Message

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Sent: 9/30/2014 1:13:01 PM
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Subject: News Update: EPA Rejects Criticisms Of BaP IRIS Assessment's Stringency In New Draft (Inside EPA)

RISK POLICY REPORT - 09/30/2014

EPA Rejects Criticisms Of BaP IRIS Assessment's Stringency In New Draft

Posted: September 29, 2014

EPA has issued an updated version of its draft assessment of the human health risks of benzo(a)pyrene (BaP) in which the agency rejects industry criticisms that the earlier 2013 version of the study was too strict, and while EPA says it has reviewed several studies industry cited to boost its claims the risk numbers appear largely unchanged.

The BaP assessment, which EPA is preparing for peer review by its Chemical Assessment Advisory Committee (CAAC), for the first time presents a cancer risk estimate for dermal exposure -- skin contact with a substance. It is also novel because the agency plans to use the finalized BaP risk numbers in an approach to estimate the human cancer risk of polycyclic aromatic hydrocarbons (PAHs) as a class of chemicals.

BaP is the best studied of this class of chemicals, and EPA several years ago informed its Science Advisory Board that it intended to use BaP as an index chemical in a Relative Potency Factor (RPF) approach for assessing risks of mixtures of PAHs, which are carcinogenic compounds stemming from a wide range of natural and industrial sources, including crude oil, asphalt and vehicle emissions.

But several industry groups have protested EPA's dermal cancer calculations over the past year, arguing that they are unrealistically strict and could lead to major, expensive changes in how the agency's Superfund office assesses cleanup sites and reaches decisions on remediation requirements.

The American Petroleum Institute argued last year that if EPA's dermal slope factor (DSF) "was a true predictive indicator of human skin cancer risk, it would mean . . . that 100% of users of pharmaceutical coal tar products should have skin cancer, when, in fact they do not. It would also mean that BaP and BaP-toxic equivalents in soil throughout the US are the cause of 30% of all human skin cancer, which cannot possibly [be] true. For these reasons, it is therefore recommended that EPA abandon the DSF entirely, but if it does not, then any future proposed DSF should be subjected to a real world validation to determine if the DSF is scientifically supportable" (*Risk Policy Report*, Dec. 9).

But in an appendix attached to its latest draft assessment released Sept. 25, EPA replies that it tried to replicate industry's calculations, but was unable to do so. It then provides its own calculations, suggesting that its DSF is not unrealistic. *Relevant documents are available on InsideEPA.com.*

"The commenters did not provide the exposure equation, [BaP] soil concentration, or assumptions used in their calculation of a 30% risk estimate. Without these details, EPA could not reproduce the exposure and associated risk estimates presented in the written comments," according to the appendix.

The updated draft assessment explains that it has calculated much lower risk estimates with the DSF using its Risk Assessment Guidelines for Superfund to "calculate average daily dermal doses and associated risks at those dermal doses . . . result[ing] in risk estimates of approximately 6x10^-6 for average lifetime exposure that occurs during childhood, and 1x10^-6 for average lifetime exposure that occurs during adulthood."

Industry groups urged EPA to include in its assessment human epidemiological studies of skin cancer risk in eczema and psoriasis patients using coal tar creams which contain BaP.

EPA responds that these studies were not helpful to its dose-response analysis because they do not provide useable dosing information, had limited followup, and other limitations. "EPA does not consider the identified studies to adequately address the question of the potential association between coal tar treatments and skin cancer due to limitations in design and conduct. Thus, EPA disagrees with the commenters' view that these studies demonstrate that [BaP] does not cause skin cancer in humans," the agency says.

The agency adds, however, that while the studies of coal tar treated patients do not bolster industry's arguments, EPA considers them to "provide *in vivo* evidence of [BaP]-specific genotoxicity (increased BPDE-DNA adducts) in human skin . . . an early key event in the carcinogenic mode of action of [BaP]."

The Utility Solid Waste Activities Group (USWAG), whose members include power companies, also questioned the utility of EPA's DSF, arguing that the approach assumes that the amount of skin in contact with BaP is irrelevant.

EPA responds that the studies it used to calculate the DSF "reported the total dose applied to skin and reported the general area treated . . . but did not quantify the actual [centimeters squared] of skin treated. For this reason, the draft [DSF] expresses risk of skin tumors from [BaP] dermal exposure as risk per [microgram per day (ug/d)]. The assumption of this dose metric is that risk at low doses

of [BaP] is dependent on absolute dermal dose and not dose per unit of skin, meaning that a higher exposure concentration of [BaP] contacting a smaller area of exposed skin could carry the same risk of skin tumors as a lower exposure concentration of [BaP] that contacts a larger area of skin."

EPA did recalculate its DSF in response to a new report provided by toxicology consulting firm Gradient, which provided additional data on a study EPA used to calculate the DSF in its 2013 draft. The additional information allowed EPA to drop an older study it used in its 2013 calculations, as well as use a different model, the agency explains. Despite the new analysis, the final DSF remains very similar to that proposed in 2013.

"EPA has revised the dose response analysis for the derivation of the [DSF] to incorporate the individual animal survival data identified by the public commenter . . . This allowed EPA to utilize the MultiStage-Weibull model, a model that incorporates dose and the time at which death with tumor occurred. Use of this model accounts for competing risks associated with decreased survival times and other causes of death, including other tumors."

The latest draft proposes a DSF of 0.006 per ug/day, very similar to the 2013 draft, which included a DSF of 0.005 per ug/day. EPA's inhalation unit risk factor, an estimation of BaP's cancer potency when inhaled, of 6x10^-4 per microgram per cubic meter (per ug/m^3) is very similar to the agency's 2013 draft estimate of 5x10^-4 per ug/m^3.

EPA's other risk calculations remain the same to the 2013 draft, including the oral slope factor (OSF), the non-cancer reference dose (RfD), or the maximum amount EPA estimates can be ingested daily over a lifetime without anticipating an associated non-cancer health effect, and the reference concentration (RfC). The RfC is analogous to the RfD by inhalation exposure.

EPA proposes an OSF of 1 per milligram per kilogram body weight per day, an RfD of 3x10^-4 milligrams per kilogram bodyweight per day and an RfC of 2x10^-6 milligrams per cubic meter.

EPA released the latest draft for CAAC peer review. A date for that meeting has yet to be scheduled. Science Advisory Board staff is taking public comments on potential peer reviewers through Oct. 2. -- *Maria Hegstad*

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