face questions about which kinds of benefits studies to use, how to aggregate studies and what role the so-called value of statistical life (VSL) method should play in determining the benefits of key programs.

Under the VSL approach, EPA assigns a fixed value to human life and then calculates the total value of lives saved by environmental rules for use in cost-benefit analysis of the programs. The resulting cost-benefit analysis is important as it can inform the stringency — and costs — of regulations.

The updated white paper on VSL is being prepared in conjunction with a revised version of an agency document, *Guidelines for Preparing Economic Analyses*, which is currently under review by the agency's independent Science Advisory Board (SAB) (*see related story*).

According to a July 8 notice in the *Federal Register*, EPA's National Center for Environmental Economics (NCEE) is working on the paper, which will propose a revision of the VSL based on new scientific literature, as well as past advice from SAB's Environmental Economics Advisory Committee (EEAC).

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Refinery Dispute Marks Early Battle Over Use Of Biomonitoring Data

Local environmentalists are calling on EPA to support an unpublished academic biomonitoring study that found significantly elevated blood levels of benzene near Corpus Christi, TX, refineries, saying the study will demonstrate the insufficiency of ambient air quality monitors that underestimate exposures by design.

The debate over benzene levels — which could inform the risk assessment for EPA's pending air toxics rule for refineries — highlights the kind of dispute regulators may face as activists and some lawmakers pressure the agency to increase its use of biomonitoring data in regulatory decisions.

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Fighting 'Acute' NO2 Proposal, Industry Decries Inadequate EPA Review

The National Association of Manufacturers (NAM) is challenging EPA's conclusion that a new primary standard for "acute," or short-term, exposures to nitrogen dioxide (NO2) is necessary to protect sensitive groups.

NAM has quietly submitted a petition to EPA under the Data Quality Act asking the agency to publish underlying data for an analysis it performed on the effects of NO2 exposure, which helped form the basis of the agency's conclusion that a first-time acute NO2 national ambient air quality standard (NAAQS) is needed to protect human health.

The challenge to EPA's basis for the acute portion of the proposal comes

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Massachusetts Study Targets EPA In Bid For Strict Perchlorate Limit

Massachusetts has published an analysis of its risk assessment of the rocket-fuel and fertilizer ingredient perchlorate, hoping to influence EPA and other jurisdictions to adopt drinking water standards similar to the state's, which is the most stringent in the country.

In a report published on *Environmental Health Perspectives*' Web site July 13, Massachusetts Department of Environmental Protection (MA DEP) staff explain the analysis behind their 2 microgram per liter (ì g/L) drinking water standard, and why they consider EPA's interim health advisory of 15 µg/L not protective of infants.

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In This Issue . . .

WAL-MART LAUNCHES 'ENVIRONMENTAL FOOTPRINT' LABELING INITIATIVE

Wal-Mart Stores, Inc.'s just-announced labeling plan to require suppliers to disclose the full greenhouse gas (GHG) and "environmental footprint" of their products is the latest example of the growing power of the retail giant to drive environmental decisions in a move that may be aimed at preempting federal regulation.

Wal-Mart CEO Mike Duke unveiled a "Sustainability Index" program that will focus on reducing energy consumption and waste, as well as introducing more sustainable products, according to a July 16 presentation. According to the presentation, the program, which could take five years or more to develop, would begin with a 15-question survey for product manufacturers focused on four areas: energy and climate; material efficiency; natural resources; and people and community. *The documents are available on InsideEPA.com.* *See page 2 for details.*

For example, in the "material efficiency" section, the retailer asks manufacturers, "Have you established publicly available sustainability purchasing guidelines for your direct suppliers that address issues such as environmental compliance, employment practices and product/ingredient safety?" It continues, "Have you obtained 3rd party certifications for any of the products that you sell to Walmart?"

The retailer is also helping to create a consortium of universities that will collaborate with suppliers, retailers, NGOs and government to develop a global database of information on the lifecycle impacts of products, according to Duke's comments. Other retailers will also be invited to contribute to the consortium. Eventually, the Index will translate the information stored in the database into a simple tool that informs consumers about the sustainability of products. The retailer also released a fact sheet about the program.

While applauding the retailer's effort, Chris Cathcart, president of the Consumer Specialty Products Association, said in a statement, "As suppliers to the retail community, it will be critical to strike the appropriate balance between the important goal of being transparent while protecting proprietary information. We are striving toward a similar objective with our industry's voluntary product ingredient communication initiative, which will become effective in January of 2010."

This is just the latest effort by the retail giant to drive more environmentally friendly industry practices. The company has already played a role in efforts to force detergent manufacturers to limit the use of harmful chemicals, and urged EPA to develop a recycling program for energy efficient light bulbs.

The *Wall Street Journal* reported that the company's plans are intended in part to get out ahead of possible federal legislation on greening labeling, though company officials deny this.

Last year, for example, Sen. Dianne Feinstein (D-CA) floated bill language among key stakeholders that would give EPA the authority to develop a framework to award "eco-labels" to consumer products that are environmentally preferable over the products' life-cycle, though the bill has not been introduced *(Risk Policy Report*, Oct 14).

While retailers and consumers have driven the move towards more disclosure about environmental impacts, efforts to develop a uniform federal labeling policy face hurdles.

For example, industry sources say the resource-intensive process of, for example, determining the lifecycle GHG emissions of a product yields questionable results for consumers. The consumers might not know how to best use the labels, for example, or might not realize that the best way to improve the lifecycle impact of a particular product could involve how the product is used, such as washing clothing at a lower water temperature. "The carbon footprint label doesn't tell the whole story and could be misleading," according to one industry source.

While some raise concerns the Wal-Mart initiative could increase costs, the environmental information will reportedly be publicly available in an an effort to drive a standard among retailers. And the program is already garnering praise from environmentalists. "A lot of suppliers are scared, but there is an opportunity here for them," Environmental Defense Fund's Michelle Harvey told the *Journal*.

CALIFORNIA SCIENCE PANEL DECLINES TO ADD BPA TO PROP. 65 LIST

A California scientific panel has decided not to list bisphenol-A (BPA) — a common chemical in plastic food and beverage containers — as a developmental or reproductive toxicant under the state's Proposition 65 toxics-warning law, raising hurdles for ongoing legislative efforts to ban the chemical's use in some products.

