OIG

OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Addendum to Pilot Study

Science to Support Rulemaking

Report 2003-P-00003 (Addendum)

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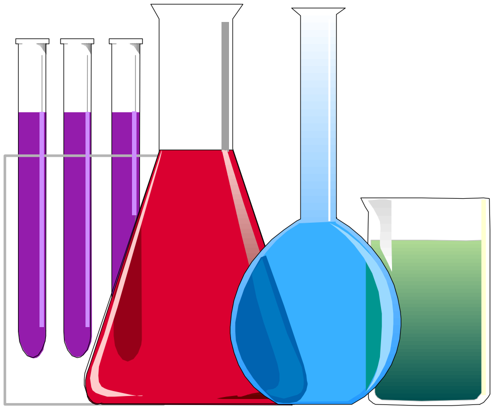

Description of Codes Used in “Tables of Critical Documents”	
AC	Academia performed the work.
C	A contract was used as the funding mechanism.
CA	a cooperative agreement was used as the funding mechanism.
ENP	Peer review was done by an external group in a non-public manner, such as a refereed journal or three external experts hired by EPA
FACA	Peer review was publicly done by a Federal advisory committee, like the Science Advisory Board or National Research Council. Some FACAs provide both peer advisement and peer review; we tried to distinguish between these when possible.
G	A grant was used as the funding mechanism.
I	EPA in-house resources were the funding mechanism, i.e., Federal salaries and expenses.
IAG	An interagency agreement was used as the funding mechanism.
II	Peer review was done by independent internal EPA reviewers, such by the risk assessment forum or by EPA Office of Research and Development (ORD) of a program office document.
IO	EPA ORD performed the work. This includes reports with an ORD cover, white papers, or memorandums clearly produced by ORD, *unless* there was an indication that the report had been prepared for EPA by a contractor.
IP	EPA program office performed the work. This includes reports with a program office cover, white papers, or memorandums clearly produced by the program office, *unless* there was an indication that the report had been prepared for EPA by a contractor.
N	No independent peer review was done, according to what we were told or had good reason to infer.
O	Other. For who funded the work, this includes reports funded by: state, local, and foreign governments; an industry; professional or trade organizations; environmental and other public interest groups; and non-governmental research institutes with no academic affiliation. For funding mechanism, this was typically in-house research by these same entities.
OEP	Peer review was done by some other public review process by external experts, such as a committee of the National Research Council.
OF	Another Federal agency besides EPA performed or funded the work.
OG	Other (non-Federal) government entity performed the work.
ORD	EPA Office of Research and Development funded the work.
PO	EPA program office funded the work.
PS	Private sector performed the work. This includes reports prepared by a contractor for EPA or another organization, or reports prepared by an industry, professional or trade organization, environmental and other public interest group, or a non-governmental research institute with no academic affiliation.
U	Unknown entity performed or funded the work, unknown funding mechanism was used, or it was unknown whether a peer review was done.

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Case 1
Municipal Waste Combustors

Rule Title: Standards of Performance for New Stationary Sources; Municipal Waste Combustors

Citation for Final Rule: 56 Federal Register 5488 (February 11, 1991)

EPA Start Action Notice: 2424

Brief description of the rule

The Administrator determined that emissions from municipal waste combustors (MWC) cause or contribute significantly to air pollution that may reasonably be anticipated to endanger public health or welfare. Therefore, under section 111(b) of the Clean Air Act and section 129 of the Clean Air Act Amendments of 1990, this rule was promulgated to limit air emissions from MWC. The emission limits were set at levels achievable by the best demonstrated system of continuous emission reduction, considering costs, nonair quality health and environmental impacts, and energy requirements. The emissions regulated included: MWC organics; MWC acid gases; MWC metals; and nitrogen oxides.

The rule applied to each new, modified or reconstructed MWC unit having a capacity to combust over 225 megagrams a day (250 tons per day). Thus, MWC units of this size for which construction, modification, or reconstruction started after December 20, 1989, much comply with the rule.

In addition, the rule included combustor operating standards, and provisions for certification of key MWC personnel and training of other MWC personnel.

EPA excluded from the rule provisions in the proposal to: separate reusable materials, divert household batteries before incineration, and prohibit the burning of lead-acid vehicle batteries.

Brief description of science input to the rule

The scientific aspects of the rule centered on identifying and measuring what was emitted from municipal waste combustors, and the effect of these emissions on human health and the environment. Also, the best demonstrated technologies had to be identified and evaluated, particularly with regard to their cost and how they affected emissions.

Description of critical documents

EPA issued a Report to Congress in June 1987 that was a compilation of the available information on MWCs, including industry characteristics, emission data, health risks, control technologies, and costs of control. This report was prepared by the EPA Office of Solid Waste and Emergency Response in conjunction with the Office of Air and Radiation and the Office of

Research and Development. Much of the information in it came from eight technical reports prepared by EPA or its contractors. This Report to Congress provided the technical basis for the decision to regulate emissions from MWCs. [See Reference 1.]

Besides the Report to Congress, the support for the promulgated regulation included two documents prepared by the program office; one was the updated regulatory and economic impact analysis of the regulation and the other summarized the comments received on the proposed regulation. These analysis evaluated the alternatives considered and the Agency's basis for selecting the one that was proposed and promulgated. The summary of comments was the basis for changes in the standard between proposal and promulgation. [See References 2 and 3.]

The regulations require compliance and performance testing. These testing methodologies were developed by EPA, by the American Society of Mechanical Engineers (ASME), or by work groups with staff from one or both of these organizations, and tested in the field. More specifically, ORD's Atmospheric Research and Exposure Assessment Laboratory developed some of these methods. [See References 12 and 15.]

Besides published literature and specific source test reports, EPA used three methods to obtain current information about operator training, facility design and operation, and emissions data. The first was to request such information from facilities. [See Reference 13.] The second was to visit facilities; an EPA contractor may have represented EPA on the visit. [See Reference 14.] The third was the Municipal Waste Combustion Multipollutant Study that was jointly funded by the program office and ORD, as well as others such as Environment Canada. For this study, EPA conducted 10 emission testing programs at 6 municipal waste combustor facilities. Quality Assurance / Quality Control Project Plans were prepared before the majority of the testing programs; for at least one site, an external QA/QC program was conducted. [See Reference 15.]

The collected information described above was either put into a database or used to characterize "model" facilities. These, in turn, were used by Agency staff or contractors to prepare a series of other documents that were needed for the previously-mentioned Report to Congress or regulatory and economic impact analysis. [See References 4 through 11.]

