

- U.S. EPA (U.S. Environmental Protection Agency). (2001b) Notice of opportunity to provide additional information and comment. FR 66:59593–59594. Available from: <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55868>.
- U.S. EPA (U.S. Environmental Protection Agency). (2002a) Guidelines for ensuring and maximizing the quality, objectivity, utility and integrity for information disseminated by the Environmental Protection Agency. Office of Environmental Information, Washington, DC. EPA/260/R–02/008. Available from: <http://www.epa.gov/oei/qualityguidelines/index.html>.
- U.S. EPA (U.S. Environmental Protection Agency). (2002b) A review of the reference dose and reference concentration process. Risk Assessment Forum, Washington, DC. EPA/630/P–02/002F. Available from: <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55365>.
- U.S. EPA (U.S. Environmental Protection Agency). (2002c) Workshop on the benefits of reductions in exposure to hazardous air pollutants: developing best estimates of dose-response functions. Science Advisory Board, Washington, DC. EPA/SAB–EC/WKSHP/02/001. Available from: <http://www.epa.gov/science1/fiscal02.htm>.
- U.S. EPA (U.S. Environmental Protection Agency). (2002d) Child-specific exposure factors handbook (interim report). EPA/600/P–00/002B. Office of Research and Development, National Center for Environmental Assessment, Washington, DC, 448 pp. Available from: <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55145>.
- U.S. EPA (U.S. Environmental Protection Agency). (2003) A summary of general assessment factors for evaluating the quality of scientific and technical information. Science Policy Council, Washington, DC. EPA 100/B–03/001. Available from: <http://www.epa.gov/osa/spc/htm/assess2.pdf>.
- U.S. EPA (U.S. Environmental Protection Agency). (2004). Final Regulatory Analysis: Control of Emissions from Nonroad Diesel Engines. Prepared by U.S. EPA, Office of Transportation and Air Quality, Washington, DC, May; EPA report no. EPA420–R–04–007. See chapter 9 and Appendix B. Available from: <http://www.epa.gov/nonroad-diesel/2004fr.htm#ria>.
- U.S. EPA (U.S. Environmental Protection Agency). (2005) Supplemental guidance for assessing cancer susceptibility from early-life exposure to carcinogens. Risk Assessment Forum, Washington, DC. Available from: <http://www.epa.gov/ncea/raf>.
- Vainio, H; Magee, P; McGregor, D; *et al.* (1992) Mechanisms of carcinogenesis in risk identification. IARC Sci. Pubs. No. 116. Lyon, France: IARC.
- Van Der Fels-Klerx, IHJ; Goossens, LHJ; Saatkamp, HW; Horst, SHS. (2002) Elicitation of quantitative data from a heterogeneous expert panel: formal process and application in animal health. Risk Anal. 22:67–81.
- Van Sittert, NJ; De Jong, G; Clare, MG; *et al.* (1985) Cytogenetic, immunological, and hematological effects in workers in an ethylene oxide manufacturing plant. Br J Indust Med 42:19–26.
- Vater, ST; McGinnis, PM; Schoeny, RS; *et al.* (1993) Biological considerations for combining carcinogenicity data for quantitative risk assessment. Regul. Toxicol Pharmacol 18:403–418.
- Vesselinovitch, SD; Rao, KVN; Mihailovich, N. (1979) Neoplastic response of mouse tissues during perinatal age periods and its significance in chemical carcinogenesis. NCI Monogr 51:239.
- Vogelstein, B; Fearon, ER; Hamilton, SR; *et al.* (1988) Genetic alterations during colorectal-tumor development. N Eng J Med 319:525–532.
- Walker, KD; MacIntosh, D; Evans, JS. (2001) Use of expert judgment in exposure assessment. Part I. Characterization of personal exposure to benzene. J Exposure Environ Epidemiol 11:308–322.
- Walker, KD; Catalano, P; Hammitt, JK; Evans, JS. (2003) Use of expert judgment in exposure assessment: part 2. Calibration of expert judgments about personal exposures to benzene. J Expo Anal Environ Epidemiol. 13:1–16.
- Waters, MD; Stack, H; F. Jackson, MA. (1999) Short-term tests for defining mutagenic carcinogens. In: McGregor, DB; Rice, JM; Venitt, S, eds. The use of short term tests for carcinogens and data on genetic effects in carcinogenic hazard evaluation. Lyon, France: International Agency for Research on Cancer. IARC Sci. Publ. No. 146, pp.499–536.
- Whitfield, RG; Wallsten, TS. (1989). A risk assessment for selected lead-induced health effects: an example of a general methodology. Risk Anal. 9:197–208.
- Whysner, J; Williams, GM. (1996) Saccharin mechanistic data and risk assessment: urine composition, enhanced cell proliferation, and tumor promotion. Pharmacol Ther 71:225:252.
- Willis, HH; DeKay, ML; Morgan, MG; Florig, HK; Fischbeck, PS. (2004) Ecological risk ranking: development and evaluation of a method for improving public participation in environmental decision making. Risk Anal. 24:363–78.
- Winkler, RL; Wallsten, TS; Whitfield, RG; Richmond, HM; Rosenbaum, AS. (1995). An assessment of the risk of chronic lung injury attributable to long-term ozone exposure. Operations Research 43:19–28.
- Woo, YT; Arcos, JC. (1989) Role of structure-activity relationship analysis in evaluation of pesticides for potential carcinogenicity. In: Ragsdale, NN; Menzer, RE, eds. Carcinogenicity and pesticides: principles, issues, and relationship. ACS Symposium Series No. 414. San Diego: Academic Press; pp. 175–200.
- Yamasaki, H. (1995) Non-genotoxic mechanisms of carcinogenesis: Studies of cell transformation and gap junctional intercellular communication. Toxicol Lett 77:55–61.
- Zeckhauser, RJ; Viscusi, WK. (1990). Risk Within Reason, Science 248:559–564.