But environmentalists have already asked state regulators to reconsider the issue and a key state senator is vowing to continue to press her bill banning the chemical from use in children's products.

The state's Developmental & Reproductive Toxicant Identification Committee (DART) July 15 voted unanimously to reject adding BPA to the state Prop. 65 list for developmental or reproductive toxicity, concluding that the available scientific evidence did not support the conclusion that BPA "clearly is shown" to cause these health problems.

Chemical industry representatives hailed the decision, saying that it strongly vindicates their arguments that attacks on the chemical by environmental health organizations are misguided and not based on science.

While there is not a direct connection between the DART decision and efforts by lawmakers to ban BPA in products sold in California and other states, an industry source said the decision is "clearly relevant, because these are the state's qualified experts." The decision is "quite relevant because it will inform ongoing efforts by California legislators what the state's qualified experts think about the science — and ultimately is a scientific issue and should be resolved" by scientists.

That could be bad news for ongoing efforts by California lawmakers who are seeking to pass a bill banning BPA in baby products (*Risk Policy Report*, May 5).

But state Sen. Fran Pavley (D), one of the bill's supporters, said in a statement that she plans to continue to push the state Assembly to pass the Senate bill banning use of the chemical. "Despite heavy lobbying from the chemical industry, I'm hopeful my colleagues in the Assembly will join me in protecting our children from this harmful toxin," she said in a statement.

The DART decision could also stymie efforts in other states seeking to ban the chemical's use. Governors in Minnesota and Connecticut this year signed into law varying bans on BPA in products used by babies or very young children, the source noted, but added that the panel's decision should also be considered by any other states considering bans.

While the DART panel did discuss potentially revisiting the issue in the coming years, based on new studies that may emerge, the source said, their current review focused to a large degree scientific conclusions reached by the National Toxicology Project (NTP), which issued a report on BPA last year that found the chemical poses "some risk" to children (*Risk Policy Report*, Sept. 9).

While the NTP study raised a number of concerns about the connection between BPA exposure and developmental or reproductive toxicity, DART and other scientists have concluded that it did not conclude BPA clearly is shown to cause these health problems, according to sources.

If DART had concluded BPA has been clearly shown to cause these effects, it would have been inconsistent with the NTP study, the industry source said.

But one source says the Natural Resources Defense Council has already asked state officials to reconsider the issue.

NAS PANEL REPORT MAY POSE PROBLEMS FOR EPA'S PERC RISK ANALYSIS

The recent National Academy of Sciences (NAS) panel report on contamination at Camp Lejeune, NC, could pose problems for EPA's assessment of the risks posed by the dry cleaning chemical tetrachloroethylene, or perc — which is under review by a separate NAS panel — because the report finds that two rat studies on which EPA based its assessment are not relevant to human health.

EPA's assessment of perc is important in part because it will be included in EPA's Integrated Risk Information System (IRIS) database, which is the basis for site cleanups and regulatory standards. The assessment of the controversial chemical, a ubiquitous groundwater contaminant, stalled during the Bush administration because of agency controversy over uncertainty analysis and how to assess cancer risk.

EPA based its assessment of perc's cancer risks on two studies of mononuclear cell leukemia in rats — a 1986 National Toxicology Program study and a 1993 Japanese Industrial Safety Association study.

But the NAS panel's recently published report, *Contaminated Water Supplies at Camp Lejeune — Assessing Potential Health Effects*, said that the two rat studies should not be extrapolated to model human health effects. The report considers contamination of two water supply systems on the Marine Corps base in North Carolina with perc and another industrial solvent, trichloroethylene, between the 1950s and the 1980s. The report includes a chapter reviewing toxicologic studies of the two solvents.

Regarding cancer studies and resulting data about perc, the panelists note "clear evidence" that lifetime inhalation to perc results in "increased incidence of liver cancer" in mice. But the Camp Lejeune report also indicates that

rat tumors EPA used in its perc risk assessment are "not relevant to humans," an argument which industry has been making since EPA released its draft perc risk assessment in June 2008 (*Risk Policy Report*, Aug. 26).

An industry source says the incidence of mononuclear-cell leukemia (MCL) in rats stems from the particular strain of rats used in the study. "This is a strain-specific peculiar response," the source says. "The spontaneous incidence is extremely high. We've seen it in two studies now, so we'll call it real. It isn't even predictive of leukemia response in other [strains of] rats, let alone humans."

The Camp Lejeune report notes that "an increased incidence of mononuclear-cell leukemia was found in male and female F344 rats that inhaled [perc] at 200 or 400 [parts per million] ppm for 103 weeks. The increases were not dose-dependent and were within the incidence range of mononuclear-cell leukemia often seen in control F344 rats. The [National Toxicology Program] is no longer using the F344 strain in its cancer bioassay program, because of its high rates of spontaneous cancer of several types. Mononuclear-cell leukemia is rare in people. Thus, that form of leukemia in F344 rats has been judged not to be relevant to humans. Animal cancer bioassay outcomes relevant to human leukemia, multiple myeloma, and non-Hodgkin lymphoma have not been reported."

The report's findings reiterate concerns raised by panelists on a separate NAS panel reviewing EPA's IRIS risk assessment of the industrial solvent, who, at a Jan. 29-30 meeting in Washington, D.C., questioned why the agency relied on the two studies (*Risk Policy Report*, Feb. 3).

At that meeting, committee members David McMillan, of the University of Nebraska Medical Center, and Ivan Rusyn of the University of North Carolina at Chapel Hill, asked EPA staff why they used the MCL data instead of something more relevant. "I didn't understand how you got from the study to the conclusion. You could look at the study and conclude it's pretty weak," McMillan said. "There's a suggestion that the tumor is limited to the rat species."

Rusyn expressed disappointment that there remains no clear evidence regarding what he described as a long-standing question about the susceptibility of the F344 rat to the tumors.

But Kate Guyton, one of the EPA perc chemical managers, told the NAS panel that "there wasn't enough information to rule it out," and the study contained "the most sensitive endpoint we considered," a means of making a more health-protective assessment. She noted that there was "a fairly clear signal," from a large amount of data in two studies.

The industry source notes that the Camp Lejeune report's position mirrors that "of the majority of scientists for many years," but adds that "we don't know the position" of the other NAS panel reviewing EPA's perc assessment, though the source notes that panel did question EPA on its use of the mononuclear-cell leukemia data at the January meeting.