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	U.S.EPA, June 1987, "Municipal Waste Combustion Study Report to Congress", Washington, DC, EPA/530-SW-87-021a	IP	PO	I	FACA
2	U.S. EPA, November 1990, "Air Pollutant Emission Standards and Guidelines for Municipal Waste Combustors: Revision and Update of Economic Impact Analysis," RTP, NC, EPA-450/3-91-003	IP	PO	I	U

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
3	U.S. EPA, January 1991, "Municipal Waste Combustion: Background Information for Promulgated Standards and Guidelines -- Summary of Public Comments and Responses", RTP, NC, EPA-450/3-91-004	IP	PO	I	U
4	U.S.EPA, June 1987, "Municipal Waste Combustion Study Assessment of Health Risks Associated With Municipal Waste Combustion Emissions", Washington, DC, EPA/530-SW-87-021g	IP	PO, ORD	I	ENP
5	U.S.EPA, August 1989, "Municipal Waste Combustion Assessment: Technical Basis For Good Combustion Practice", RTP, NC, EPA-600/8-89-063	PS	ORD	C	U
6	U.S.EPA, August 1989, "Municipal Waste Combustion Assessment: Combustion Control at New Facilities", RTP, NC, EPA-600/8-89-057	PS	ORD	C	N
7	U.S.EPA, August 1989, "Municipal Waste Combustors - Background Information for Proposed Standards: Control of NOx Emissions", RTP, NC, EPA-450/3-89-27d	PS	PO	C	U
8	U.S.EPA, August 1989, "Municipal Waste Combustors - Background Information for Proposed Standards: Post-Combustion Technology Performance", RTP, NC, EPA-450/3-89-27c	PS	PO	C	U
9	U.S.EPA, August 1989, "Municipal Waste Combustors - Background Information for Proposed Standards: 111(b) Model Plant Description and Cost Report", RTP, NC, EPA-450/3-89-27b	PS	PO	C	U
10	U.S. EPA, January 1991, "Municipal Waste Combustion: Background Information for Materials Separation," RTP, NC, EPA-450/3-90-021	PS	PO	C	U
11	Memorandum from Rayburn M. Morrison (EPA), Baseline Risk Analysis to Support Municipal Waste Combustor New Source Performance Standard and Emission Guideline Development, to The Files, dated November 22, 1989.	IP	PO	I	U
12	U.S. EPA, June 1988, "Guidelines For Stack Testing Of Municipal Waste Combustion Facilities", EPA-600/8-88-06	IP, IO, OG	PO, ORD, O	U	U

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
13	Information provided by industry in response to Clean Air Act section 114 letters from EPA.	PS	O	U	U
14	Information obtained during site visits to MWCs.	PS	PO	C	U
15	U.S. EPA, September 1989, "Municipal Waste Combustion Multipollutant Study", RTP, NC	PS	PO, ORD	C	U

Methodology

The majority of the documents identified as critical were described or specifically identified by the primary contact. He did this via e-mails, an interview, and telephone conversations with members of the pilot study team.

With this information, we went to the air docket (A-89-08) and found the documents. In addition, we picked up a few documents we considered critical from the docket that the primary contact had not identified. With one exception, all the critical documents came from the docket.

Miscellaneous Other Information

The promulgated rule omitted three requirements that had been proposed: a 25 percent reduction in the weight of waste material combusted because of recycling; separation of household batteries; and a prohibition on burning lead acid batteries. The reason recycling was not made mandatory was primarily cost rather than science. The Agency was uncertain about the net financial cost estimate, recycling would have reduced the flexibility of local government, landfills were not required to recycle, and there was not enough evidence that energy and environmental benefits could be achieved. Concerning household batteries, the Agency could not show that battery separation would significantly effect the amount of mercury emissions. The prohibition on lead acid batteries was dropped because the Agency decided there was already a strong regulatory mechanism in place to discourage combustion of lead batteries.

Case 2
Synthetic Chemicals Monitoring

Rule Title: National Primary Drinking Water Regulations -- Synthetic Organic Chemicals and Inorganic Chemicals; Monitoring for Unregulated Contaminants; National Primary Drinking Water Regulations Implementation; National Secondary Drinking Water Regulations.

Citation for Final Rule: 56 Federal Register 3526 (January 30, 1991)

EPA Start Action Notice: Unknown

Brief description of the rule

EPA promulgated maximum contaminant level goals (MCLGs) and National Primary Drinking Water Regulations (NPDWRs) for 26 synthetic organic chemicals (SOCs) and 7 inorganic chemicals (IOCs). The NPDWRs consist of maximum contaminant levels (MCLs) or treatment techniques for the SOCs and IOCs and include monitoring, reporting, and public notification requirements for these compounds. This rule includes the best available technology (BAT) upon which the MCLs are based and the BAT for the purpose of issuing variances. EPA also promulgated secondary MCLs (SMCLs) for two contaminants and one-time monitoring requirements for approximately 30 SOCs and IOCs that are not regulated by NPDWRs.

The Safe Drinking Water Act (SDWA), as amended in1986, requires EPA to publish "maximum contaminant level goals" (MCLGs) for contaminants which, in the judgment of the Administrator, "may have an adverse effect on the health of persons and which [are] known or anticipated to occur in public water systems" (section 1412(b)(3)(A)). MCLGs are to be set at a level at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" (section 1412(b)(4)). At the same time EPA publishes an MCLG, which is a non-enforceable health goal, it must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either (1) a maximum contaminant level (MCL), or (2) a required treatment technique (sections 1401(1), 1412(a)(3), and 1412(b)(7)(A)). A treatment technique may be set only if it is not "economically or technologically feasible" to ascertain the level of a contaminant (sections 1401(1) and 1412(b)(7)(A)). An MCL must be set as close to the MCLG as feasible (section 1412(b)(4)). “Feasible" means "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds are available, after examination for efficacy under field conditions and not solely under laboratory conditions (taking cost into consideration)" (section 1412(b)(5)). NPDWRs also include monitoring, analytical and quality assurance requirements, specifically, "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels." (Section 1401(1)(D)). Section 1445 of SDWA also authorizes EPA to promulgate monitoring requirements.

Brief description of science input to the rule

Establishment of an MCLG depends on the evidence of carcinogenicity from drinking water exposure or the Agency's reference dose (RfD), for each specific contaminant. Decisions on cancer classifications are made by the Cancer Risk Assessment Verification Endeavor group, and decisions on EPA reference doses (using non-cancer endpoints only) are made through the Agency Reference Dose work group. Decisions by both groups represent policy decisions for the Agency and are used by the respective regulatory programs as the basis for regulatory decisions. Both are published in the Agency's Integrated Risk Information System (IRIS).

The RfD is an estimate, with an uncertainty spanning perhaps an order of magnitude, of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious health effects during a lifetime. The RfD is derived from a no- or lowest-observed-adverse-effect level (a NOAEL or LOAEL, respectively) that has been identified from a subchronic or chronic scientific study of humans or animals. The NOAEL or LOAEL is then divided by an uncertainty factor to derive the RfD. Uncertainty factors range from 10-1000, based on the type of evidence (e.g., human vs animal). From the RfD, a drinking water equivalent level (DWEL) is calculated by multiplying the RfD by an assumed adult body weight (generally 70 kg) and then dividing by an average daily water consumption of 2 L per day. The DWEL assumes the total daily exposure to a substance is from drinking water exposure. The MCLG is determined by multiplying the DWEL by the percentage of the total daily exposure contributed by drinking water (generally assumed to be 20 percent, unless other exposure data for the chemical are available).

