Meeting Minutes

Air Toxics Science Advisory Committee Ethylene Oxide Webinar

June 2, 2017, 9 a.m.
DEQ Headquarters, Conference Room 714
700 N.E. Multnomah Street
Portland, Oregon 97232

List of Attendees

Two ATSAC members, Dave Farrer and Kent Norville, attended in person. Other three ATSAC members called in, including Bill Lambert, Max Hueftle and Dean Atkinson.
DEQ staff who attended in person: Sue MacMillan, Sarah Armitage, Jeffrey Stocum.

Audience members who called in included:

Ken Kearns, DOW Chemical
Melissa Schisler, DOW Chemical
Nicolas Georges, Director of Scientific Affairs, Consumer Specialty Products Association (CSPA)
Chris Klosen, Balchem Corporation
Bill Gulledge, American Chemical Council
Jake Vandervort, Ethylene Oxide Sterilization Association, Inc.
Jason Johnson, ACTA Group, LLC
Jeff Wiser, 3M Corporation
Samantha Freeman, association unknown
Nicole Savoy, association unknown
Steven Siler, association unknown
Mimi Falcon, association unknown

Introduction

Sue MacMillan, DEQ lead for the ATSAC, presented three slides related to ethylene oxide information she had prepared, and quickly went through them as a way to start the discussion. The Air Toxics Science Advisory Committee was provided with links to relevant papers, and Bill Lambert had provided a pdf file for one of the key papers, Steenland 2003, related to the December 2016 EPA Integrated Risk information System, or IRIS, values for ethylene oxide.

Bill Lambert, committee chair, then led the discussion. ATSAC members and DEQ staff formally introduced themselves, and about half the attending audience members stated their names and associations. Other audience names were identified from the webinar list of participants.

Discussion of new toxicity information for ethylene oxide

The four main uses and/or sources of ethylene oxide: 1) sterilization at commercial facilities and hospitals; 2) fumigation of foods and spices; 3) in the manufacture of surfactants; and 4) emissions from ethylene oxide distribution facilities.
In 2005, the ATSAC chose to use the Unit Risk Estimate, or URE, value for ethylene oxide that was available in 1987 from California's Office of Environmental Health

State of Oregon Department of Environmental Quality

Your Program or Region Name Here
700 NE Multnomah St.
Suite 600
Portland, OR 97232
Phone: 503-229-5696
800-452-4011
Fax: 503-229-5850
Contact: Sue MacMillan at503.229.6458 or macmillan.susan@deq.state.or.us
www.oregon.gov/DEQ

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Hazard Assessment, or OEHHA, to calculate the ABC. This was the only toxicity factor available for ethylene oxide in 2005. The 1987 URE value is 8.8×10^{-5} per ug/m^3, which converts to an ABC of 0.01 ug/m^3. Max Hueftle explained that OEHHA had applied a multi-stage model to a rodent study in order to extrapolate a URE value relevant to the protection of human receptors.

In December 2016 two different UREs were published by the EPA for the Integrated Risk Information System (IRIS) in the document entitled *Evaluation of the Inhalation Toxicity of Ethylene Oxide*, EPA 635/R-16/350Fc. One URE of 3×10^{-3} per ug/m^3 was based on adult exposure, with the related endpoints of lymphoid cancer and breast cancer in females. If an ABC were calculated using this URE value, the ABC would be 0.0003 ug/m^3. EPA calculated this adult-based URE by first subtracting 16 years from the lifetime assumption of 70 years to make sure only the adult exposure period was being considered; then the results were averaged over a 70-year period of time.

The second EPA IRIS URE value considered by the ATSAC was 5×10^{-3} per ug/m^3, which would result in an ABC of 0.0002 ug/m3. This URE value was calculated using the same data and most of the same assumptions as the first URE value, but age-dependent adjustment factors (ADAFs) were applied to account for the greater vulnerability of children to ethylene oxide. Ethylene oxide has mutagenic effects, which means that early-life DNA mutations caused by exposure to this chemical at the more-vulnerable child life stages increases the lifetime potency of this carcinogen. However, per previous ATSAC policy, ABCs will not be adjusted using ADAFs. The ATSAC continues to recommend instead that ADAFs be used within the context of any human health risk assessment that is conducted.

The December 2016 URE values are considered by the ATSAC to be based on robust and well-conducted epidemiological studies (Steenland 2003; Steenland 2004; Stayman 1993, among others) using a very large National Institute for Occupational Safety and Health (NIOSH) cohort of workers exposed to ethylene oxide during use of the compound for sterilization purposes. These values are nearly 30 years newer than the 1987 OEHHA value used to identify the current ABC for ethylene oxide, and are based on direct epidemiological (human) exposure data, rather than the rodent data which served as the basis of the 1987 OEHHA value. Because human data rather than animal data was used to generate the 2016 URE values, there is significantly less uncertainty associated with the 2016 URE values.

Dave Farrer of the Oregon Health Authority stated that as the difference between the two potential ABC values is very small, 0.0003 ug/m^3 versus 0.0002 ug/m^3, he would have no problem supporting the use of the URE value of 3×10^{-3} per ug/m^3 as the basis of a revised ABC of 0.0003 ug/m^3 for ethylene oxide. Because the slightly-more-protective value of 0.0002 ug/m^3 would be based on the application of ADAFs, and ATSAC policy is not to use ADAFs in the adjustment of an ABC, the committee did not recommend the use of this slightly-lower value as the ABC for ethylene oxide.

Conclusion

The ATSAC voted unanimously to recommend the adoption of the value of 0.0003 ug/m^3 as the new ABC for ethylene oxide. This value will be based on the EPA IRIS December 2016 URE value of 3 x 10^{-3} ug/m^3.

Audience comments

The audience was invited to ask questions or provide comments. Bill Gulledge of the American Chemical Council stated that his organization has performed studies of their own, as well as reviewed existing studies related to ethylene oxide toxicity, and he feels that the 2016 EPA number is much too conservative and doesn't reflect realistic exposure and toxicity information. He then went on to mention a couple of papers published by Valdez et al. in 2010 and 2013 which present a critical review of the type of model that the EPA used to generate their 2016 value, and which argue that the results from the EPA model are not accurate. He also explained that the International Agency for Research on Carcinogens had labeled ethylene oxide only as a weak carcinogen, and he believes that the NIOSH study was a weak one technically. He said that EPA used ethylene oxide exposure studies conducted from 1943 into the 1980s, when ethylene oxide concentrations in workplace air were much higher than they are now, and believes this skews EPA's calculations. He will provide DEQ with all of this information and the related papers during the public comment period on the ATSAC rules.

Next steps

Sue MacMillan explained that the public comment period on the Air Toxics Benchmark Review rulemaking would open in mid-July 2017, with DEQ scheduled to address the Oregon Environmental Quality Commission in November 2017 regarding revised rules that will reflect ABC recommendations made by the ATSAC during this current term, which began in December 2014.

With the intent of the meeting completed, the ATSAC webinar ended at approximately 9:45 a.m.