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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.

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