For chemicals suspected as carcinogens, the assessment for non-threshold toxicants consists of the weight of evidence of carcinogenicity in humans, using bioassays in animals and human epidemiological studies as well as information that provides indirect evidence (i.e., mutagenicity and other short-term test results). The objectives of the assessment are (1) to determine the level or strength of evidence that the substance is a human or animal carcinogen and (2) to provide an upper bound estimate of the possible risk of human exposure to the substance in drinking water.

Category I contaminants are those which EPA has determined there is strong evidence of carcinogenicity from drinking water ingestion and the MCLG is set at zero. Category II contaminants are those which EPA has determined that there is limited evidence for carcinogenicity from drinking water ingestion. The MCLG for Category II contaminants is calculated using the RfD/DWEL with an added margin of safety to account for cancer effects or are based on a risk range of 10^{-5} to 10^{-6} when data are inadequate to derive an RfD. Category III contaminants are those which there is inadequate evidence of carcinogenicity by drinking water ingestion. For Category III contaminants, the MCLG is established using the RfD. The science issues with respect to the MCLGs thus involve health risk assessments that deal with all the above aspects for each of the pollutants.

The statutory standard for "best available technology" (BAT) under 1412(b)(5) represented a change from the provision prior to 1986, and EPA read the rule to allow EPA to select a technology that was not necessarily in widespread use, or had not been tested for each specific contaminant, as long as it has been field tested beyond the laboratory. EPA thus derived the MCLs based on an evaluation of (1) the availability and performance of various technologies for removing the contaminant, and (2) the costs of applying those technologies. For Category I contaminants, the Agency also evaluated the health risks that are associated with various levels of the contaminants, with the goal of ensuring that the maximum risk at the MCL falls within the 10^{-4} to 10^{-6} risk range. EPA made an engineering assessment of technologies capable of removing a contaminant from drinking water, and developed occurrence documents for each pollutant. To determine the “best” technologies, EPA reviewed the available data to determine which ones had the highest removal efficiencies, were compatible with other water treatment processes, and were not limited to a particular geographic region. Based on the removal capabilities of the various technologies, EPA calculated the level of each contaminant that is achievable by their application to large systems with relatively clean raw water sources.

The feasibility of setting an MCL at a precise level is also influenced by laboratory ability to reliably measure the contaminant in drinking water. EPA derives practical quantitation levels (PQLs) which reflect the level that can be measured by good laboratories under normal operating conditions within specified limits of precision and accuracy. This factor is critically important in determining the MCL for contaminants for which EPA sets the MCLG at zero, a number which by definition can be neither measured nor attained. Limits of analytical detection require that the MCL be set at some level greater than the MCLG for these contaminants. In these cases, EPA examined the reduction capability of BAT and the accuracy of analytical techniques as reflected in the PQL to establish the appropriate MCL level. Only the analytical procedures specified in the final rule can be used for compliance monitoring after the rule is promulgated. The rule also dealt with laboratory certification requirements. The science inputs with respect to BAT and PCLs thus have to do with engineering data and judgement and analytical chemistry and quality assurance.

In developing the compliance monitoring requirements for the contaminants in this rule, EPA considered (1) the likely source of drinking water contamination, (2) differences between ground and surface water systems, (3) how to collect samples that are representative of consumer exposure, (4) sample collection and analysis costs, (5) the use of historical monitoring data to identify vulnerable systems and subsequently specify monitoring requirements for vulnerable systems, (6) the limited occurrence of some contaminants, and (7) the need for States to tailor monitoring requirements to system- and area-specific conditions. The science inputs to compliance monitoring generally have to do with sampling statistics, but do not appear to have had much impact relative to cost and practical constraints on monitoring.

EPA proposed monitoring requirements for approximately 110 "unregulated" organic chemicals and six inorganic chemicals divided into two priority groups. EPA adopted a monitoring scheme that requires all systems to monitor for the highest priority organics, unless a vulnerability assessment determines the system is not vulnerable. Any science issues reflected the concern about the chemicals on the two lists. The rule also required one-time monitoring of 30 unregulated organic and inorganic contaminants.

EPA proposed secondary maximum contaminant levels (SMCLs) based on taste and odor detection levels for seven organic chemicals (o-dichlorobenzene, p-dichlorobenzene, ethylbenzene, pentachlorophenol, styrene, xylene, and toluene) and for silver and aluminum. These organic chemicals had reported taste or odor detection levels lower than the proposed (or final)

MCLs. EPA believed it appropriate to set SMCLs for these compounds to protect against aesthetic effects (such as odor) which could be present at levels below the proposed MCLs. EPA dropped the organics SMCLs but retained the existing odor SMCL of 3 Total Odor Number (TON). EPA finalized an SMCL for aluminum (due to discoloration of water) with the precise level for each system being determined by the State. Furthermore, EPA deleted an MCL for silver and finalized an SMCL to protect against skin discoloration or argyreia from lifetime exposure. Science issues with respect to SCMLs have to do with the effects of the contaminants on tastes, odors, colors, and cosmetic effects.

Description of critical documents

This rule established primary MCLs for 33 chemicals, secondary MCLs for two chemicals, and monitoring requirements for 30 chemicals. Most of the referenced documents had been removed from the docket and archived. Consequently, we decided to concentrate on the criteria documents for all the chemicals. In addition, we reviewed the documents referenced in two of the criteria document (nitrate/nitrite and 1,2 dichloropropane), which we chose at random. We also looked at the occurrence document for Chromium. The results for the referenced documents may not be characteristic of those for the other 31 chemicals.

There is no overall background information document for the rule. The preamble to the proposed rule [Reference 1] explains the basis for the various regulations, and the preamble to the final rule [Reference 2] contains the response to comments, but the preambles seldom explicitly reference the items in the docket. We therefore had to infer the importance of the other referenced documents.

The first group of other referenced documents supporting the final rule are the occurrence documents. There are five occurrence documents for the metals prepared under contract to OGDW by Wade Miller Assoc [Reference 3], a draft final report on the occurrence and human exposure to pesticides [Reference 4], and a draft final report on the occurrence of the remaining organics [Reference 5]. The occurrence documents are critical in determining the cost-effectiveness of the rule, because they serve as the baseline against which reductions in risk are determined.

There are 33 health criteria documents associated with the final rule [References 6-36]. Seventeen of the criteria documents carried forward to the final rule, and sixteen criteria documents were revised between proposal and final. The documents were produced either under the supervision of the Criteria and Standards Division (CSD) of the Office of Drinking Water or the ORD Environmental Criteria and Assessment Office (ECAO). Both groups relied largely on contractors to develop the documents, with various degrees of involvement by internal scientists. The ECAO documents identify who worked on the documents, and who the peer reviewers were (including their affiliations), while the CSD documents did not indicate the reviewers, or often the contractors who contributed.

It was difficult to determine whether the analytical methods cited were critical, inasmuch as water suppliers were given the option to choose among EPA methods manuals (developed by what was then EMSL-Cincinnati, an ORD laboratory), and manuals by the U.S. Geological

Survey, the American Society of Testing and Materials, the American Public Health Association, and in some cases, the manufacturer of the instrument. However, the only method allowed for asbestos fibers was developed by ORD's Athens laboratory [Reference 37].