The NAS panel's report on EPA's perc assessment is expected to be published in late 2009, according to the NAS Web site. — *Maria Hegstad*

DISPUTE MARKS EARLY BATTLE IN BIOMONITORING DEBATE . . . begins on page one

In a July 13 letter to EPA Administrator Lisa Jackson, activists call for EPA to support a study conducted by the Texas A&M School of Rural Public Health that found benzene in the blood of Corpus Christi residents at levels that were more than twice as high as the blood of people who are occupationally exposed to the chemical. *Relevant documents are available on InsideEPA.com. See page 2 for details.*

The environmentalists' calls were prompted by a recent presentation by industry consultants that criticized the biomonitoring study, saying the blood levels the study purports to have found are "implausible" given the ambient air quality levels documented in what they say are more-rigorous monitoring data from the area's extensive monitoring network.

Environmentalists and their supporters in Congress have been seeking to increase use of biomonitoring data in regulatory decisions, saying it shows the extent to which humans are contaminated. Last month, for example, the Government Accountability Office (GAO) urged EPA to seek new authority to require industry to disclose biomonitoring data when regulating harmful industrial chemicals — a recommendation EPA rejected but which Democratic senators have said they plan to provide the agency.

GAO quoted the Centers for Disease Control & Prevention saying that "biomonitoring measurements are the most health-relevant assessments of exposure because they measure the amount of the chemical that actually gets into people from all environmental sources (e.g., air, soil, water, dust, or food) combined."

But industry officials oppose use of the data, saying it does not demonstrate hazards. Instead, industry officials are seeking to determine how biomonitoring data can be used in risk assessments rather than as a stand-alone determinant of hazards.

The dispute in Corpus Christi — which has one of the highest concentrations of refineries nationwide — comes as EPA is set to re-propose this month the contentious refinery residual risk rule, which is intended to limit health risks from air toxics after implementation of the agency's Maximum Achievable Control Technology (MACT) rule

from refineries.

The rule will determine whether the remaining risk warrants issuance of a more stringent national emission standard for hazardous air pollutants (NESHAP). The Bush EPA issued a final NESHAP rule for the sector in the last days of the previous administration, boosting emissions requirements for cooling towers based on new data and adding a new emissions control option for refinery storage tanks, but making few other changes to the existing standards.

But the Obama administration delayed the rule in response to concerns from environmentalists that the agency had not adequately considered the risks posed by the facilities. In comments on the Bush administration's proposal, environmentalists even submitted a preliminary version of the biomonitoring study — conducted by researchers at the Texas A&M School of Rural Public Health — to draw attention to the risks posed to nearby communities from the facilities, though the study concluded that a variety of potential sources could have caused the toxic exposures.

In comments to the docket, several national environmental groups called on EPA to require fence-line monitoring around refineries to gather better data but stopped short of calling for use of biomonitoring data as a stand-alone risk factor.

The agency did not respond to a request for information on its plans for releasing the new refinery proposal. And in response to a request for comment on the letter, an agency spokeswoman said, "We received the letter and will respond accordingly."

But in one indication the agency may be concerned about the accuracy of emissions data, the agency has granted a data quality petition from the City of Houston to reconsider its method for estimating refinery emissions, a move that could result in more stringent risk calculations.

Regardless of EPA's proposal, concerns about benzene are likely to ensue as a controversy. For example, EPA was already considering calls by a bipartisan coalition of Great Lakes lawmakers to review BP's compliance with all air, water and ground discharges at its refineries in the Great Lakes basin after the company disclosed multi-year violations of benzene emission limits at its Whiting, IN, facility.

In their July 13 letter to Jackson, Sierra Club and Citizens for Environmental Justice decry efforts by Regional Health Awareness Board (RHAB), an industry consulting group and EPA Office of Environmental Justice partner, to work with the Centers for Disease Control & Prevention to "redo" the upcoming Texas A&M biomonitoring study.

An activist involved with the study says the Corpus Christi biomonitoring data — which has already been collected and analyzed — is part of a larger study by the school to document exposures at several sites in the state.

But in a spring presentation on benzene air monitoring in Corpus Christi, scientific consultants ToxStrategies, Inc. — which has been hired by refinery operator Flint Hill Resources, Inc. — said that "the results of the Texas A&M study should be interpreted with caution," because the significantly high blood levels detected in the study "seem implausible," particularly because so-called "personal air" exposures estimated by the blood levels would need to be significantly higher than what the area's monitoring network detects.

The consultant's presentation says that Corpus Christi's "extensive monitoring network" has consistently documented ambient benzene at levels well below that which the Texas Commission on Environmental Quality considers to be a health concern.

"*If* measured levels [in the Texas A&M study] are accurate, it is unlikely that they are due to ambient air," says the presentation. The author did not respond to requests for comment.

But local activists argue that the Texas A&M study demonstrates that ambient air quality monitoring in Corpus Christi is insufficient to determine the risk borne by the local community. Activists say that air monitoring ignores dangerous benzene-containing compounds and particulates, and that monitoring methodology and equipment used in the area underestimates ambient levels of benzene by design.

One of the main reasons that environmentalists criticize state and other parties' ambient monitors in the area is that they collect samples over a period of time and average them, a methodology the activists say disguises harmful emission peaks. "Hourly and annual benzene averages may not represent the worst-case benzene exposures to people living near the refineries, since peak benzene levels may be higher. It is disingenuous to suggest that monitor averages, whether hourly or longer, are equal to benzene exposures to people," according to an attachment to the activists' letter.

The letter asks Jackson to "support recommending the [Agency for Toxic Substances & Disease Registry] and CDC suspend the request by industry's RHAB regarding a second Corpus Christi biomonitoring study at this time until the first biomonitoring study by [Texas A&M] has been completed and published and a debate conducted by the EJ community."

A petroleum industry source says this request amounts to an attempt "to suppress the data." The source says that any part of the industry-requested study should be "open to audit," but that the environmentalists should not be able to prevent the CDC study from going forward. Neither CDC nor RHAB were available for comment at press time.

Flint Hills Resources — the Koch Industries Inc. subsidiary that commissioned the ToxStrategies study — declined to provide interview access to a company official who serves on the RHAB board, but a Flint Hills spokeswoman defended the first-of-its-kind consultant study, as well as the underlying data and methodology.

