

Reevaluating Cancer Assessments

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SUPPLEMENTARY INFORMATION: Under §§ 280.20 and 280.22 of the Code of Federal Regulations, facilities may petition the Agency to remove their wastes from the hazardous waste management system by excluding them from the lists of hazardous wastes contained in §§ 261.31 and 261.32. Petitioners must provide sufficient information to EPA to allow the Agency to determine that the waste to be excluded does not meet any of the criteria under which the waste was listed as a hazardous waste. In addition, the Administrator must determine that factors other than those for which the waste was listed (including additional constituents) would not warrant retaining the waste as a hazardous waste. The overall intent of the delisting process is to ease the regulatory burden on handlers of listed wastes that may have been improperly captured by the broad listing definitions. In addition, the delisting process can be used to exclude listed wastes that are sufficiently treated so that they no longer pose an adverse threat to human health or the environment.

On October 10, 1993, the Administrator formally extended the delegation of the Federal hazardous waste delisting authority to the Regional Administrators (Delegation of Authority 8-19). The Agency believes that decentralizing the delisting authority to the Regional Administrators would result in more timely responses to delisting petitions.

Under RCRA, States authorized to administer a delisting program in lieu of the federal program also may exclude wastes from hazardous waste regulations. Facilities that manage their wastes in States with delisting authorization should petition that State for an exclusion rather than EPA. Even in unauthorized States, EPA encourages petitioners to contact State authorities to determine what procedures might be necessary for delisting under State laws.

Regional delisting decisions will carry the same authority as a Headquarters delisting decision. A Regional delisting decision will be applicable in all States not currently authorized for delisting, regardless of the EPA Region in which they are located. EPA recommends that petitioners contact relevant state and

EPA Regional Offices to determine where the petition should be submitted. The list of Regional delisting contacts is provided below:

Regional Delisting Contacts

EPA Region I, Sharon Leitch, John F. Kennedy Bldg., Mail Code CHW, Hazardous Waste Unit, Boston, MA 02203, (617) 565-4879.

EPA Region II, Ernst Jabouin, 290 Broadway, Hazardous Waste Facilities Branch (22nd Floor), New York, NY 10007, (212) 637-4104.

EPA Region III, David Friedman, 841 Chestnut Building, Hazardous Waste Management Division, Mail Code 3HW70, Philadelphia, PA 19107, (215) 566-3595.

EPA Region IV, Alan Farmer, 348 Courtland Street, NE, RCRA Branch, Mail Code 4WQ-RCRA, Atlanta, GA 30385, (404) 317-3473.

EPA Region V, Judy Kleiman, 77 West Jackson Blvd., Waste, Pesticides, and Toxics Division, Mail Code HRP-8J, Chicago, IL 60604, (312) 588-1482.

EPA Region VI, Bill Gallagher, 1445 Ross Avenue, Oklahoma/Texas Section, Mail STOP 6PD-6, Dallas, TX 75202, (214) 885-8775.

EPA Region VII, Ken Herstowski, 726 Minnesota Avenue, Air, RCRA, and Toxic Division, RCRA Permits and Compliance Branch, Kansas City, KS 66101, (913) 551-7837.

EPA Region VIII, Mike Ganasick, 999 18th Street, Hazardous Waste Program, Suite #500, Mail Code 8PZ-HW, Denver, CO 80202, (303) 312-6150.

EPA Region IX, Paula Bisson, 78 Hawthorne Street, RCRA Permit Section, Mail Code H-3-2, San Francisco, CA 94105, (415) 744-2052.

EPA Region X, Jamie Sikorski, Linda Liu, 1200 Sixth Avenue, Office of Waste and Chemical Management, Mail Code WCM-128, Seattle, WA 98101, (206) 553-6153 (Sikorski), (206) 553-1447 (Liu).

Dated: June 10, 1996.

Michael Shapiro,

Director, Office of Solid Waste.

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MAILING CODE 688-00-0

[FRL-5526-6]

Proposed Process for Reevaluating Cancer Assessments

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

ACTION: Notice.

SUMMARY: On April 23, 1996, EPA issued a proposal to revise its 1986

Guidelines for Cancer Risk Assessment (61 FR 17980). Today, EPA is proposing a process for using the new guidelines to reevaluate cancer hazard and dose-response assessments developed using the 1986 guidelines.