The key technologies and cost document was Technologies and Costs for the Removal of Synthetic Organic Chemicals from Potable Water Supplies. U.S. EPA ODW [Reference 38]. Treatment techniques for the removal of inorganic contaminants from drinking water regulations. ORD EPA-600-8-77-005 [Reference 39] appears to be the comparable document for inorganics. There are numerous addenda listed to Draft Regulatory Impact Assessments for Inorganic and Synthetic Organic Chemicals, all apparently produced by ODW.

Moving on to other critical references, we looked at two health assessments, nitrate/nitrite developed by CSD, and 1,2-dichloropropane, developed by ORD/ECAO. We also looked at the occurrence document for Chromium.

The Drinking Water Criteria Document for Nitrate/Nitrite [Reference 12] was prepared by Life Systems, Inc., a subcontractor to ERG, who prepared many of the Criteria Documents for CSD. Although many references were included, basically two epidemiological studies conducted in the early 1950's [References 40 and 41] yielded the lowest NOEL and LOAEL, and nine later studies all yielded higher values, so the RfD was based on the two earlier studies, making them critical. Most of the later studies were conducted in parts of the world that had quite high nitrate/nitrite levels in water supplies, and most appear to have been funded by foreign governments or international health organizations.

Bosch, et al (1950) [Reference 40] had the most extensive data on methemoglobinemia in Minnesota, where some of the highest nitrate concentrations in drinking water are found. Methemoglobinemia is a disease in infants caused by nitrite binding hemoglobin and causing cyanosis or "blue baby" syndrome. Walton et al. (1951) [Reference 41] used data from a survey letter sent to all of the States by the American Public Health Association, to identify the lowest nitrate/nitrite concentrations associated with methemoglobinemia,. Most of the cases of methemoglobinemia occurred in three states (MN, IL, and NE), and only 5 cases (5% of the sample) were associated with the 10-20ug/L N concentrations, the lowest range in the survey. The Drinking Water Committee of EPA's science advisory board reviewed this report, and asked that the discussion of the basis for this RfD be expanded and that the study be reviewed by a statistician - the final discussion was expanded to eleven lines, and apparently no review was conducted. Lukens (1987) [Reference 42] was cited to show that 10% of nitrate is reduced to nitrite in infants stomachs, making that the most sensitive criterion upon which to base the MCL.

The Criteria Document for 1,2 dichloropropane [Reference 22] was prepared by ECAO, Cincinnati by Syracuse Research Corp. and several staff of the ORD ECAO. The scientific reviewers were a member of EPA's Carcinogen Assessment Group and two ODW staffers. This report was indicative of the difficulty of establishing MCLGs. The Summary states:

> "The data base for the toxicity of 1.2-dichloropropane is limited, consisting of a number of studies from the older literature and the NTP (1986) report of toxicology and carcino-

> genesis studies. No drinking water criteria have been recommended due to the inadequacy of the available toxicological studies."

However, based on the National Toxicology Program (1986) report [Reference 43], criteria for cancer risks could be established using EPA's 1986 Cancer Risk Guidelines [Reference 44] for 10E-4 to 10E-6 risk levels, which were used to set the MCLG and MCLs. Also, based on Ames Test data, the chemical was elevated from group C to B2, so these data significantly affected the cancer risk levels. Of four sources cited, only two could be found, DeLorenzo et al. (1977) and Stolzenburg and Hine (1980) [References 45and 46].

A review of the occurrence document for Chromium [Reference 3] indicted several sources for the occurrence data: a report by Pacific Northwest Laboratory (1984) Chemical attenuation rates, coefficients, and constants in leachate migration. V.1. A critical Review [Reference 47]; EPA (1979) Water-related environmental fate of 129 priority pollutants. EPA 440/4-79-029a [Reference 48]; and Britton (1983) National Stream Quality Assessment Network [Reference 49]. There also are references to several studies by ODW: the 100 city study (1964), Community Water Supply Studies (1969 and 1978), rural water supply study (1978-80) and the National Inorganics and Radionuclides Survey [Reference 50]. The latter survey caused the occurrence studies for the inorganics to be revised between 1987 and 1990.

Table of critical documents

Ref.	Document/Study	Who Performed It? (Category)	Who Funded It? (Category)	Funding Mechanism	Peer Review?
1	Synthetic Organic Chemicals, Inorganic Chemicals, and Microorganisms: Proposed Rule. 50 FR 46936. 1985	IP	PO	I	N
2	National Primary Drinking Water Regulations -- Synthetic Organic Chemicals and Inorganic Chemicals; Monitoring for Unregulated Contaminants; National Primary Drinking Water Regulations Implementation; National Secondary Drinking Water Regulations 56 FR 3526 1991	IP	PO	I	N
3	Occurrence and Exposure Assessment for Cadmium (Copper/Mercury/Nitrate/Nitrite/Selenium) in Public Water Drinking Supplies. EPA ODW, 1990. (5 reports)	PS	PO	C	N
4	Draft Final Report on the Occurrence and Human Exposure of to Pesticides in Drinking Water, Food, and Air in the U.S.A. EPA ODW 1990	IP	PO	I	U
5	Occurrence of Synthetic Organic Chemicals in Drinking Water. Food, and Air. EPA ODW 1987.	PS	PO	C	N
6	Drinking Water Criteria Document for Asbestos (ECAO-CIN-422) April 1988	IO	ORD	C	II

Ref.	Document/Study	Who Performed It? (Category)	Who Funded It? (Category)	Funding Mechanism	Peer Review?
8	Final Draft for the Drinking Water Criteria Document on Barium (TR-832-92) Dec 1987	PS	PO	I	U
9	Final Draft for the Drinking Water Criteria Document on Cadmium (TR-832-93) Dec 1986	PS	PO	C	U
10	The Drinking Water Criteria Document on Chromium (TR-1242-64) Oct 1990	PS	PO	C	U
11	Drinking Water Criteria Document for Mercury (ECAO-CIN-025) July 1988	IP	ORD	I	ENP
12	Drinking Water Criteria Document on Nitrate/Nitrite (TR-1242-60) Dec 1990	PS	PO	C	FACA
13	The Drinking Water Criteria Document on Selenium (TR-1242-65) Oct 1990	PS	PO	C	U
14	Final Draft for the Drinking Water Criteria Document on Acrylamide (TR-832-104A) July 1987	PS	PO	C	U
15	Quantification of Toxicological Effects for Arochlor May 1990	PS	PO	C	U
16	Drinking Water Criteria Document for Aldicarb (ECAO-CIN-420) Jan 1988	IO	ORD	I	N
17	Drinking Water Criteria Document for Atrazine May 1990	PS	PO	C	U
18	The Drinking Water Criteria Document on Carbofuran (TR-1242-59)	PS	PO	C	U
19	Drinking Water Criteria Document for Heptachlor, Heptachlor Epoxide and Chlordane (ECAO-CIN-406) Aug 1990	PS	ORD	C	ENP
20	Drinking Water Criteria Document for 1,2 dibromo-3-Chloropropane (DBCP) (ECAO-CIN-410) Mar 1988	PS	ORD	C	II
21	Draft Criteria Document for ortho-Dichlorobenzene, meta-Dichlorobenzene and para-Dichlorobenzene June 1988	U	PO	U	U
22	Criteria Document for 1,2 dichloropropane (ECAO-CIN-404) Aug 1990	PS	ORD	C	II
23	Drinking Water Criteria Document for Dichloroethylenes Dec 1990	PS	PO	C	U
24	Final Draft for the Drinking Water Criteria Document for 2,4-Dichlorophenoxyacetic acid (2,4-D) (ECAO-CIN-418) Mar 1988	PS	ORD	C	ENP
25	Drinking Water Criteria Document for Epichlorohydrin (ECAO-CIN-413) Feb 1987	IO	ORD	C	ENP
26	Drinking Water Criteria Document for Ethylbenzene (ECAO-CIN-430)	PS	ORD	C	ENP