"Ambient air monitors provide invaluable data indicative of what citizens in the community are exposed to," the spokeswoman told *Inside EPA*. "Biomonitoring if done correctly and with robust procedures such as what the CDC is known for may also be a valuable tool." — *Molly Davis*

as other industry groups are raising broader questions about the adequacy of the agency's scientific review for its overall proposed NAAQS for NO2.

Currently, no areas in the United States violate the existing NO2 NAAQS, which was set in 1971 at 53 parts per billion (ppb) on an annual average.

However, EPA Administrator Lisa Jackson June 26 proposed to set a new 1-hour NO2 NAAQS between 80 and 100 ppb, which if finalized would put many areas of the country out of attainment and impose strict NO2 reduction requirements, largely on mobile sources, which are the biggest source of the emissions.

Industry groups are broadly challenging the basis of the scientific conclusions, saying EPA has not complied with transparency requirements in its assessment. EPA is holding an Aug. 3 public hearing in Arlington, VA, where industry concerns will likely be raised.

Industry groups have been consistently critical of EPA's stated need for a new short-term standard over the course of the NO2 NAAQS review, saying scientific evidence does not justify such a standard or the significantly stricter measures it would mandate to control the pollutant.

For example, a short-term standard set at 100 ppb would effectively mean that some area-wide concentrations would have to be limited far below that due to large emissions of the pollutant from roadways, according to the EPA proposal. "If NO2 concentrations near roads are 100 percent higher than concentrations away from roads, a standard level of 100 ppb could limit area-wide concentrations to approximately 50 ppb," the proposal says.

NAM in a June 2 Data Quality Act petition asked EPA to publish a meta-analysis it performed on various studies of the effects of NO2 exposure, which statistically combines the results of various studies to determine a common effect.

For the review, EPA updated a meta-analysis of controlled human exposure studies. The meta-analysis results suggest that short-term exposures between 30 minutes and three hours at near-ambient concentrations of NO2 between 200 and 300 ppb "can alter airway responsiveness in people with mild asthma," EPA says in its proposal. The meta-analysis also indicates that ambient NO2 concentrations can increase risk of death by nearly 4 percent per 30 ppb increment over a 1-hour averaging time.

NAM is calling on EPA to release the underlying data in the meta-analysis in order to justify its proposal and comply with the transparency mandate of the statute.

"Rather than being transparent, the process by which EPA performed this meta-analysis is entirely opaque. The failure of EPA to provide any details concerning the methodology used to prepare this meta-analysis, or otherwise to subject the methodology it used to any form of scientific review, constitutes a severe violation of the EPA Guidelines," the NAM petition says. "EPA must prepare and release a report that includes a detailed description and justification of the methodology used in the unpublished 'meta-analysis' of the relationship between short-term NO2 exposure and non-specific airway responsiveness." *Relevant documents are available on InsideEPA.com. See page 2 for details.*

NAM is also raising concerns about the entirety of the review, which it says was subject to change throughout the process, compromising the conclusions.

"In the case of the current periodic review for the NO2 NAAQS, the generic five-year process for periodic review envisioned by the 2006/2007 policy was compressed to four years, and the anticipated 19 months between issuance of a draft [integrated science assessment (ISA)] and the final ISA was reduced to 11 months. When combined with EPA's decision to make late modifications and changes to the methodology EPA used for the ISA, this accelerated schedule has contributed to the deficiencies in information quality that are the subject of this" request for correction.

The petition does not make mention of the last-minute decision by EPA to withdraw an advance notice of proposed rulemaking (ANPR) for the rule, which was just before NAM issued the petition. Administrator Jackson's decision to withdraw the ANPR, which was based on the conclusion that it was largely politically driven and not based in science, also subsequently drew industry criticism for quashing debate on the standard (*Risk Policy Report,* June 2).

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EPA UNLIKELY TO CHANGE AIR TOXIC 'RISK' DECISIONS DUE TO PEER REVIEW

EPA is unlikely to change more than a dozen air toxics standards the agency set after reviewing the "residual" risk posed by a range of industrial sectors, even if the agency's science advisors find flaws in the agency's risk assessment methodologies during an ongoing peer review of the approach, agency officials say.

The agency is conducting a peer review of the framework it uses to determine the human health and environmental risks that remain even after facilities have met the first round of air toxics controls which require installation of maximum achievable control technologies (MACT) to come into compliance with the agency's national emission standards for hazardous air pollutants (NESHAP).

However, agency officials told members of the agency's Science Advisory Board that are reviewing the framework that the agency is unlikely to revise the residual risk reviews it has already conducted for 16 emissions source categories, even if the peer review finds fault with the agency's framework.

"We are admittedly inventing this process as we go along," Roy Smith, an EPA toxicologist told SAB members on a June 30 conference call. In response to an advisor's question, Smith said it is unlikely that EPA would change the reviewed standards due to changes recommended by the board, but said that it would be a policy decision.

Ted Palma of EPA's Office of Air Quality Planning & Standards echoed this idea, saying EPA would go back to the completed reviews to see if they would be impacted by any changes recommended by the advisors, but said it is unlikely the rules would be affected because the standards EPA has reviewed apply to low-risk sources.

The sectors for which EPA has completed residual risk reviews include synthetic organic chemical manufacturing, coke oven batteries, industrial cooling towers, dry cleaning and gasoline distribution.

The SAB panel is conducting a peer review of the agency's *Report on the EPA's Risk and Technology Review (RTR) Risk Assessment Methodologies*. The document "describes the Agency's methodologies for conducting baseline exposure and risk assessments for categories of industrial sources that emit hazardous air pollutants, highlighting the application of those methodologies with case studies on two source categories: petroleum refineries and Portland cement manufacturing," according to a June 15 memo that describes the review. *Relevant documents are available on InsideEPA.com. See page 2 for details.*

EPA has made changes to its RTR process as a result of a 2000 SAB review of its assessment for lead smelters and a 2006 SAB review of its proposed residual risk methodologies. EPA now seeking a formal consensus peer review of the revised methodology and the agency may change its approach for future assessments if the review finds problems with its current method.

