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THE NEED FOR A RCRA SCIENCE ADVISORY COMMITTEE

To achieve the goal of improving the scientific and technical bases for RCRA regulatory decision-making, the Congress should establish a new scientific advisory committee to provide EPA with sound scientific advice in connection with its identification and regulation of hazardous wastes. The need for unbiased, independent scientific advice is particularly acute in the case of determinations to restrict or ban the land disposal of certain wastes because of the significant consequences of such determinations.

Obtaining independent scientific review of the scientific data underlying regulatory decisions is consistent with and would implement the recent recommendations of the Committee on the Institutional Means for Assessment of Risks to Public Health of the National Academy of Sciences ("NAS") in a report entitled "Risk Assessment in the Federal Government: Managing the Process" (March 1983) and of the Administrative Conference of the United States in "Federal Regulation of Cancer-Causing Chemicals" (June 1982). Establishment of a scientific advisory committee under RCRA also would be consistent with the Congress' creation of scientific advisory panels under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136w(d), and the Consumer Product Safety Act, 15 U.S.C. § 2077.

The NAS Report

The NAS Report stresses the importance of a sound science base for regulatory decisions. Key considerations for achieving that objective are:

- maintenance of a clear conceptual distinction between the scientific assessment of risks and regulatory evaluation of alternatives of risk management;
- preparation of risk assessments providing a scientific review of all scientific data, including health data and exposure data; and
- early review by independent scientific panels of the adequacy of the data base and the validity of the scientific evaluation.

The NAS Report recommends the creation of independent science panels in regulatory agencies to provide peer review of risk assessments. It states, "Agencies and programs with mandated peer review panels . . . produce final risk assessments

in support of regulatory decisions that are generally of high scientific quality and are accepted by the public and the regulated parties." NAS Report at 144. The report goes on to say that "[c]ontinuity and independence of review panels help to ensure that such panels are sensitive to regulatory needs while retaining the necessary scientific objectivity." Id. at 145. The report stresses the need for early involvement of the advisory panels in the regulatory process and recommends rotation of members for staggered, fixed terms to reduce the development of an institutional bias.

Recommendation of the Administrative Conference

The Administrative Conference of the United States ("ACUS") has also supported the need for peer review of the scientific basis of regulatory decisions. As it has stated, "Peer review of experimental findings and scientific judgments is an important means of validating the technical bases of regulatory decisions concerning carcinogens." Administrative Conference of the United States, Recommendation 82-5, "Federal Regulation of Cancer-Causing Chemicals," 47 Fed. Reg. 30701, 30712 (July 15, 1982). The ACUS has recommended that "[t]o the extent compatible with existing law, agencies should structure their decisional processes to incorporate mechanisms for scientific peer review." Id. The use of advisory panels is recommended by the Administrative Conference as one means of obtaining peer review, since

[a]dvisory panels can contribute objectivity as well as expertise to agency decisions. Their advice has sometimes prevented erroneous regulatory actions; more frequently, their role has been to illuminate complex issues and enhance the quality and thus the credibility of agency scientific analysis.
(Id.)

THE PROPOSAL FOR A RCRA SCIENCE ADVISORY COMMITTEE

Functions of the Science Panel

The proposed science advisory panel would be located within EPA and would be called the Resource, Conservation and Recovery Act Science Advisory Committee ("RCRASAC"). The functions of RCRASAC would be to evaluate all scientific data and risk assessments relating to the health and environmental impacts of hazardous wastes which form the basis for:

- the criteria for identifying hazardous wastes under Sec. 3001(a);
- the criteria for listing hazardous wastes that are subject to regulation under Sec. 3001(a);
- the identification of characteristics of hazardous wastes under Sec. 3001(b); and
- the listing of a waste as hazardous under Sec. 3001(b).
- proposed standards for generators under Sec. 3002;
- proposed standards for transporters under Sec. 3003; and
- proposed standards for owners and operators of hazardous waste facilities under Sec. 3004, including proposals to restrict or ban the land disposal of specified wastes by one or more means of land disposal.

The Evaluation Process

The Administrator of EPA would submit to RCRASAC for its evaluation all scientific data and risk assessments for substances the Administrator plans to add to the list of hazardous substances or which the Administrator has determined should be prohibited from being disposed of on land by one or more means of land disposal. The Administrator would also submit to RCRASAC all scientific data relating to any proposed criteria for the identification of characteristics of hazardous wastes, any proposed criteria for the listing of hazardous wastes, any proposed identification of the characteristics of hazardous wastes, and any proposed standard for generators, transporters or hazardous waste facility owners or operators. This referral would occur as early as possible in the regulatory process prior to publishing any proposed regulation standards or criteria relating to RCRASAC's functions. The Chairman of RCRASAC would publish in the Federal Register within ten days of such referral a notice of the referral and an invitation for public scientific input into the evaluation process.