Ref.	Document/Study	Who Performed It? (Category)	Who Funded It? (Category)	Funding Mechanism	Peer Review?
27	Drinking Water Criteria Document for Ethylene Dibromide (EDB) (ECAO-CIN-412) July, 1987	PS	ORD	C	ENP
28	Drinking Water Criteria Document for Lindane (ECAO-CIN-402) Oct 1990	PS	ORD	C	ENP
29	Drinking Water Criteria Document for Methoxychlor (ECAO-CIN-425)	PS	ORD	C	N
30	Drinking Water Criteria Document for Polychlorinated Biphenyls (ECAO-CIN-414) April 1988	AC	ORD	C	ENP
31	Drinking Water Criteria Document for Styrene (ECAO-CIN-409) Jan 1991	PS	ORD	C	ENP
32	Tetrachloroethylene - Quantification of Toxicological Effects Dec 1990	U	PO	U	U
33	Drinking Water Criteria Document for Toluene (ECAO-CIN-408) July 1990	PS	ORD	C	ENP
34	Drinking Water Criteria Document for Toxaphene (ECAO-CIN-426) Feb 1987	PS	ORD	C	ENP
35	Drinking Water Criteria Document for 2(2,4,5-Trichlorophenoxy) Propionic Acid (ECAO-CIN-419) Sept 1987	PS	ORD	C	ENP
36	Drinking Water Criteria document for Xylenes (ECAO-CIN-416) June 1987	PS	ORD	C	II
37	Analytical methods for the determination of asbestos fibers in water. EPA - 600/4-83-043	PS	ORD	C	II
38	Technologies and Costs for the removal of synthetic organic chemicals from potable water supplies. U.S. EPA ODW	IP	PO	C	U
39	Treatment techniques for the removal of inorganic contaminants from drinking water regulations. ORD EPA-600-8-77-005.	IO	ORD	I	ENP
40	Bosch, et al (1950) J. AWWA 42:161.	OG	O	G	ENP
41	Walton et al. (1951) Survey of literature relating to infant methemoglobinemia due to nitrate contaminated water. Am. J. Pub. Health. 41: 986-996.	OG	OF	O	ENP
42	Lukens, J. 1987. The legacy of well--water methemoglobinemia, JAMA 257:2793-2795	AC	U	U	ENP
43	NTP (1986). NTP Technical Report no 263 on the toxicology and carcinogenicity studies of 1,2-dichloropropane in F344/N rats and B6C3F1 mice (gavage study). NIH Rept. No 83-2519	OF	OF	C	FACA

Ref.	Document/Study	Who Performed It? (Category)	Who Funded It? (Category)	Funding Mechanism	Peer Review?
44	U.S. EPA Guidelines for Carcinogen Risk Assessment. 51 FR 33992.	IP/IO	PO/ORD	I	FACA
45	DeLorenzo, et al. 1977. Mutagenicity of pesticides containing 1,2 -dichloropropane. Cancer Res. 37: 1915-1917.	AC	O	C	ENP
46	Stolzenburg and Hine (1980) Mutagenicity of 2- and 3- carbon halogenated compounds in the Salmonella/mammalian microsome test. Environ. Mutagen. 2: 59-66	AC	O	G	ENP
47	Battelle, Pacific Northwest Labs, 1984. Chemical attenuation rates, coefficients, and constants in leachate migration. V.1. A critical Review. Prepared for EPRI Project #2198-1.	OF	O	C	U
48	U.S. EPA 1979. Water-related environmental fate of 129 priority pollutants. 2 vols. Office of Water Planning and Stds. EPA 440/4-79-029a&b	IP/PS	PO	C	ENP
49	Britton (1983) National Stream Quality Assessment Network. U.S.G.S. Open File Rept. 80-594	OF	OF	I	U
50	Various ODW Surveys	U	PO	U	U

Methodology

We received two replies to the questionnaire. The primary contact indicated that his job had been to pull the entire rule together, but that he did not have detailed knowledge about each of the 33 chemicals regulated in the rule. A senior OW official also indicated that his memory was pretty hazy on the rule. We approached the rule by going directly to the docket, identifying the major technical support documents, and then reading several of the occurrence papers and criteria documents. Because most of the referenced documents had been archived, we generally searched for these sources in the EPA library in Research Triangle Park and the University of North Carolina Library system, and even did some searches through interlibrary loans. It was often very difficult to locate the referenced documents.

Miscellaneous Other Information

Our experience with this rule led us to wonder how the NTP (a toxicology program of the National Institutes of Environmental Health Sciences with a multi-agency steering committee, including the Administrator of EPA) worked. More specifically, given the fact that many of the chemicals that EPA regulates require that standards be set under several (or even many) different statutes, does EPA or NTP have an organized strategy to reduce the uncertainty in the toxicology of these compounds? An interview with an EPA senior scientist familiar with both the NTP and EPA’s efforts said that for a time, EPA actually discouraged NTP from its activities, because

EPA was requiring industry to conduct toxicology studies as part of TSCA and FIFRA reviews. This came about in part because EPA was being “outspent” by industry (e.g., EPA would conduct a toxicology study, and then industry would spend three times as much on further studies to cast doubt on the validity of the original tests). He also said that the administrative requirements of rule-makings, which typically costs $150K/rule, were taking substantial funding away from toxicology. EPA has since dropped it’s opposition to NTP testing, but the program typically focuses more on NIH priorities. The staffer also said that in the early 1990's, an EPA branch chief tried to organize a cross-agency group to prioritize chemicals for toxicology testing, but that it failed due to lack of support by the Assistant Administrators.

We were advised that we should also look at how the process of NPDWR formulation had changed since 1991. Actually, we also did a 1998 NPDWR rule in the pilot. Just as we were finishing this study, the Office of Ground Water and Drinking Water announced its preliminary decision not to revise NWPDRs for 68 chemical contaminants. EPA stated that the 68 chemical NPDWRs should not be revised at this time for one of the following reasons:

- 36 NPDWRs were undergoing EPA health risk assessments. These assessments are not expected to be complete in time to make its final revise/not revise decisions.

- 17 NPDWRs remained appropriate and any new information available to EPA supports retaining the current regulatory requirements.

- 12 NPDWRs had new health, technological, or other information that indicated a potential revision to MCLG and/or MCL; however, EPA believed any potential revision would result in minimal gain in the level of public health protection and/or provide negligible opportunity for significant cost-savings.

