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Subject: EPA Cancer Risk Assessment Guidelines Released

*U.S. Environmental Protection Agency (EPA) News for release March 29, 2005: EPA Issues "**Guidelines for Carcinogen Risk Assessment**" and **Supplemental Guidance on Risks From Early-Life Exposure**.*

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(Washington, D.C.-March 29, 2005) Two documents released today provide principles and procedures to guide EPA scientists assessing cancer risk from exposures to environmental pollutants. The documents, "Guidelines for Carcinogen Risk Assessment (**Cancer Guidelines**)," and "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (**Supplemental Guidance**)" reflect EPA's evolving approach to cancer risk assessment. The guidelines are prospective only and **will apply to the agency's current and future risk assessments of environmental pollutants.**

"These guidelines will help us apply the most up-to-date science and to incorporate new science as it becomes available in assessing the risks associated with environmental exposures to carcinogens," said Acting Assistant Administrator for the Office of Research and Development Tim Oppelt. "EPA's guiding principle is that our cancer risk assessments be public health protective."

The new cancer guidelines result from significant strides in scientific knowledge, and in EPA's 20-plus years of experience in applying risk assessment principles and practices. The cancer guidelines were last revised in 1986. The cancer guidelines issued today set forth a revised set of recommended principles and procedures to guide EPA scientists and others in assessing the cancer risks resulting from exposure to chemicals or other agents in the environment. The guidelines are also used to inform agency decision makers and the public about risk assessment procedures.

The additional Supplemental Guidance describes possible approaches that EPA could use in assessing cancer risks exposures to children from 0 to 16 years of age. This marks the first time that Supplemental Guidance specifically related to children has been issued. It includes a review of existing scientific literature on chemical effects in animals and humans. The Supplemental Guidance also summarizes the results of the cancer studies that investigated early-life exposure, EPA's analysis of those studies, and analysis to strengthen the scientific basis for adjusting from studies conducted in adults to children. This document is consistent with the National Research Council's 1994 recommendation that "EPA assess risks to infants and children whenever it appears that their risks might be greater than those of adults."

The draft cancer guidelines and draft Supplemental Guidance were announced in the Federal Register on March 3, 2003. Both documents issued as final today have undergone extensive public comment and independent scientific peer review. Both documents and additional information are available at: <http://www.epa.gov/cancerguidelines>.

Background: There is record of 5 sets of guidance (1976, 1986, 1996, 1999, and 2005) for risk assessment of carcinogenic potential. The most recently applied EPA guidance for carcinogenicity classification is presented in the July 1999 "Review Draft of the Guidelines for Carcinogen Risk Assessment". DRAFT NCEA-F-0644. See http://www.epa.gov/ncea/raf/pdfs/cancer_gls.pdf. These Draft Final Guidelines were released for public comment in March 2003, and used as the basis for the Final Guidelines.

Specifically, on March 29, 2005, EPA issued "**Final Guidelines for Carcinogen Risk Assessment**", replacing the 1986 cancer risk assessment guidelines. These guidelines specify that conclusions must include a weight-of-evidence descriptor as follows:

1. ***Carcinogenic to humans***
1. ***Likely to be carcinogenic to humans***
2. ***Suggestive evidence of carcinogenic potential***
3. ***Inadequate information to assess carcinogenic potential***
4. ***Not likely to be carcinogenic to humans***

Resources:

1. August 17, 2004 posting to NJinPAS website. 'Chemicals Evaluated for Carcinogenic Potential' list @ <http://www.pestmanagement.rutgers.edu/NJinPAS/postings/EPAcancerevalchem704.pdf>. This document provides a list of carcinogens current to July 2004. The risk assessment model used at the time the specific chemicals were assessed is listed.
2. August 17, 2004 posting to NJinPAS Listserv. EPA has released 'Chemicals Evaluated for Carcinogenic Potential'. <http://www.pestmanagement.rutgers.edu/NJinPAS/postings/704carcList.pdf>. Narrative explaining the list above.
3. "Final Guidelines for Carcinogen Risk Assessment". http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=439345 (PDF, 166 pp, 462 KB)
4. "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens" http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=439346

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