

Peer Review Plan for a Scientific or Technical Work Product

Product Title: Peer review plan for OPPT work plan risk assessment of 1-bromopropane (“1-BP”)

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This plan is for External Review and Public Availability.

The White House Office of Management and Budget (“OMB”) Peer Review Category for the assessment is Influential Scientific Information Product because the U.S. Environmental Protection Agency (hereinafter “EPA” or the “Agency”) reasonably anticipates the information will have or does have a clear and substantial impact on important public policies or private sector decisions.

The Peer Review Category was identified by the Agency according to the EPA Standard Operating Procedures for Peer Review. These are important products which have high programmatic relevance and may be expected to provide complementary support to Agency rule-making, regulatory, or policy decisions. This designation is in accord with OMB’s final guidance issued on December 16th, 2004, on peer reviews of scientific information by federal agencies.

Document Summary

Product Description:

As part of EPA’s continuing comprehensive approach to [enhance the Agency’s existing chemicals management program](#), in March 2012, EPA identified a work plan of over eighty high priority chemicals for further assessment under the [Toxic Substances Control Act \(“TSCA”\)](#). EPA identified seven of these chemicals for risk assessment in 2012. EPA intends to use the [TSCA Work Plan Chemical assessments](#) to help focus and direct the activities of the Existing Chemicals Program over the next several years.

1-Bromopropane (CASRN 106-94-5): 1-Bromopropane or 1-BP is a volatile organic chemical that is considered moderately persistent in the environment but does not have the potential to bioaccumulate in fish or other animals. The majority of the 1-BP production volume (~ 47%) is used as a vapor degreaser for optics electronics, plastics, and metals. 1-BP also is used as an aerosol solvent in cleaning products, as a spray fixative in arts and crafts, and as a spot cleaner in various industrial/commercial/consumer sectors.

Focus of the Risk Assessment: The assessment will focus on uses of 1-BP in commercial (*i.e.*, vapor degreasing, spray adhesives, and dry cleaning) and consumer applications (*i.e.*, aerosol solvent cleaners and spray adhesives). Given the range of endpoints (*i.e.*, cancer, non-cancer; the latter includes potential effects on the developing fetus), susceptible populations are expected to include adults (including pregnant women) in commercial uses and children (as bystanders) and adults of all

ages (including pregnant women) for consumer uses. Thus, the assessment will focus on all humans/lifestages.

Purpose:

EPA anticipates issuing draft risk assessments for public review and comment as they are completed. At the conclusion of the review process, if an assessment of specific uses indicates significant risk, EPA will evaluate and pursue appropriate risk reduction actions, as warranted. If an assessment indicates no significant risk, EPA will conclude its work on the assessment for the specified targeted uses of the chemical. Over time, additional chemicals will be added to the workplan as more data are developed and more chemicals screened.

Intended Audience:

Draft workplan assessments will be released for public comment and peer review. This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency determination or policy.

In addition, this peer review plan should not be interpreted to be a precedent for peer review plans of future workplan assessments. EPA may revisit the process for conducting peer review for workplan chemicals in the future.

Peer Review Plan Includes:

Consultations with EPA staff outside of OPPT includes from the Office of Children’s Health Protection, Office of Air and Radiation. In addition, other Agencies, Occupational Safety and Health Administration (OSHA) and National Institute of Occupational Safety and Health (NIOSH) have been involved in consultations on problem formulation of this work plan assessment.

Several assessments from other governmental agencies were consulted in the preparation of these risk assessments, including:

CARB, 2011. *Development of Updated ARB Solvent Cleaning Emissions Inventories, Final Report; Agreement No. 06-322*. Prepared by: University of California, Riverside, Bourns College of Engineering, Center for Environmental Research and Technology. May, 2011 Available at: <http://www.arb.ca.gov/research/apr/past/06-322.pdf> (Accessed September 3, 2013).

CDC, 2008. Neurological Illness Associated with Occupational Exposure to the Solvent 1-Bromopropane – New Jersey and Pennsylvania, 2007-2008. *Morbidity and Mortality Weekly Report*. 57 (48); 1300-1302. December 5, 2008.

Department of Labor (DOL). 2013 “OSHA and NIOSH issue hazard alert on 1-bromopropane, urge efforts to safeguard workers from exposure to toxic chemical” Available at:

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=24456 (Accessed September 26, 2013).

Eisenber and Ramsey, 2010. Evaluation of 1-Bromopropane Use in Four New Jersey Commercial Dry Cleaning Facilities. Judith Eisenberg, MD, MS and Jessica Ramsey, MS. NIOSH Health Hazard Evaluation Report: HETA # 2008-0175-3111 New Jersey Department of Health and Senior Services. Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2008-0175-3111.pdf> (Accessed July 2010).

EPA. 2013. SNAP Regulations. Available at: <http://www.epa.gov/ozone/snap/regulations.html> (Accessed September 26, 2013).