EPA is inviting public comment on its proposal to identify, prioritize and select agents for reevaluation. This proposal outlines opportunities for public involvement in the reevaluation process, and requests comment on the proposed process. The new process would take effect when the Proposed Guidelines are issued as final.

In addition, this notice also discusses the use of the Proposed Guidelines in ongoing or new cancer assessments.

DATES: Comments on this proposal must be submitted on or before September 23, 1996.

ADDRESSES: This notice contains the full proposed process for reevaluating cancer assessments.

Submitting Comments: Comments on the proposed process should be submitted to: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (8102), Attn: File CAN-96-01, Waterside Mall, 401 M St. SW, Washington, DC 20460. Please submit one unbound original with pages numbered consecutively, and three copies. For attachments, provide an index, number pages consecutively, provide comment on how the attachments relate to the main comment(s), and submit an unbound original and three copies. Please identify all comments and attachments with the file number CAN-96-01. Mailed comments must be postmarked by the date indicated. Comments may be also submitted electronically by sending electronic mail (e-mail) to: A-and-R-Docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments in electronic form must also be identified by the file number CAN-96-01. No Confidential Business Information (CBI) should be submitted through e-mail.

The docket and information center is open for public inspection and copying between 8:00 a.m. and 5:30 p.m., weekdays, at the Air and Radiation Docket and Information Center (8102), Room M-1500, 401 M St. SW, Washington, DC 20460. The docket and information center is located on the ground floor of Waterside Mall. The file index, materials and comments are available for review in the information

The following 18 States are authorized to implement the RCRA delisting program, including Alabama, Colorado, Georgia, Idaho, Illinois, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Nebraska, North Carolina, New Jersey, North Dakota, Oregon, South Dakota, Utah, and Wyoming. Note that Michigan has only obtained a "partial" delisting authorization for wastes involving closure or partial closure activities. Kentucky would soon receive delisting authorization (61 FR 18504).

center, or copies may be mailed on request from the Air and Radiation Docket and Information Center by calling (202) 260-7548 or -7549. The FAX number for the Center is (202) 260-4400. A reasonable fee may be charged for copying information materials.

Please note that all technical comments received in response to this notice will be placed in the public record. For that reason, commentors should not submit personal information such as medical data or home addresses, confidential business information or information protected by copyright. Due to limited resources, acknowledgments will not be sent.

Requesting Copies of Proposed Guidelines

To obtain a copy of the Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17860), interested parties should consult the April 23 Federal Register notice or contact ORD Publications, Technology Transfer and Support Division, National Risk Management Research Laboratory, U.S. Environmental Protection Agency, 26 W. Martin Luther King Drive, Cincinnati, OH 45268; telephone: 513-568-7568. Please provide your name, mailing address, document title (Proposed Guidelines for Carcinogen Risk Assessment), and EPA number (EPA/600/P-92/003C).

FOR FURTHER INFORMATION ON TODAY'S NOTICE CONTACT: Jennifer Orme-Zavaleta, Office of Water, Telephone Number (202) 260-7577.

Proposed Implementation Strategy for Reevaluating Existing Assessments Using the Final Revised Guidelines

Background

EPA has applied the 1988 Guidelines for Carcinogen Risk Assessment to hundreds of environmental agents. The results of many of these cancer hazard and dose-response assessments (hereafter referred to as assessments) can be found on EPA's Agency-wide Integrated Risk Information System (IRIS) database. Other assessments are maintained separately within individual EPA programs (e.g., certain pesticides). Information on IRIS and the other assessments are used as guidance to support Agency decisions.

Once the Proposed Guidelines are finalized, EPA will continue to rely on existing assessments as they are still viewed as scientifically acceptable based on the 1988 Guidelines. However, EPA recognizes that under some circumstances, it will be appropriate to reassess an existing assessment taking into account new risk assessment

methods, principles and data. As EPA's current compendium of cancer assessments is the product of many years of analysis, it is reasonable to assume that revisiting all existing assessments could require comparable amounts of time and resources. Therefore, it would not be practicable to reassess all these existing assessments and balance our commitment to assess new agents as well. Given these circumstances, EPA is proposing a process for applying the revised Cancer Guidelines that moves the Agency forward with new assessments, while also addressing reassessments of some environmental agents.