- 3 NPDWRs data gaps or research needs that needed to be addressed before EPA could make definitive regulatory decisions. When the data gaps have been resolved, EPA plans to consider the results in the next review cycle.

Agency Comments and OIG Response

As part of the comments from the Office of Water, the Office of Ground Water and Drinking Water suggested specific changes related to synthetic chemical monitoring. Since the changes clarified our meaning or improved factual accuracy, we revised Case 2 as suggested by the Office Water.

Case 3

Acid Rain Permits

Rule Title: Acid Rain Permits, Allowance System, Emissions Monitoring, Excess Emissions and Appeals Regulations Under Title IV of the Clean Air Amendments of 1990

Citation for Final Rule: 58 Federal Register 3590 (January 11, 1993)

EPA Start Action Notice: 2886

Brief description of the rule

Title IV of the Clean Air Act (CAA), as amended November 15, 1990, required EPA to establish an Acid Rain Program to reduce the adverse effects of acidic deposition. Prior to publication of acid rain proposed regulations, EPA solicited ideas and comments from organizations and individuals that would be affected by acid rain rules. The resulting Acid Rain Advisory Committee (ARAC) was formed and included 44 members that represented stakeholder groups that included: utility companies, emissions control equipment vendors, State Public Utility Commissioners, academicians, coal companies, State air pollution control agencies, labor, and environmental groups. There were six ARAC public meetings attended by hundreds of people and the discussions and input from those stakeholders was helpful in drafting proposed rules. During the public comment period for the proposed rule, stakeholders communicated over 7,800 individual comments focused on over 850 major and minor issues.

The emission of concern for this rule was sulfur dioxide (SO^2). SO^2 emissions, along with Nitrogen Oxide (NOx, regulated in a later EPA rule) are released into the atmosphere from the burning of fossil fuels, primarily coal and oil. Once in the air, SO^2 and NOx may undergo various chemical reactions, resulting in transformation of the emissions into sulfates, nitrates, sulfuric acid and nitric acid. These compounds can fall to earth near the emission sources of SO^2 and NOx or be transported hundreds of miles. Acid rain is also referred to as acidic deposition and these compounds can be either dry (gases, aerosols, and particles) or wet (precipitation such as rain, fog, or snow). SO^2 and NOx emissions and their byproducts damage ecosystems and man-made materials, are suspected of posing a threat to human health, and reduce visibility.

The centerpiece of the Acid Rain Program Rule is a unique trading system in which allowances (each authorizing the emission of up to one ton of SO^2) are bought and sold at prices determined in a free market. Existing utility sources are allocated allowances based on their historic fuel use and the emissions limitations specified in the Act. Utility units are required to limit SO^2 emissions to the number of allowances they hold, but since allowances are fully transferrable, utilities may meet their emissions control requirements in the most cost-effective manner possible.

In order to operate, each affected source must apply for a permit in which the source certifies that it will hold a sufficient number of allowances to cover its SO^2 emissions, and specifies the source's planned method of compliance. Each affected source must install a system to continuously monitor the emissions and to collect, record, and report emissions data to ensure that source compliance results in achieving nationally mandated reductions in SO^2 and NOx. If an affected unit exceeds its emissions limitation for either SO^2 or NOx, the Act requires the affected (violating) sources to pay penalties and, for SO^2, to forfeit the excess SO^2 allowances.

Brief description of science input to the rule

To prepare the rule, EPA needed to determine the precision, accuracy, and reliability of continuous emissions monitoring systems (CEM). Specifically, EPA needed to determine that continuous emissions monitors work (measuring the amount of gas flow) and how well the monitors worked (measuring the concentration of gas). Also, EPA needed to determine what companies are to do when the continuous emissions monitors are not working (devising a way to determine what's going out when the monitors are not working).

Description of critical documents

The key support for this rule was the CEM technology development to determine that CEMs would measure the amount of gas flow and the concentration of the gas flow. [See References 6, 11-12]. Additional support for the final rule were technical documents pertaining to performance evaluations that measured emissions from CEMs and reviewed the monitoring systems at power plants which helped determine emissions limitations and calculations when CEMs are not working. [See References 7-10]. Survey results from vendors of flow monitoring and gas monitoring equipment were helpful in developing the emissions monitoring technology. [See References 1 - 2]. An equipment user survey on flow monitoring was useful in CEM technology development, as well as technical information on velocity stratification. [See References 3-4]. Finally, a limited amount of data gathered showed a correlation between boiler parameters and stack volumetric flow rates. [See Reference 5].

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	Entropy Environmentalists, Inc. November 26, 1990. Draft Summary Report: Flow Monitor Vendor Survey Results.	PS	ORD, PO	C	FACA
2	Entropy Environmentalists, Inc. December 21, 1990. Draft Summary Report: Gas Monitor Vendor Survey Results.	PS	ORD, PO	C	FACA
3	Entropy Environmentalists, Inc. January 11, 1991. Draft Summary Report: Flow Monitoring Equipment User Survey.	PS	ORD, PO	C	FACA
4	Entropy Environmentalists, Inc. February 28, 1991. Draft: Velocity Stratification.	PS	PO	C	FACA

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
5	Entropy Environmentalists, Inc. March 1991. Draft: Determination of Flue Gas Flow Rates Using Boiler Parameters.	PS	PO	C	FACA
6	U.S.E.P.A. April 1991. Protocol for the Field Validation of Emission Concentrations from Stationary Sources. OAQPS & AREAL.	IO, IP	ORD, PO	I	FACA
7	Entropy Environmentalists, Inc. May 1991. Draft: Flow Monitor Performance Evaluation, Kurz 455T Mass Velocity Monitor, Southeast Resource Recovery Facility, Long Beach, CA	PS	ORD, PO	C	FACA
8	Entropy Environmentalists, Inc. May 31, 1991. Technical Guidance on Selected Flow Monitoring Procedures and Equipment, Report 1, Flow Monitor Performance Evaluation, Central Illinois Public Service Company.	PS	ORD, PO	C	FACA
9	Entropy Environmentalists, Inc. June 14, 1991. Draft: Flow Monitor Performance Evaluation, Big Rivers Electric Corp., D.B. Wilson Station, Central City, Kentucky, and United Services, Inc., Ultra Flow 100 Ultrasonic Flow Rate Monitor.	PS	ORD, PO	C	FACA
10	Entropy Environmentalists, Inc. July 31, 1991. Draft: Flow Monitor Performance Evaluation, Kansas City Power and Light La Cygne Generating Station, La Cygne, Kansas.	PS	ORD, PO	C	FACA
11	EPA Proposed Rule for Acid Rain Program: Permits, Allowance System, Continuous Monitoring, and Excess Emissions. December 3, 1991	IP	PO	I	FACA
12	Regulatory Impact Analysis of the Proposed Acid Rain Implementation Regulations. September 16, 1991	PS	PO	C	FACA

Methodology

Originally, we went to the air docket and identified some documents we considered critical to the continuous emissions monitoring part of the rule. We then met with the primary contact on two occasions and he identified the science documents he considered critical. Using the information provided by the primary contact, we went to the docket and pulled the documents identified. The primary contact also suggested obtaining minutes of the advisory board minutes to get a better understanding of the rulemaking, which we did. The primary contact did not disagree with those chosen as critical when he reviewed the summary.