Harney JM, Hess J, Reh CM, Trout D. 2002. *NIOSH Health Hazard Evaluation Report. STN Cushion Company, Thomasville, NC*. HETA 2000-0410-2891. Cincinnati, OH: National Institute for Occupational Safety and Health. 54 pp. Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2000-0410-2891.pdf>

Harney JM, Nemhauser JB, Reh CM, Trout D. 2003. *NIOSH Health Hazard Evaluation Report. Marx Industries, Inc., Sawmills, NC*. HETA 99-0260-2906. Cincinnati, OH: National Institute for Occupational Safety and Health. 64 pp. Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/1999-0260-2906.pdf> (Accessed September 26, 2013).

National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP). 2003. “NTP-CERHR Monograph on the potential Human Reproductive and Developmental Effects of 1-Bromopropane.” Available at: http://ntp.niehs.nih.gov/ntp/ohat/bromopropanes/1-bromopropane/1BP_monograph.pdf (Accessed August 30, 2013).

NTP, 2011. *NTP Technical Report on the Toxicological and Carcinogenesis Studies of 1-Bromopropane in F344/N Rats and B6C3F1 Mice*. National Toxicological Program. National Institute of Health Public Health Service. NTP TR 564. NIH Publication No. 11-5906. Available at: http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/TR564.pdf (Accessed September 9, 2013).

NTP, 2012. Report on Carcinogens (RoC) Concept: 1-Bromopropane. August 2012. Available at: http://ntp.niehs.nih.gov/NTP/roc/thirteenth/Concepts/1-BP_ConcDocRoC8-30-12_508.pdf (Accessed September 3, 2013).

NTP, 2013. *Revised Draft Report on Carcinogens Monograph for 1-Bromopropane*. National Toxicology Program. U.S. Department of Health and Human Services. January 18, 2013. Available at: http://ntp.niehs.nih.gov/NTP/roc/thirteenth/Monograph_Drafts/RevisedDraftRoC1BP_monograph_508.pdf (Accessed September 4, 2013).

Reh CM, Nemhauser JB. 2001. *NIOSH Health Hazard Evaluation Report. Trilithic, Inc., Indianapolis, Indiana*. HETA 2000-0233-2845. Cincinnati, OH: National Institute for Occupational Safety and

Health. 16 pp. Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2000-0233-2845.pdf>
(Accessed September 6, 2013)

Reh CM, Mortimer V, Nemhauser JB, Trout D. 2002. *NIOSH Health Hazard Evaluation Report. Custom Products, Inc., Mooresville, NC*. HETA 98-0153-2883. Cincinnati, OH: National Institute for Occupational Safety and Health. 46 pp. Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2000-0410-2891.pdf> (Accessed September 5, 2013).

Public Availability and Public Comments Will Include Multiple Opportunities - There will be an opportunity for the public to nominate peer reviewers for the peer review with 30 day public comment period. In addition, the availability of an External Review Draft of this risk assessment will be announced in the Federal Register for public review with a comment period of 60 days. Public comments will be made available for viewing on the Agency's electronic docket system before independent external peer reviewers conduct their review. Oral presentation of public comments will also be allowed at the panel review meetings. Federal register notice of meetings will provide more information about meetings logistics including how to register and provide public comments at meetings

External Review - The Peer Review Mechanism chosen for these workplan assessments is a **panel review**. This peer review is being arranged for this influential work plan assessment based upon need and following the Agency's peer review guidance. The format will include independent expert(s)/ consisting of *ad hoc* panel meetings.

Selection of Peer Reviewers - The independent external peer reviewers will be selected by an independent contractor based upon critical scientific expertise identified by the Agency. The draft panel will be [published in federal register notice for public comment and input received will be considered by contractor and EPA according to Agency peer review guidance. The number of external peer reviewers anticipated for each peer review panel will include between seven and nine independent experts.

Primary Disciplines Needed in the 1-BP Peer Review Panels:

- Toxicology of 1-BP (reproductive and developmental toxicity, neurotoxicity, and carcinogenicity)
- Exposure of volatile organics
- Experts on use of volatiles as vapor degreasers, spray adhesives, and dry cleaning agents in the commercial setting
- Experts on use of volatiles as solvent cleaners and spray adhesives in consumer applications
- Experts on chemical risk assessment
- Experts on environmental release data (*i.e.*, Toxic Release Inventory and the National Emissions Inventory) and associated modeling/interpretation

Information Requested that is Highly Relevant to this Assessment – EPA is requesting the following information from stakeholders and the public to assist with fully understanding specific market segments for 1-BP-containing products containing:

- Weight percent in formulation of 1-BP in consumer spot cleaners
- Market penetration and/or sales volume of consumer spot cleaner products
- Weight percent in formulation of 1-BP in consumer spray adhesives
- Market penetration and/or sales volume of consumer spray adhesives

Anticipated Schedule

Nominations from the public on proposed peer reviewers <i>via</i> Federal Register Notice (“FRN”)	July 2014
External review drafts of risk assessment will be available <i>via</i> FRN for public comment and review	August 2014
Public comments deadline on external review draft as identified in FRN	November 2014
Kick off of peer review of draft risk assessment	November 2014
Anticipated receipt of peer review reports	January 2015
Revise risk assessment in response to peer review	January/March 2015
Anticipated posting of revised, final risk assessment	April/June 2015