Proposed Reassessment Process

EPA proposes the following process to involve the public in the identification, prioritization and selection of candidate environmental agents for reevaluation. The intent is to ensure that agents that warrant reevaluation are given the highest priority.

EPA envisions the following process:

- (1) EPA publishes an annual notice in the Federal Register requesting candidates for reevaluation.
- (2) Candidates are submitted.
- (3) Candidates are reviewed and prioritized within the Agency.
- (4) Candidates selected are published in a Federal Register notice. Submitters are notified on the status of their submission.
- (5) Reassessment is initiated in the next fiscal year. The reassessment is reviewed in accordance with EPA's Peer Review Policy and placed on IRIS.

In selecting candidates for reevaluation, EPA will consider the following:

- (1) whether application of the new guidelines will appreciably change the existing cancer assessment;
- (2) completeness and validity of the scientific information;
- (3) EPA priorities;
- (4) Resources.

Discussion

On an annual basis, EPA will publish in the Federal Register a list of agents for which EPA plans to initiate cancer hazard and dose response assessments in the following year. A rationale will be given. This list may include reassessments as well as new assessments to meet Agency needs, focusing on evidence that application of the new guidelines is expected to change the assessment.

Call for Candidates and Screening Criteria

In addition, the above notice will ask the public for candidates for

reassessment. For all nominations, EPA will ask the public to provide evidence that application of the revised guidelines is likely to appreciably change the existing cancer assessment. This requirement represents the criterion that the Agency will use to screen candidates for reassessment. Along with this nomination, EPA will encourage the public to propose a revised cancer assessment which applies the revised guidelines; this could greatly facilitate the review for selection. If an interested party is not able to provide a revised assessment, then the nomination should be accompanied by a justification explaining the importance of reassessing that agent. Candidates for reassessment will be accepted during a 90-day period.

Prioritization and Peer Review

An Agency screening team will review all nominations. The team will first determine if the above criterion is met. Then, the screening team will prioritize the submissions based on completeness and quality of the supporting information and consistency with Agency priorities. It is the intent of the Agency to involve peer review of the scientific validity and relative ranking of the candidates proposed for reassessment. The peer review can assist EPA in the final prioritization of requests for reevaluation. A number of peer review mechanisms can be used, including the Science Advisory Board, an annually constituted expert panel specifically charged with reviewing the ranking of chemicals, targeted mail reviews to expert independent reviewers, or other peer review mechanisms.

(c) Completeness and scientific validity of the supporting information. The screening team will consider the extent to which a request for reevaluation is supported by a complete reassessment or justification. A complete, high-quality reassessment should address all the principles of the new Guidelines.

EPA expects that commentors may be interested in submitting candidates based on minor changes, e.g., change in interspecies scaling factor. Revising risk assessments based on minor changes may or may not be consistent with Agency priorities. Thus, commentors are encouraged to apply all elements of the Guidelines in their supporting materials.

(b) Agency priorities. Following review of the screening criterion and supporting scientific information, the Agency screening team will weigh the list of candidates according to the following Agency priorities:

Degree of public health protection.
Protecting the maximum number of people including sensitive subgroups.
Addressing the public interest.
Addressing multimedia exposure.
Addressing agents where there is scientific controversy.
Addressing the potential to change a regulation.

Prioritization of candidates will be case-by-case depending on issues identified above. The screening team may give higher priority to those agents for which public health protection is of concern to ensure that those agents with the potentially highest risk are addressed first. Other factors such as potential for widespread exposure, particularly to sensitive members of the population, may also place an agent higher on the list.

Selection and Notification

Once the candidate list has been prioritized, the Agency will evaluate the availability of resources for final selection of candidates for reassessment. The Agency must balance resource needs for new assessments as well as reassessments in making this decision. Resources include the availability of staff time as well as resources for conducting peer reviews.