The agency is seeking feedback from the reviewers about the accuracy of various pieces of their methodology, according to the memo. For example, the reviewers have been directed to assess the adequacy of the agency's emissions models compared to monitored emissions and emission factors.

In some instances in the case studies, there were substantial differences between the agency's modeled data and the monitored data and emission factors, Smith said. For example, for one refinery in the case study, the agency's model underestimated monitored benzene emissions by two-fold, Smith said, but noted, "In this business two-fold isn't really all that terrible."

There is also a three-fold difference between refinery risk estimates based on EPA's residual risk models and risk estimates based on emission factors, Smith said. Although both estimates found an incidence of around 30 cases of cancer per million people from any one refinery, the estimate based on emission factors found that 41 facilities posed a cancer risk of more than ten-in-one million, while the estimate based on EPA's residual risk models found 5 facilities posed that risk, according to a presentation prepared for the conference call.

EPA is also asking the panelists to review the agency's methodologies for multipathway exposure and risk assessment, which looks at the different ways people are exposed to pollution, for example through inhalation and ingestion.

The agency has established a "screen" that would set a *de minimus* emissions level to protect against a worst-case scenario exposure to 14 different persistent and bioaccumulative air toxics, which are pollutants that stay in the environment a long time and that increase in concentration up the food chain. In the case study for the Portland cement sector, all the facilities failed the screen for dioxin, and EPA then moved on to a more refined, site-specific risk analysis, the presentation says.

Panelists on the call also raised concerns about EPA's method for assessing the combined risk of different air toxics standards, since one facility may be governed by several different standards. EPA's David Guinnep said there is nothing that triggers an analysis of combined risk, but that EPA was planning to delay considering these risks until the agency reviews the last standard for a particular kind of facility.

EPA has directed the members of the panel to prepare their draft comments on the assessment by July 21, and the panel plans to meet and discuss the comments at a July 28-29 meeting in Research Triangle Park in North Carolina.

"We wrote it because it's a topic of national interest that we had put a lot of effort into," Mike Hutcheson, of MA DEP's office of research and standards and one of the paper's authors, said in an interview with *Risk Policy Report*. "By getting it published in a peer-reviewed journal, we could get it out" to a wider audience. *The paper is available on InsideEPA.com. See page 2 for details.*

MA DEP published its drinking water standard in 2006, four years after perchlorate was found near a military reservation on Cape Cod. The state needed a drinking water standard to assess and clean the site, but "at the time, EPA's schedule was not one to produce a drinking water standard in a reliable amount of time," Hutcheson said. That was "the impetus for the whole thing."

The state's standard is health-protective where the interim health advisory that the Bush EPA released in January is not, according to the MA DEP analysis. EPA released the interim advisory in January after it failed to reach a final determination on whether to regulate perchlorate in drinking water. MA DEP's publication reflects some of the criticisms EPA's Children's Health Protection Advisory Committee (CHPAC) raised in a letter to former EPA Administrator Stephen Johnson last fall regarding the agency's preliminary determination not to regulate perchlorate in drinking water (*Risk Policy Report*, Oct. 28).

MA DEP's analysis points out that EPA's interim advisory level of 15 ì g/L "would substantially exceed" for infants the reference dose (RfD), or safe daily oral dose, that the National Academy of Sciences (NAS) calculated in 2007 and which EPA adopted. "At the health advisory level of 15 ìg/L, a bottle-fed infant would receive a dose of perchlorate five times higher than the [NAS] RfD, suggesting a perchlorate advisory level of 3 ìg/L would be needed to protect children's health," MA DEP writes.

Industry disputes this argument, with the Perchlorate Information Bureau arguing that "low levels of perchlorate are not dangerous to public health" and that public health, including infants, would be protected by the 15 µg/L standard. The bureau is supported by Aerojet, American Pacific Corp., Lockheed Martin and Tronox. "We're talking about an amount that has no measurable effect on the body," a spokesman writes in an e-mail. "NAS pointed out the first measurable effect is Iodine Uptake Inhibition (IUI) which it noted occurs at about 245 ppb [245 µg/L], and emphasized as being a non-adverse effect."

NAS calculated an RfD of 0.7 micrograms per kilogram bodyweight per day (µg/kg/day), compared to the MA DEP RfD of 0.07 ì g/kg/day. MA DEP's paper also compares these RfDs to that calculated by California's Environmental Protection Agency (Cal/EPA), which set an RfD of 0.37 ì g/kg/day in 2007.

Each RfD is based on the same principal study, which exposed 37 healthy adult volunteers to perchlorate in drinking water for two weeks. Cal/EPA and the NAS calculated the RfD using a benchmark dose approach, while MA DEP chose a lowest observable affect level approach for its dose response assessment. "Both are valid approaches. It comes down to a professional decision," Hutcheson explains.

Cal/EPA and NAS chose a 5 percent IUI response rate to calculate the point of departure and from it, the RfD, according to MA DEP. But Massachusetts was "not comfortable saying 5 percent was safe," explained Tsedash Zewdie, a MA DEP toxicologist and another author of the paper.

MA DEP was also more conservative in its use of uncertainty factors (UF). Where Cal/EPA and NAS included an UF of 10 to account for the variability between individual people's responses in their RfD calculations, MA DEP used a UF of 100. In addition to considering human variability, Massachusetts' larger UF is intended to also account for database deficiencies and other sources of uncertainty in the calculation.

MA DEP's analysis faults EPA's reliance on a model of predicted IUI, which the state considered flawed and noted that EPA did not apply it to premature infants. Additionally, MA DEP points to animal and human data, which it says "suggest that perchlorate exposure may impact thyroid function at doses predicted to cause little IUI." Based on this information, MA DEP notes that EPA's interim advisory "may not sufficiently protect sensitive life-stages."

The authors noted that additional research has been published since Massachusetts, California and NAS released their assessments of perchlorate, which Hutcheson and Zewdie said is supportive of MA DEP's approach. Zewdie pointed to recent findings of perchlorate in breast milk and two controversial reports using Centers for Disease Control & Prevention (CDC) research. The first found that the body's thyroid hormone regulation pattern was disturbed in 36 percent of women with low iodine levels as a result of perchlorate exposure (*Risk Policy Report*, Oct. 10, 2006).

Industry, however, disputes the results of these studies. The first CDC study "never indicated that perchlorate was causing hormone changes, and where hormone changes were observed, they were all within normal ranges," the Perchlorate Information Bureau spokesman writes.

