



March 3, 2003

**FACT SHEET: RELEASE OF EPA'S DRAFT
FINAL CANCER GUIDELINES AND ASSOCIATED
DRAFT SUPPLEMENTAL GUIDANCE FOR PUBLIC
REVIEW AND COMMENT**

ACTIONS: The U.S. Environmental Protection Agency (EPA or Agency) has completed a draft final document entitled, "Guidelines for Carcinogen Risk Assessment," along with an associated draft document entitled "Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens." EPA is soliciting comments from the public on these 2003 drafts during a 60-day comment period. A *Federal Register* notice, published March 3, 2003, announced: 1) the public availability of the draft final document and the start of the comment period; 2) specific issue areas on which EPA would like the public to focus; and 3) the availability of the draft supplemental guidance document for public review and comment. The *Federal Register* notice also included information on how and where to submit comments.

SUMMARY: EPA publishes, and periodically updates/revises, a series of guidelines whose purpose is to assist risk assessors both within EPA and outside in evaluating the risks of environmental hazards. The guidelines were developed to promote high technical quality and Agency-wide consistency in the human health risk assessment process. One of these documents specifically addresses the assessment of cancer risks. EPA is nearing completion of its revision of the 1986 *Guidelines for Carcinogen Risk Assessment*. The Agency began the revision of the 1986 guidelines in light of significant scientific advances in our understanding of the processes of carcinogenesis and the modes of actions of disease at the cellular level. The revision of these guidelines is in keeping with the Agency's original intent when it issued the first risk assessment guidelines in 1986. The guidelines were meant to be dynamic, flexible documents that would evolve to reflect the current state of the science and risk assessment practices.

EPA has issued a *Federal Register* notice announcing the public availability of the 2003 draft final *Guidelines for Carcinogen Risk Assessment* and the start of a 60-day public comment period. Because this current draft has already benefitted from extensive public comment and multiple rounds of expert scientific review by EPA's Science Advisory Board, the Agency is requesting that public comments focus on discussions of specific science issues that are substantively revised or newly addressed since the publication of the 1999 revised draft cancer guidelines. These science issues include: the nature and use of default options; definition and application of hazard descriptors; identification of carcinogenic mode(s) of action; and the default low-dose extrapolation approach for non-linear carcinogens. After receipt of public comments, the Agency will address those comments in its final revised *Guidelines for Carcinogen Risk Assessment*.

In addition, the *Federal Register* notice requests public comment on a draft supplemental guidance document entitled, "Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens." This draft supplemental guidance will be reviewed by EPA's Science Advisory Board. The draft document focuses on assessing the effects of early life stage exposure and includes a review of existing scientific literature on chemical effects in animals and humans, as well as human exposure to ionizing radiation. Because the areas of carcinogenicity, genesis of disease, and effects on susceptible life stages and populations are constantly and quickly evolving, the EPA expects that this will be the first of several supplemental guidance documents to the *Guidelines for Carcinogen Risk Assessment*. These companion documents will

provide additional information on how to address specific aspects of cancer risk assessment. To enhance Agency's understanding of age-related cancer susceptibility, EPA's Office of Research and Development is expanding its research through an initiative that focuses on exploring appropriate measures of dose, response characteristics, and exposure variables that may be affected by age. This research will be done through a combination of studies in EPA laboratories, the Agency's Science to Achieve Results (STAR) grants program, and collaborations with other federal agencies.

BACKGROUND: On September 24, 1986, EPA issued risk assessment guidelines relating to five areas: carcinogenicity, mutagenicity, chemical mixtures, developmental toxicants, and estimating exposures (<http://www.epa.gov/ncea/raf/rafguid.htm>). Since 1986, EPA has applied the Guidelines for Carcinogen Risk Assessment to hundreds of environmental agents. The results of many of these cancer hazard and dose-response assessments can be found on the Agency's Integrated Risk Information System (IRIS) database (<http://www.epa.gov/iris/>). Other assessments are maintained separately within individual EPA programs (e.g., certain pesticides). Information contained in IRIS and the other assessments is used to support Agency decisions.

DOCUMENT AVAILABILITY:

Draft Final Guidelines for Carcinogen Risk Assessment: The primary method for document availability is via the Internet at <http://www.epa.gov/ncea/raf/cancer2003.htm>. A limited number of paper copies are available from: Technical Information Staff (8623D), U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, 1200 Pennsylvania Avenue NW, Washington, DC 20460; Telephone: 202-564-3261; Facsimile: 202-565-0050; Email: nceadc.comment@epa.gov.

Draft Supplemental Guidance Document: The primary method for document availability is via the Internet at <http://epa.gov/ncea/raf/cancer2003.htm>. A limited number of paper copies are available from: Technical Information Staff (8623D), U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, 1200 Pennsylvania Avenue NW, Washington, DC 20460; Telephone: 202-564-3261; Facsimile: 202-565-0050; Email: nceadc.comment@epa.gov.

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