RCRASAC would review the relevant scientific data referred to it on an expedited basis and would submit to the

Administrator a written scientific evaluation and a discussion of the latest available science. Such evaluations would have to be performed within 120 days of the submission of the Agency's risk assessment to the Committee. The proposal thus ensures that review by the Committee will be expeditious and not delay the regulatory process.

RCRASAC would be authorized to create subpanels composed of both committee members and outside experts, to evaluate any scientific matter referred to RCRASAC. The Committee also would be authorized to use contractors as needed to aid in the performance of its duties.

The evaluation made by RCRASAC would be advisory in nature; however, if at any point in the rulemaking process the Administrator departs from the scientific evaluations of RCRASAC, the Administrator would be required to publish an explanation of reasons for such departure at the same time the Administrator publishes the rulemaking relating to the evaluation.

It is important that referrals be made and scientific advice be provided early in the decisional process. Such advice can expedite decision-making by providing EPA with a sound scientific basis for establishing priorities and proceeding with the identification and regulation of wastes which constitute significant health hazards. One example of how a science panel can operate efficiently and effectively is the EPA's Scientific Advisory Panel, which the NAS Report praises. "The participation of the Panel probably has improved the quality of EPA analyses and added to their credibility among both environmental and industrial groups." NAS Report at 128.

Membership of the Panel

RCRASAC would be composed of twelve members appointed for staggered four-year terms by the EPA Administrator from a list of scientists nominated by the National Academy of Sciences. The NAS would solicit nominees from organizations of professional scientists, faculties of colleges and universities, heads of Federal and state agencies, and distinguished members of the scientific community. The selection of members of RCRASAC would be based solely on their scientific expertise. Members would also be subject to conflicts of interest regulations promulgated by the Administrator and penalties for unauthorized disclosure of confidential information.

Conclusion

AIHC urges that the recommendations of the National Academy of Sciences and the Administrative Conference of the

Senator John H. Chafee

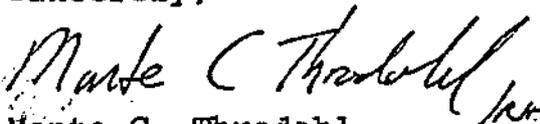
June 15, 1983

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United States be implemented by amending RCRA to provide a panel of individual scientists to evaluate the scientific data and risk assessment underlying EPA's regulation of hazardous wastes.

As noted above, proposed amendments to accomplish these results are attached. We would be pleased to supply any additional information desired by the Committee.

Sincerely,



Monte C. Throdahl
Chairman, Science Policy
Task Force

cc: Josephine S. Cooper
Professional Staff Member

The Solid Waste Disposal Act
Amendments to Establish a
RCRA Science Advisory Committee

Subtitle C of The Solid Waste Disposal Act, as amended, is further amended by inserting after Section 3013 the following new section:

"RESOURCE CONSERVATION AND RECOVERY ACT SCIENCE
ADVISORY COMMITTEE

"SEC. 3014.(a)(1) There is established a Resource Conservation and Recovery Act Science Advisory Committee, which shall evaluate risk assessments and scientific data referred to it by the Administrator pursuant to subsection (b).

"(b) The Administrator shall submit to the Committee for evaluation as to the impact on human health and the environment risk assessments and scientific data which in the opinion of the Administrator involve a significant science issue and which underlie --

"(1) any proposed criteria for identifying hazardous waste under Section 3001(a) of this Act;

"(2) any proposed criteria for listing hazardous wastes that are subject to regulation under Section 3001(a) of this Act;

"(3) any proposed identification of characteristics of hazardous waste under Section 3001(b) of this Act;

"(4) any proposed listing of a waste as hazardous under Section 3001(b) of this Act;

"(5) any proposed standard for generators of hazardous waste under Section 3002 of this Act;

"(6) any proposed standard for transporters of hazardous waste under Section 3003 of this Act; and

"(7) any proposed standard for owners and operators of hazardous waste facilities under Section 3004 of this Act, including any proposed regulation prohibiting one or more methods of land disposal of specified hazardous wastes.

"(c) The Administrator shall refer all risk assessments and relevant scientific data to the Committee in sufficient time to permit appropriate, expeditious review prior to the publication of any such proposed regulation, standard, or criteria.

"(d) Within ten days after receipt of a risk assessment referred to the Committee pursuant to subsection (b) the Chairman of the Committee shall publish a notice of such referral and an invitation for public scientific input to the evaluation process.

"(e)(1) The Committee shall review all scientific evidence which the Committee believes is relevant to a risk assessment referred to the Committee pursuant to subsection (b) and shall submit a written scientific evaluation of the risk assessment to the Administrator as expeditiously as reasonably feasible but no later than one hundred and twenty days after receipt of the risk assessment.

"(2) The Committee shall include in its written evaluation the specific findings of the Committee and a discussion of the basis for its findings, including any relevant scientific developments.

"(3)(a) The evaluation of the Committee shall be advisory in nature but no final regulation based on a risk assessment required to be submitted to the Committee for evaluation by subsection (b) shall be issued until the Administrator has received the Committee's evaluation or the time period provided for such evaluation in subsection (e)(1) has expired, unless the Administrator finds that regulatory action is required prior to receiving the Committee's evaluation to respond to an imminent hazard.