MA DEP also criticizes the findings of an EPA Inspector General (IG) cumulative analysis of perchlorate and other chemicals and factors inhibiting the body's uptake of iodine. The IG report concluded that EPA's Office of Water had been correct in its preliminary determination that there would be insufficient benefits to regulating perchlorate. Instead, the IG said that other agencies should release policies on including iodine in all prenatal vitamins, a suggestion that the MA DEP authors took issue with (*Risk Policy Report*, March 17).

"We believe that this is an insufficient response as, in the case of contaminated water supplies, it shifts the responsibility for protecting public health from environmental pollutants to the individual," according to the MA

DEP report. “Additionally, under this intervention approach, protection of infants from adverse health effects attributable to perchlorate contaminated water supplies would be completely dependent on the mother’s ability to achieve the necessary iodide supplementation. We believe that more comprehensive policies to reduce exposures to thyroid toxicants are also needed.”

Their report notes that the IG analysis does not “fully consider” the limitations of the epidemiological data used and didn’t address the CDC studies

Finally, MA DEP explains that its 2 µg/L drinking water standard is based on a risk management decision following the scientific analysis. The state determined that some perchlorate in drinking water was a byproduct of chlorinated disinfection processes at some water treatment plants. “A standard of 2 ìg/L minimizes possible disincentives to adequate chlorination, which could raise drinking water risks from pathogens,” the state concludes. “MA DEP concluded that this standard reasonably balanced potential perchlorate exposure and infectious disease concerns and was also within the range of scientific uncertainty regarding perchlorate toxicity.” — *Maria Hegstad*

EPA VALIDATES LAST ASSAY IN ENDOCRINE SCREEN, QUESTIONS REMAIN

EPA has announced the validation of the final assay in its long-delayed endocrine disruption screening program (EDSP), but industry and activists are already criticizing the test for failing to adequately measure the chemicals’ effects.

Industry argues the assay will produce too many false positives, overstating the risks of chemicals run through the screen, while a source with the Endocrine Disruption Exchange (TEDX) argues that EPA should have included a different assay in the screen.

Congress, through the Food Quality Protection Act of 1996, mandated EPA create the EDSP to screen for and determine chemicals’ potential for disrupting human hormones. The assay is the last in the EDSP’s first tier of assays to be validated, a key concern when EPA last year sent the program for White House review before the estrogen-receptor binding assay was validated. Industry argued last fall that the EDSP could not begin without the estrogen-receptor binding assay, described “by many as a keystone to this process,” the president of pesticide industry association CropLife America said at the time (*Risk Policy Report*, Oct. 14).

But in comments the chemical industry association American Chemistry Council (ACC) sent the agency in March, the group raised concerns about the validation process and what ACC considered “high variability” between labs testing the assay for EPA. ACC also raised concerns about the “[p]roposed use of expert judgment in lieu of a quantitative standard for interpreting a positive, which was necessitated by the high variability” and the “[i]nsufficient number of truly negative results.” *Relevant documents are available on InsideEPA.com. See page 2 for details.*

The EDSP is designed to screen for endocrine-disrupting chemicals in two tiers. The first is intended to detect if a chemical is capable of interacting with the estrogen, androgen or thyroid hormone systems. A chemical flagged in tier one will undergo tier-two testing, which is designed to provide data for hazard assessment. Industry and animal rights groups have for some time raised concerns that assays in the first tier will yield too many false positives, requiring more chemicals than necessary to undergo tier two tests that are more expensive and use more lab animals.

In a report concluding that the assay is validated following review by an independent panel of experts, EPA acknowledges that “[t]he criteria used for classifying a chemical as interactive or not err on the side of classifying a chemical as interactive, which is appropriate for a screening assay. Since additional assays will be used in Tier 1 screening before a final determination of the potential for interaction is assigned, and additional Tier 2 assays will be performed to confirm the interaction and provide dose-response information before risk is assessed, the bias towards false positives is appropriate.”

EPA continues, “Despite the bias towards false positives, chemicals that truly do not interact in any way with the estrogen receptor . . . consistently test negative in this assay.”

The agency charged the peer review panel to determine whether the assay “is biologically and toxicologically related to its stated purpose” — which the five-member panel found to be true. But several of the experts also raised concerns about complications that could make the assay more difficult to interpret, leading one reviewer, Ingemar Pongratz of Sweden’s Karolinska Institute, to conclude the assay is “only partially” related to the purpose of determining if a chemical would disrupt estrogen hormones.

The reviewers also noted that results varied between labs testing the assay, with reviewer Patrick Balaguer of the French National Institute for Health and Medical Research concluding that “the assay is sensitive to many details of preparation and technique and can show wide variability if not performed exactly as stated in the protocol.”

Reviewer Marie-Louise Scippo, a professor at the University of Liège, Belgium, concluded that the assay’s “main weakness comes from the use of animals to prepare the binding fraction, with not only ethical, but technical consequences (lack of reproducibility of receptor preparations.)”

A source with TEDX noted the reviewers’ concerns, and argued that EPA should have used a different assay, known as the MCF7 assay, instead of the estrogen-receptor assay included. The MCF7 assay could have been

validated more quickly due to its longstanding use in many labs around the world, the source says.

"I will continue to wonder if the last 13 years were not a waste of time when the MCF7 assay could have been adapted and validated early on as the estrogen screen," the source says.

An EPA spokesman points to advice the agency received from an expert panel regarding EDSP design. The committee's August 1998 report noted that tests such as the MCF7 using human cells "are rapidly being developed and offer both advantages and disadvantages over the above assay, one advantage being the use of the human rather than the rat [estrogen receptor]. However, being relative[ly] new, they have not been standardized in their examination of xenoestrogens."

The source argues that the MCF7 test, which has not gone through the same validation process that EPA's estrogen receptor test recently completed, is preferable because of some of the exact concerns industry and the reviewers raised. According to the source, the MCF7 does not indicate false positives, it is simple to perform, and because it is based on an existing line of human cells, it does not require the use of lab animals. — *Maria Hegstad*

EPA GRAPPLES WITH COST-BENEFIT QUESTIONS . . . begins on page one

An EPA spokesperson says the agency is still working on the VSL paper, which will be sent to SAB to review this fall.