Miscellaneous Other Information

Of the approximately 26 million tons of SO^2 emitted annually from all sources in the U.S. in 1980, approximately 17 million tons of SO^2 were emitted by electric utilities. Title IV of the Act required EPA to establish an Acid Rain Program and a national emissions cap of 8.95 million tons per year on electric utility SO^2 emissions to be implemented in two phases. Phase I began in 1995 and affected 263 units at 110 mostly coal-burning electric utility plants located in 21 eastern and mid-western states. An additional 182 units joined Phase I of the program as substitution or compensating units, bringing the total of Phase I affected units to 445. Phase II, which began in the year 2000, tightened the annual emissions limits imposed on these large, higher emitting plants and also set restrictions on smaller, cleaner plants fired by coal, oil, and gas, encompassing over 2,000 units in all. The program affects existing utility units serving generators with an output capacity of greater than 25 megawatts and all new utility units. In 2001, Acid Rain Program affected sources emitted 10.6 million tons of SO^2 — nearly 7 million tons below 1980 levels, which is an approximately 40% reduction.

Agency Comments and OIG Response

In their comments on the draft report, staff from the Office of Air and Radiation suggested specific changes related to acid rain permits. Since these changes improved the factual accuracy of the report, we changed Case 3 as suggested.

Case 4
Land Disposal Restrictions

Rule Title: Land Disposal Restrictions: Phase II (Universal Treatment Standards, and Treatment Standards for Organic Toxicity Characteristic Wastes and Newly Listed Wastes); Phase III (Decharacterized Wastewaters, Carbamate Wastes and Spent Potliners); and Phase IV (Treatment Standards for Wood Preserving Wastes, and Treatment Standards for Metal Wastes, and Zinc Micronutrient Fertilizers, and Carbamate Treatment Standards, and K088 Treatment Standards)

Citation for Final Rule: 59 Federal Register 47982 (September 19, 1994), 61 Federal Register 15565 (April 8, 1996), 63 Federal Register 28555 (May 26, 1998), and 64 Federal Register 25408 (May 11, 1999)

EPA Start Action Notice: Unknown

Brief description of the rule

The Hazardous and Solid Waste Amendments (HSWA), RCRA section 3004(m) required EPA to develop treatment standards for hazardous waste to substantially diminish the toxicity or mobility of hazardous wastes. As instructed by Congress, the standards were based on the best demonstrated available technology instead of risk.

Once a hazardous waste is prohibited from land disposal, the statute provides only two options for legal land disposal: meet the treatment standard for the waste prior to land disposal, or dispose of the waste in a land disposal unit that has been found to satisfy the statutory no-migration test. A no-migration unit is one from which there will be no migration of hazardous constituents for as long as the waste remains hazardous. (RCRA section 3004(d), (e), (g) (5).

The treatment standards may be expressed as either constituent concentration levels or as specific methods of treatment. For purposes of the restriction, land disposal includes any placement of hazardous waste in a landfill, surface impoundment, waste pile, injection well, land treatment facility, salt dome formation, salt bed formation, or underground mine or cave. (RCRA section 3004(k). Land Disposal Restrictions (LDR) were needed to minimize short and long-term threats to human health and the environment.

For wastes identified or listed as hazardous waste after the 1984 HSWA, Congress required EPA to promulgate LDR treatment standards within six months of the date that the listing or identification became final. EPA did not meet this statutory deadline for all of the wastes identified or listed after the 1984 amendments. As a result, a suit was filed by the Environmental Defense Fund (EDF). EPA and EDF signed a consent decree that established a schedule for adopting prohibitions and treatment standards for newly identified or listed wastes. As a result, the following rules were promulgated subject to a demanding court-ordered schedule. The Phase II rule basically established treatment standards for newly listed coke by-product and chlorotuene production wastes, and for the D018-D043 TC wastes (TC wastes identified as hazardous because of the presence of organic hazardous constituents), with some exceptions. The Phase III rule amends the treatment standards for initially characteristic wastewaters managed in centralized wastewater management systems containing land disposal units. The amended treatment standards require treatment that destroys, immobilizes, or removes the hazardous constituents present in the initially characteristic wastewaters. The Phase IV rule deals with treatment of wood preserving wastes, paperwork reduction, TC metal wastes, and mineral processing wastes.

Brief description of science input to the rule

To prepare these rules, EPA needed to obtain technology performance information to determine the best demonstrated available technologies and the universal treatment standards that applied to the various wastes.

Description of critical documents

The treatment standards for the LDR Phase II-IV rules were technology based, not risk based. Therefore, the critical documents consisted of treatment performance analyses, treatment capacity analyses, and economic analysis documents. [See References 1, 2, 4, 7, 10, 13, 17, 24, 36, 58, 60, 61, 63, 70, 73, and 78-85]. The rest of the support were appendices on analytical methods, treatment performance databases, and other technological and cost information for the various hazardous wastes.