Within Reason, Science 248:559–564.

[FR Doc. 05–6642 Filed 4–6–05; 8:45 am]

BILLING CODE 6560–50–C

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7895–1]

Notice of Availability of the Document Entitled Supplemental Guidance for Assessing Susceptibility From Early-Life Exposure to Carcinogens

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of availability of final document.

SUMMARY: This Notice announces the availability of the final document entitled *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, hereafter referred to as Supplemental Guidance.

DATES: The Supplemental Guidance is available for use by EPA risk assessors as of March 29, 2005.

ADDRESSES: The Supplemental Guidance document is available electronically through the EPA Web site at <http://www.epa.gov/cancerguidelines>. A limited number of paper and CDROM copies will be available from the EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: (800) 490–9198 or (513) 489–8190; facsimile: (513) 489–8695. Please provide your name, mailing address, the title and the EPA number of the requested publication (EPA/630/R–03/003F). Additionally, copies of the Supplemental Guidance will be available for inspection at EPA headquarters and regional libraries, through the U.S. Government Depository Library program.

FOR FURTHER INFORMATION CONTACT: Dr. William P. Wood, Risk Assessment Forum, National Center for Environmental Assessment (8601D), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: (202) 564–3361; facsimile: (202) 565–0062; or e-mail: risk.forum@epa.gov.

SUPPLEMENTARY INFORMATION:

Background

In another notice in today's **Federal Register**, EPA has announced the availability of final *Guidelines for Carcinogen Risk Assessment* (EPA/630/P–03/001F), hereafter referred to as the Guidelines. The background and scope of the Guidelines are explained in that notice. The Guidelines explicitly call for

consideration of possible sensitive subpopulations and/or lifestages (such as childhood). The consideration of childhood risks in the final Guidelines has been augmented by the development of the Supplemental Guidance document announced in this Notice. The Supplemental Guidance is issued separately from the Guidelines so that it may be more easily updated in a timely manner given the expected rapid evolution of scientific understanding about the effects of early-life exposures.

A draft of the Supplemental Guidance was subjected to public comment and was peer reviewed by the Agency's Science Advisory Board (SAB) in May 2003. In response to one of the SAB's recommendations EPA developed additional analyses of the available data. This analysis is included in the Supplemental Guidance and has been accepted for publication in the National Institute of Environmental Health Sciences journal, *Environmental Health Perspectives*. A separate peer review of the analysis also was conducted earlier in 2005.

Scope of the Supplement

The Supplemental Guidance recommends consideration of all studies on the effects of early-life exposures. For the common case where there are no

early-life studies on a potential carcinogen, the Guidelines suggest consideration of the carcinogen's mode of action. The Supplemental Guidance addresses a number of issues pertaining to cancer risks associated with early-life exposures generally, but provides specific guidance on suggested actions only for carcinogens acting through a mutagenic mode of action. The Supplemental Guidance addresses carcinogens with a mutagenic mode of action because the currently available early-life studies are generally for carcinogens with a mutagenic mode of action. This Supplemental Guidance recommends for such agents, a default approach using estimates from chronic studies (*i.e.*, cancer slope factors) with appropriate modifications to address the potential for differential risk of early-lifestage exposure. As new research leads to more conclusive evidence, EPA intends to update this Supplemental Guidance to address other modes of action. The Agency expects to produce additional guidance documents for other modes of action, as data from new research and toxicity testing indicate it is warranted. EPA intends to focus its research, and work collaboratively with its federal partners, to improve understanding of the implications of early life exposure to carcinogens.

EPA intends to use, to the extent practicable and consistent with Agency statutes and regulations, the best available science in its risk assessments and regulatory actions, and this Supplemental Guidance is not intended to provide any substantive or procedural obstacle in achieving that goal. Therefore, the Supplemental Guidance has no binding effect on EPA or on any regulated entity. EPA expects its risk assessments to reflect emerging science even if the Supplemental Guidance has not been updated to reflect it. EPA intends to use the approaches in the Supplemental Guidance to develop risk assessments, when EPA has determined the approaches are suitable and appropriate. Thus, EPA is not establishing any substantive, binding "rules" under the Administrative Procedure Act or any other law in publishing this Supplemental Guidance, but is issuing the Supplemental Guidance as a non-binding statement of policy.

Dated: March 29, 2005.

Stephen L. Johnson,

Acting Administrator.

[FR Doc. 05-6641 Filed 4-6-05; 8:45 am]

BILLING CODE 6560-50-P