In the fourth quarter of each fiscal year, EPA will publish in the Federal Register a list of agents that have been selected for reevaluation. Those who submitted comments will be notified in writing. If a chemical is not selected for reassessment in the upcoming cycle, EPA will explain its reasons for not including the requester's candidate and invite the requester to resubmit its request during the next cycle (with any updated supporting information, if desired or necessary). A decision to not include a chemical in any given cycle does not mean that the Agency does not consider reassessment of the chemical to be appropriate; and it certainly does not mean that the Agency will not reassess the chemical in some later cycle. The decision merely means that given Agency resources for the performance of reassessments in the upcoming cycle and the other candidates presented, the Agency will not be able to reassess the requester's candidate in the next cycle. For purposes of judicial review, the Agency does not consider this prioritization decision to be a final Agency action on a request to reassess a chemical.

Once an assessment (including reevaluations) has been completed by EPA, it will undergo peer review in accordance with the Agency's Peer Review Policy. Consistent with previous practices for conducting assessments,

EPA may also consult with other Federal agencies. The final reassessment, reflecting Agency consensus and peer review, will be summarized in IRIS.

The Office of Pesticide Programs is conducting new or updated cancer assessments on certain pesticides according to timetables established for its reregistration, registration and special review programs. A list of potential candidate chemicals to be evaluated in reregistration during FY97 was published for comment in the Federal Register on May 15, 1996. The comment period for that notice ends July 15, 1996. Therefore, requests to reevaluate previous assessments associated with the listed pesticides are not necessary under the process outlined above.

Issues for Comment

EPA requests comments on the proposed process for reevaluating existing cancer hazard and dose response assessments. Specifically, EPA seeks public opinion on four topics:

- (1) The screening criterion.
- (2) The relative importance of the different prioritization factors in determining where an agent falls on the list. Other factors that can usefully be considered:
- (3) The utility and appropriateness of the peer review mechanism(s) suggested for peer review of the ranking of chemicals for reevaluation. Please note that peer review of each completed EPA assessment (both new and reevaluated) will proceed as outlined above.
- (4) Other relevant issues pertaining to this proposed process.

Interim Use of the Proposed Guidelines Pending Finalization in New Assessments

EPA will continue in most circumstances to rely on the assessment information currently available on IRIS as guidance for use in regulatory and non-regulatory decisions. Existing assessments which applied the 1988 Guidelines continue to be scientifically acceptable.

At the same time, the Agency's 1988 Guidelines for Carcinogen Risk Assessment provide for use of data on mode(s)/mechanism(s) of action and biologically-based models whenever such information is available. The 1988 Guidelines state that they are intended to accommodate new knowledge and methods regarding cancer assessment as they emerge. Accordingly, EPA has used new approaches to cancer assessment for agents (such as in EPA's pending reevaluation of dioxin risks) when there

has been sufficient scientific foundation to support the new approaches.

Thus, pending publication of the final revised guidelines and in keeping with advancing knowledge on cancer assessment, the principles and approaches of the Proposed Guidelines will be applied in part or in whole, on a case-by-case basis for new assessments as data warrant. Such use of the Proposed Guidelines will allow EPA to gain more experience before they are finalized. The assessment will state the rationale for applying the Proposed Guidelines. When the Guidelines are adopted by the Agency as final, they will provide guidance for all new cancer hazard and dose-response assessments. EPA will continue to use appropriate peer review processes during this time.

In summary, EPA recognizes the possible need to reevaluate cancer assessments developed using the 1988 Guidelines for Carcinogen Risk Assessment. In addition, EPA must also address new chemicals to meet Agency priorities. Thus, EPA is proposing a process that will enable it to move forward in conducting new assessments while also reevaluating existing assessments using the new guidelines.

Dated: June 17, 1996.

Henry L. Langston,
Acting Assistant Administrator for Research and Development.
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FEDERAL COMMUNICATIONS COMMISSION

FCC To Hold Open Commission Meeting-Thursday, June 27, 1996

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, June 27, 1996, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, NW., Washington, DC.

Item No., Bureau, Subject

- 1-Wireless Telecommunications—
Title: Amendment of the Commission's Rules to Permit Flexible Service Offerings in the Commercial Mobile Radio Services, WT Docket No. 96-8). Summary: The Commission will consider action to allow commercial mobile radio service providers more flexibility to provide fixed wireless services.
- 2-Wireless Telecommunications—
Title: Interconnection and Resale Obligations Pertaining to Commercial