SAB has begun requesting the nomination of additional experts to participate in a review of the white paper on VSL, according to the notice. "NCEE has requested an SAB peer review of the white paper, which will include a description of the approach used for deriving estimates for mortality risk valuation, a list of selection criteria detailing how the Agency selected studies for inclusion in the analysis, and the VSL that results from the revised approach," the notice says.

The paper could deal with a number of controversial issues surrounding VSL. For example, stakeholders disagree over the use of revealed preference studies or stated preference studies, according to a source with the Institute for Policy Integrity (IPI) at New York University, which largely supports the use of cost-benefit analysis in regulatory review. Revealed preference studies are based on actual decisions made by people in the workforce, while stated preference studies are based on studies comprised of hypothetical decisions made by survey respondents.

For example, in February 26 comments filed on the guidelines, the American Petroleum Institute (API) said that estimates derived from survey-driven, stated-preference studies "can be highly speculative, subject to manipulation, and highly uncertain, with the potential to significantly distort net-benefit estimates."

The groups continues, "Given the methodological problems and limitations associated with [stated preference (SP)] techniques, API recommends that SP-derived estimates not be integrated into the Agency's benefit-cost estimates — rather it would be more appropriate to report such benefits separately." Further, API suggests EPA quantify the uncertainty associated with the estimates, which would "facilitate public review and guard against highly uncertain benefit estimates" from driving the outcome of the analysis.

Many support the use of revealed preference studies because they measure actual behavior and because they allow researchers to see trends because they are based on more data than the small groups often used in stated preference studies, the IPI source says. Still, stated preference studies are become more experimental in their design, while revealed preference studies are increasingly taking concerns about representation into account, which could lead to increased convergence between the two, the source adds.

But a source with environmental think tank Resources for the Future (RFF) says new behavior economics literature seems to support the use of stated preference studies, which allow for a controlled environment that can help study subjects make more rational decisions, unlike the real-world market environment that is the basis of revealed preference studies.

Revealed preference studies can also have an inappropriate context for VSL, the RFF source says. For example, they are often based on workforce data, which skews towards younger, healthier people, while the deaths discussed in the studies are accidental and instantaneous, whereas deaths from air pollution are not.

Beyond study type, there are questions about how to aggregate different studies about VSL, the IPI source says. "How do you aggregate different studies using different methodologies," especially considering that there are oftentimes technical barriers to using sophisticated techniques to aggregate different studies looking at mortality valuation, the source says. For example, in 2007 the EEAC determined that meta-regression, a popular form of meta-analysis, was not appropriate for combining VSL estimates in policy decisions.

"The SAB does, however, agree that meta-regression is a useful statistical technique for identifying various aspects of study design or population characteristics that are associated with differences in VSL estimates," according to the group's final report. "Once important sample characteristics, model and estimation factors affecting the VSL have been identified, the Agency must determine a set of criteria for what constitutes a set of acceptable empirical studies of the VSL."

Other contentious issues surround the use of VSL, including whether VSLs should be different for different demographics. "Is one VSL the right way to go across demographic characteristics?" the source says. "Is one VSL the way to go for different contexts," like air pollution, transportation issues or cancer.

There is also a debate between the use of VSL versus other methods, such as the value of a statistical life year (VSLY), sometimes referred to as the value of statistical year lost (VOLY) due to premature mortality. In early 2008, SAB deter-

mined that scientific research does not support using VSLY in cost-benefit calculations of agency programs.

But VSLY supporters believe it would produce less-exaggerated calculations of regulatory benefits than VSL, although critics have called the method a "senior death discount" because it assigns a lower value to reducing risks to the elderly based on their shorter expected lifespans.

In its February comments, API suggested using the VSL in conjunction with the VSLY approach, which has been used to evaluate policy options for reducing air pollution in Europe. API says the technique is consistent with advice in the Office of Management & Budget's Circular A-4 on weighing costs and benefits of regulation.

Using VSLY, or VSLY in conjunction with VSL, "would provide risk managers a more robust range of economic benefit values to consider," the comments say.

API also says EPA should incorporate a 2006 study by the New Energy Externalities Development for Sustainability (NEEDS) Project into its analysis, which focused on "VOLY lost by air pollution mortality, thereby avoiding significant benefit transfer-related concerns." The studies EPA has been relying on to calculate VSL have largely focused on accidental deaths, API says.

The RFF source says there are also questions about private good versus public good, an important issue for EPA. "For a public program, you really want to know what people would pay to improve public health, to reduce death in the community."

But most studies ask about private good, and there are issues with studies looking at communities, revolving around the issue of altruism and defining whether the altruism is paternalistic or non-paternalistic. — *Aaron Lovell*

EPA URGED TO EXPAND COST-BENEFIT GUIDE TO WEIGH DEREGULATION, CLIMATE

A key group of EPA science advisors is urging the agency to expand its guideline for conducting economic analysis to address complex environmental problems like climate change and the valuation of "non-monetized benefits" from ecosystems services, as well as the costs and benefits of deregulatory approaches.

In its July 9 draft letter, the Science Advisory Board's (SAB) Environmental Economics Advisory Committee (EEAC) provided initial comments to the *Guidelines for Preparing Economic Analyses*, a document being revised by EPA's National Center for Environmental Economics. The draft is the most recent version of the comments and will be discussed by the chartered SAB on an Aug. 6 teleconference. *The letter is available on InsideEPA.com. See page 2 for details.*

Some more controversial topics, including value of a statical life (VSL), have been spun out into separate white papers and chapters to be reviewed separately (*see related story*).

EPA performs economic analyses on all its rules projected to cost $100 million or more, as well as other, less costly rules where possible, in order to help justify costly interventions to reduce pollution. The guidelines are used by every EPA office, as well as external academic institutions, but are especially important for EPA's air office, which most often promulgates rules with the biggest costs and benefits, EPA staff said at a SAB meeting last October. The guidelines were last issued by the agency in 2000.

Citing EPA's lifecycle analysis of biofuels as an example, the SAB suggests the guidelines document "anticipate a changing role for economics" amidst the complex problems posed by global warming. "The *Guidelines* are implicitly focused on conventional point source pollutants," the letter says. "Attention to emerging challenges from nonpoint pollutants, changes in carbon and other biogeochemical processes, invasive species, etc. would give the *Guidelines* a more contemporary and forward looking view."

