Message

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Sent: 9/14/2015 6:39:39 PM
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Subject: News Update: Advisors Reiterate Call For EPA To Bolster Novel Skin Cancer Risk For BaP (InsideEPA)

DAILY NEWS

Advisors Reiterate Call For EPA To Bolster Novel Skin Cancer Risk For BaP

Posted: September 14, 2015

EPA science advisors are reiterating calls for EPA to add two studies to bolster the agency's novel skin cancer risk estimate in its draft assessment of human health risks of the petroleum chemical benzo(a)pyrene (BaP), and to better justify other aspects of the assessment, including a risk value for exposure through ingestion.

During a recent conference call, a panel of EPA's Science Advisory Board (SAB) responded to an agency request for advisors to clarify their criticism that the novel skin cancer risk estimate for BaP lacks adequate justification, and that the agency should have included two additional studies to bolster the risk.

"We're suggesting that it's important that they're considering these two studies, and [that] the criteria used for exclusion was inadequate to exclude them for risk assessment purposes," panel chairman Elaine Faustman, of the University of Washington, said during the call.

The Chemical Assessment Advisory Committee (CAAC), a subgroup of the SAB, is finalizing peer review of EPA's September 2014 draft Integrated Risk Information System (IRIS) assessment of BaP, which includes EPA's first-ever skin cancer risk estimate. The BaP IRIS assessment is also significant because the agency intends to use BaP as a reference chemical to estimate the toxicity of mixtures of polycyclic aromatic hydrocarbons (PAHs).

During the Sept. 2 call, CAAC members said they intend to finalize their recommendations to EPA in the coming weeks and forward them to the SAB for review.

The panel has generally backed EPA's draft conclusions that BaP poses neuro-developmental, reproductive and immune system risks, as well as EPA's proposal to classify the substance a human carcinogen.

But in a July 24 draft review, the CAAC also criticized EPA's approaches for calculating the first-time skin cancer risk estimate, as well as its non-cancer inhalation and oral risk estimates. The group has called for EPA to add two additional studies -- a 1983 study, Nesnow, and a 1977 study, Levin -- to bolster its skin cancer estimate.

Last month, EPA's top risk assessor asked the CAAC to clarify its call for additional studies, saying the agency sought to include only studies that were most appropriate for dose-response analysis and for deriving a cancer slope factor for lifetime dermal exposure to BaP.

Vincent Cogliano, EPA's IRIS program director, in comments to the CAAC, cited criteria for choosing studies, including that they expose mice for approximately two-years duration, or lifetime, and said less-than-lifetime studies might underestimate risk by overlooking the potential for developing tumors later in life.

Additional Studies

During the CAAC's Sept. 2 conference call, panelists reiterated their push for bolstering the skin cancer risk with two additional studies, arguing that IRIS documents put the exposure criteria for including studies at one year, rather than two. One of the studies the CAAC recommends including exposed animals for more than a year, and the other for just under a year, not a significant enough difference to warrant exclusion, panelists said.

"There is no mention in the IRIS review document that studies considered for dose response were limited to those of approximately 2-years duration," panelists say in a draft response to EPA's request. "This is new information."

Panelists also refined additional recommendations for EPA to strengthen the draft assessment by providing better justification for its proposed reference dose (RfD), a risk estimate calculated to protect against non-cancer effects from ingestion exposure to BaP.

The CAAC, in its July 24 draft review, questioned EPA's justification for its choice of developmental endpoints for setting an RfD, and suggested the agency give greater consideration of reproductive outcomes, including cervical hyperplasia and cervical inflammation cited in a 2011 Gao, et al. study, or explain why the endpoints were not selected.

During the Sept. 2 call, Barry McIntyre, of the National Institute of Environmental Health Sciences, said EPA's draft assessment "just discounted the [Gao] study without giving any perspective of why."

In a draft update to the CAAC recommendations, panelists say, "The Gao study is compelling in establishing a relationship amongst BaP exposure, cervical hyperplasia and inflammation," adding that a pair of studies of another endpoint, yielded inconsistent results. "Therefore, it is unclear as to why EPA would base an RfD on an apical, apparently inconsistent, response as compared to a single study comparing multiple endpoints and routes of administration."

Panelists recommend that EPA either include the Gao study or explain why it is not relevant for risk assessment.

Risk Estimate

EPA's draft BaP assessment is important for several reasons, including the agency's first-time attempt to calculate a skin cancer risk estimate, something the agency has never included in another IRIS study.

Also, the re-assessment of BaP's risks comes after a 2010 SAB panel pressed EPA to update its 1994 IRIS assessment of BaP before using it as a reference chemical in estimating the toxicity of mixtures of PAHs.

The draft assessment is also one of the first three the relatively new CAAC is peer-reviewing, as part of the agency's efforts to strengthen the IRIS program following a critical review from the National Academy of Sciences in 2011.

In Aug. 26 comments to the SAB, the Utilities Solid Waste Activities Group (USWAG) says the CAAC's concerns regarding EPA's development of the novel skin cancer risk estimate back the group's past criticism that the study lacks adequate scientific backing, and urges the panel to strengthen its calls for EPA to bolster the review.
"USWAG agrees that a robust evaluation of the issues raised in the Draft [SAB] Report will be critical to the development of a scientifically defensible risk assessment," the group says. "USWAG urges the CAAC Panel to increase the firmness with which it advises EPA to revisit its risk assessment. -- *Dave Reynolds*(dreynolds@iwpnews.com)

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