"(b) If at any point in the rulemaking process the Administrator departs from the scientific evaluations of the Committee, the Administrator shall publish an explanation of reasons for such departure at the same time the Administrator publishes the rulemaking relating to the evaluation.

"(f)(1) The Committee shall be composed of twelve members who shall be appointed by the Administrator in accordance with paragraphs (2) and (3).

"(2) Each member appointed to the Committee shall be qualified and distinguished by education, training and experience to assess and evaluate scientific and technical information relating to criteria, standards and regulations under Subtitle C of the Act.

"(3) The Administrator shall make the appointments from sufficient nominations selected by the National Academy of Sciences to provide a reasonable choice by the Administrator. The nominations shall be selected from among individuals who meet the requirements specified in paragraph (2). The National Academy of Sciences shall solicit recommendations by organizations of professional scientists, faculties of colleges and universities, heads of Federal and state agencies, and distinguished members of the scientific community.

"(g)(1) Except as provided in paragraph (2), each member of the Committee shall be appointed for a term of four years.

"(2) Of the members first appointed to the Committee, three members shall be appointed for a term of one year, three members shall be appointed for a term of two years, and three members shall be appointed for a term of three years.

"(h)(1) A vacancy on the Committee shall be filled in the manner of the original appointment.

"(2) Any member appointed to fill a vacancy occurring before the expiration of the term for which the predecessor was appointed shall be appointed for the remainder of such term.

"(i) Members of the Committee may be reappointed to serve an unlimited number of terms.

"(j) The Administrator shall appoint a Chairman each year from among the members of the Committee.

"(k) Seven members of the Committee shall constitute a quorum, and official actions of the Committee shall be taken only on the affirmative vote of at least seven members.

"(1)(1) The Committee is authorized to establish subpanels to review any risk assessment referred to the Committee under subsection (b).

"(2) Each risk assessment referred to the Committee for its consideration in accordance with subsection (b) may be referred by the Chairman to one or more subpanels, as the Chairman deems appropriate.

"(3) Each subpanel shall be composed of at least six members who are appointed by the Chairman of the Committee.

"(a) Each subpanel shall consist of --

"(i) at least two members of the Committee, and

"(ii) non-Committee scientists who are experts in the field to be studied.

"(b) Non-Committee scientists shall be appointed by the Administrator, as needed, on the recommendations of the Chairman of the Committee from nominations selected by the National Academy of Sciences in accordance with the requirements specified in subsection (f)(3), to serve as members of a subpanel throughout the consideration of the risk assessment or scientific matter under review.

"(c) Members of the subpanels shall be subject to the same rules and regulations as members of the Committee.

"(4) The written report of a subpanel relating to each risk assessment referred to the subpanel under paragraph (2) shall be submitted to the Committee under such rules and regulations as the Committee may prescribe and shall be reviewed by the Committee on an expedited basis.

"(m) The Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the Committee and of any subpanel.

"(n) Each member of the Committee and member of any subpanel shall be entitled to receive per diem compensation at a rate not in excess of that fixed for GS-18 of the General Schedule under section 5332 of title V of the United States Code, as may be determined by the Administrator.

"(o) The Administrator is authorized and empowered to enter into such contracts as are necessary to carry out the functions of the Committee as described in subsection (e).

"(p)(1) The Committee shall preserve the confidentiality of any trade secret or any privileged or confidential commercial information obtained by or presented to the Committee, subject to the provisions of paragraph (3).

"(2) Any data or material, or portions thereof, that is submitted to the Committee which is a trade secret or commercial or financial information shall be clearly marked and may be submitted to the Committee separately from other data or material submitted.

"(3) Any data or information marked as confidential pursuant to paragraph (2) shall not be disclosed by any member or employee of the Committee unless the Committee has first determined that disclosure is necessary to protect against an unreasonable risk of injury to human life, health or the environment.

"(4) Data and information otherwise protected from disclosure to the public under this section may be disclosed to contractors and employees of such contractors if, in the opinion of the Committee, such disclosure is necessary for the satisfactory performance by the contractor of a contract for the performance of work in connection with this section and under such conditions as the Committee may specify. The Committee shall require as a condition to the disclosure of data or information under this subsection that the person receiving it shall preserve such confidentiality and take such security precautions respecting the data and information as the Committee shall prescribe by regulation.

"(5) Any officer or employee of the United States, or former officer or employee of the United States, who, by virtue of such employment or position, has obtained possession of or has access to material or data the disclosure of which is prohibited by this subsection, willfully discloses the material or data in any manner to any person not entitled to receive it, shall be fined not more than \$5,000 or imprisoned for not more than one year, or both.

"(6) For the purposes of this subsection, any contractor who is furnished information as authorized by paragraph (4), or any employee or such contractor, shall be considered an employee of the United States.

"(g) The Committee is authorized to make such rules as are necessary for the orderly transaction of its business."