The letter and comments also highlighted the importance of valuing the benefits of protecting ecosystems and ecosystem services. "Monetizing ecosystem services remains an area of significant challenge and there are many times in benefit-cost analysis when some such services will not be adequately monetized," the letter says. "The *Guidelines* should acknowledge and discuss situations where 'non-monetized' benefits are expected to be a significant portion of the regulatory outcome including advice for practitioners in this case and noting that adherence to formal dollar-based benefit-cost analysis can lead to incorrect efficiency signals."

The Institute for Policy Integrity (IPI) at New York University, which generally supports expanded use of cost-benefit analysis, applauded the changes to the guidelines, and also pointed out that the SAB encouraged the use of cost-benefit analysis when looking at deregulatory or non-regulatory proposals.

In the draft letter, the EEAC says, "Non-regulatory approaches can bring both sizable costs and benefits and the same can be said for deregulatory decisions. The *Guidelines* should indicate that decisions to deregulate or adopt a non-regulatory approach can be as much informed by economic analysis as those that are purely regulatory in nature."

A source with the IPI says that, during the last administration, economic analysis was not conducted for many deregulatory actions, including changes to the new source review rules, which require new or modified sources to install strict pollution controls. The source says it is "important that the SAB realized the systemic problem about how cost-benefit analysis has been used in the past" by pointing out the need for analysis for deregulatory actions.

The IPI source also applauds SAB's discussion of how regulation can lead to innovations that could reduce costs to industry over time. Applying existing technology to the estimated compliance costs is always going to portray the worst case scenario, which skews the regulatory choices, the source says.

ECOSYSTEM SERVICES PROGRAM SEEKS TO OVERCOME FUNDING CHALLENGES

EPA's ambitious new program intended to value the services ecosystems provide humans and the environment faces curtailed funding and staffing challenges as it attempts to get off the ground — in large part due to a lack of statutory backing — even though some agency science advisors see it as a key approach to studying broad environmental concerns like climate change.

"The [Ecosystem Services Research Program (ESRP)] faces challenges, many of which we believe slow, but do not negate, the Program's continued future progress," EPA staff write in a planning document presented to an EPA Science Advisory Board (SAB) panel at a July 14-15 meeting. The program's anticipated fiscal year 2010 budget is less than half of the $150 million staff believe is necessary to implement the sweeping change the program could bring to the agency.

Ecosystem services is the emerging concept that people depend on ecosystems for many benefits, including water, food production and flood control. It enables analysts to quantify or even monetize these benefits. EPA is adopting the controversial approach to help decision-makers better calculate the costs of these services' loss or damage (*Risk Policy Report*, Jan. 22, 2008).

The concept is increasingly being accepted by state and federal government agencies, and proponents are "past the selling of ecosystem services" as a concept, an agency source says. The source points to the recent opening of the U.S. Department of Agriculture's Office of Ecosystem Services and Markets, noting the department "can have tremendous influence, because they pay for conservation lands . . and "any [ecosystem] service could potentially be a market." A bill before the Oregon state Senate encourages state decision-makers to utilize the ecosystem services concept in land management decisions, and creates a board of experts to study how best to set up an "integrated ecosystem services market" for the state.

But planning documents and ESRP staff at the meeting outlined the ongoing challenges the program faces, starting with its budget. ESRP grew out of the Office of Research & Development's (ORD) ecological research program, which received some $100 million in funding in FY04. That level fell to $70 million in FY09, and the administration's FY10 budget request for the program is about $71 million, an agency source says. The level of full-time equivalent employees (FTE) is expected to stay the same as in FY09, at 270, the source says. *Relevant documents are available on InsideEPA.com.* *See page 2 for details.*

But asked by one SAB panelist, Peter Chapman of Golder Associates, if the program will be able to maintain the employees currently assigned, program director Rick Linthurst said at the meeting, "This is a problem. We don't have any management clout right now. We're an all-volunteer army."

Another SAB panelist, Greg Biddinger of ExxonMobil Biomedical Sciences, noted that "the real challenge, the 800-pound gorilla, is the lack of regulatory authority" to drive funding. He added that the staff's wish list of $150 million funding "really is the recipe forward." ESRP plans detail a wish list, including $30 million for regional offices to partner with the program, $10 million for assistance with outreach and education from the agency's information and education offices, and $5 million for the agency's environmental economics office to assist ESRP in performing valuation.

"This really is where the whole ORD is trying to go," another SAB panelist, Terry Daniel of the University of Arizona said of the ESRP. "Let's double the budget!" Chapman agreed, adding the ESRP staff needs to find "higher champions" in government to get the program the funding it needs.

Despite its limited resources, staff says the ESRP is making steady progress. Staff presented implementation plans and updates to the SAB panel for many of the program's key components, including those for three pilot geographical areas of the country that the program will study and several overarching issues: an ecosystem services atlas, coral reefs, decision support, nitrogen and wetlands.

ESRP continues to struggle with the agency's limited emphasis on social sciences, and the small number of economists, decision science and sociological experts at the agency, an ongoing problem that the SAB has for some time urged EPA to address. This limitation, and the limited funds available to hire external experts, led SAB to voice concerns with the program's overarching goal of building a decision support platform, or tool, that local or regional decision makers could use to inform land use decisions — even though they strongly supported the overall policies the program is espousing (*Risk Policy Report*, April 15, 2008).

"I think we've recognized in the last year and a half that we're not going to get there. We've been rethinking that," the agency source says of the decision-support tool. The original idea of creating "some huge model would not be helpful" because decision makers in different positions need different information and operate in different ways, the source says, adding that instead, "the idea will be to develop tailored tools to different" decision-makers.

Additionally, the report notes, "The relationship between ecosystem services and human health and well-being is an area of exciting new science with important implications for the Agency, but with few FTE." This problem is a traditional one of split disciplines, according to the source, who notes that ecologists rarely work with economists. The idea is to get a diverse group of experts working together on the same problem, the source says.

The program considered a test case during a meeting in Denver, CO, last week, the source says, with various experts from the new program considering the health of and benefits provided by inland streams. "The normal progress of things is science leads to policy, [and it] is a long, long process," the source says. "We could dramatically speed this up by all working together." — *Maria Hegstad*