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	DOCID..: F-1994-CS2F-S0026 Final Best Demonstrated Available Technology (BDAT), Background Document for Wastes from the Production of Chlorinated Aliphatic Hydrocarbons F024	PS	PO	C	N
2	DOCID..: F-1994-CS2F-S0028 ..: Final Best Demonstrated Available Technology (BDAT), Background Document For Universal Standards, Volume A: Universal Standards For Nonwastewater Forms of Listed Hazardous Wastes Rorg.. U.S. EPA Office of Solid Waste	PS	PO	C	N
3	DOCID..: F-1994-CS2F-S0028.A Attachment A: Analytical Methods For Constituents Selected For Regulation Under Universal Standards	PS	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
4	DOCID..: F-1994-CS2F-S0046 ..: Final, Best Demonstrated Available Technology (BDAT), Background Document For Universal Standards, Volume B: Universal Standards For Wastewater Forms of Listed Hazardous Wastes	PS	PO	C	N
5	DOCID..: F-1994-CS2F-S0046.A Appendix A: Analytical Methods for Constituents for Regulation under Universal Standards	PS	PO	C	N
6	DOCID..: F-1994-CS2F-S0046.B Appendix B: Method Detection Limits Based on Epa-approved Analytical Methods	PS	PO	C	N
7	DOCID..: F-1994-CS2F-S0047 ..: Final, Best Demonstrated Available Technology (BDAT), Background Document for Coking Wastes K141-K145, K147, and K148	PS	PO	C	N
8	DOCID..: F-1994-CS2F-S0047.A Appendix A: Treatment Performance Database and Methodology for Identifying Universal Standards for Constituents in Nonwastewater Forms of K141-145, K147, and K148 Wastes	PS	PO	C	N
9	DOCID..: F-1994-CS2F-S0047.B Appendix B: Treatment Performance Database and Methodology for Identifying Universal Standards for Constituents in Wastewater Forms of K141-145, K147, and K148 Wastes	PS	PO	C	N
10	DOCID..: F-1994-CS2F-S0048 ..: Final, Best Demonstrated Available Technology (BDAT), Background Document For Chlorinated Toluene Wastes K149, K150, And K151	PS	PO	C	N
11	DOCID..: F-1994-CS2F-S0048.A Appendix A: Treatment Performance Database And Methodology For Identifying Universal Standards For Constituents in Nonwastewater Forms of K149, K150, And K151 Wastes	PS	PO	C	N
12	DOCID..: F-1994-CS2F-S0048.B Appendix B: Treatment Performance Database and Methodology for Identifying Universal Standards for Constituents in Wastewater Forms of K149, K150, and K151 Wastes	PS	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
13	DOCID..: F-1994-CS2F-S0049 ..: Final, Best Demonstrated Available Technology, Background Document For Organic Toxicity Characteristic Wastes D018-D043 And Addendum to Non-wastewater Forms of Pesticide Toxicity Characteristic Wastes D012-D017	PS	PO	C	N
14	DOCID..: F-1994-CS2F-S0049.A Appendix A: Treatment Performance Database And Methodology For Identifying Universal Standards For Constituents in Nonwastewater Forms of D018-D043 Wastes	PS	PO	C	N
15	DOCID..: F-1994-CS2F-S0049.B Appendix B: Treatment Performance Database And Methodology For Identifying Universal Standards For Constituents in Wastewater Forms of D018-D043 Wastes	PS	PO	C	N
16	DOCID..: F-1994-CS2F-S0049.C Appendix C: TRI Release Data Corresponding to the Organic TC Constituents Regulated in D012-D043 Wastes for 1987-1990	PS	PO	C	N
17	DOCID..: F-1994-CS2F-S0074 ..: Background Document for Capacity Analysis for Land Disposal Restrictions Phase II - Universal Treatment Standards, and Treatment Standards for Organic Toxicity Characteristic Wastes and Other Newly Listed Wastes (Final)	PS	PO	C	N
18	DOCID..: F-1994-CS2F-S0074.E Appendix E: Data on Newly Identified TC Organic Mixed Radioactive Wastes	PS	PO	C	N
19	DOCID..: F-1994-CS2F-S0074.F Appendix F: Data on Deep Well Injected Wastes	PS	PO	C	N
20	DOCID..: F-1994-CS2F-S0075 . Regulatory Impact Analysis of Land Disposal Restrictions For Newly Identified Wastes And Hazardous Soil (Phase II LDRs), Final Rule	PS	PO	C	N
21	DOCID..: F-1994-CS2F-S0075.B Appendix B: Analysis of UTS Impacts, Wastestreams With Changing Treatment Standards	PS	PO	C	N
22	DOCID..: F-1994-CS2F-S0075.C Appendix C: Percentage (By Volume) of TC Wastes Assigned to Treatment Technologies (Including Average)	PS	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
23	DOCID..: F-1994-CS2F-S0075.D Appendix D: Unit Costs Used in Phase II Rule TC Analysis	PS	PO	C	N
24	DOCID..: F-1994-CS2F-S0075.E Appendix E: Cost of Affected Tc Waste by Tc Code and Physical Form	PS	PO	C	N
25	DOCID..: F-1994-CS2F-S0075.F Appendix F: Example Calculations for Estimating Emissions (Human Health Benefits - Air Pathway)	PS	PO	C	N
26	DOCID..: F-1994-CS2F-S0075.G Appendix G: Baseline and Post-regulatory Leachate Concentrations for Carcinogenic Constituents	PS	PO	C	N
27	DOCID..: F-1994-CS2F-S0075.H Appendix H: Gems/gams Modeling Analysis	PS	PO	C	N
28	DOCID..: F-1994-CS2F-S0075.I ..: Appendix I: Waste Minimization Commercial TSD Analysis	PS	PO	C	N
29	DOCID..: F-1994-CS2F-S0075.K Appendix K: Sensitivity Analysis of Ground-water Population Risk Assumptions	PS	PO	C	N
30	DOCID..: F-1996-PH3F-S0001..: Regulatory Impact Analysis of the Phase III Land Disposal Restriction Final Rule	PS	PO	C	N
31	DOCID..: F-1996-PH3F-S0001.A Appendix A: Results of Screening Analyses of the Organic Chemical Industry	PS	PO	C	N
32	DOCID..: F-1996-PH3F-S0001.B Appendix B: Results of Screening Analyses of the Petroleum Refining Industry	PS	PO	C	N
33	DOCID..: F-1996-PH3F-S0001.C Appendix C: Results of Screening Analyses of the Pesticides Industry	PS	PO	C	N
34	DOCID..: F-1996-PH3F-S0001.D Appendix D: Results of Screening Analyses of the Inorganic Chemical Industry	PS	PO	C	N
35	DOCID..: F-1996-PH3F-S0001.E Appendix E: Results of Screening Analyses of the Iron and Steel Industry Docdate: 19960215	PS	PO	C	N
36	DOCID..: F-1996-PH3F-S0001.F Appendix F: Summary of Analyses for Steam Electric Generators	PS	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
37	DOCID..: F-1996-PH3F-S0001.G Appendix G: Results of Screening Analyses of the Electronics and Electrical Components Industry	PS	PO	C	N
38	DOCID..: F-1996-PH3F-S0001.H Appendix H: Results of Screening Analyses of the Food Industry	PS	PO	C	N
39	DOCID..: F-1996-PH3F-S0001.I ..: Appendix I: Results of Screening Analyses of Metal Products And Machinery And Electroplating/metal Finishing	PS	PO	C	N
40	DOCID..: F-1996-PH3F-S0001.J ..: Appendix J: Results of Screening Analyses of The Pulp And Paper Industry	PS	PO	C	N
41	DOCID..: F-1996-PH3F-S0001.K Appendix K: Results of Screening Analyses of the Pharmaceutical Industry	PS	PO	C	N
42	DOCID..: F-1996-PH3F-S0001.L Appendix L: Results of Screening Analyses of Industrial Laundries	PS	PO	C	N
43	DOCID..: F-1996-PH3F-S0001.M Appendix M: Results of Screening Analyses of the Leather Treating Industry	PS	PO	C	N
44	DOCID..: F-1996-PH3F-S0001.N Appendix N: Results of Screening Analyses of Federal Facilities	PS	PO	C	N
45	DOCID..: F-1996-PH3F-S0001.O Appendix O: Results of Screening Analyses of the Transportation Equipment Cleaning Industry	PS	PO	C	N
46	DOCID..: F-1996-PH3F-S0001.P Appendix P: Approach and Results of the Screening Analyses of The Biennial Report Survey (BRS)	PS	PO	C	N
47	DOCID..: F-1996-PH3F-S0001.Q Appendix Q: Cost Methodology for the Organic Chemical and Petroleum Refining Industries	PS	PO	C	N
48	DOCID..: F-1996-PH3F-S0001.R Appendix R: Economic Impact Calculations	PS	PO	C	N
49	DOCID..: F-1996-PH3F-S0001.S Appendix S: Risk Assessment Equations	PS	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
50	DOCID..: F-1996-PH3F-S0001.U Appendix U: Analysis of the Effect of the Hazardous Waste Identification Rule (HWIR) on the Affected Universe for the Petroleum Refining and Organic Chemicals Industries	PS	PO	C	N
51	DOCID..: F-1996-PH3F-S0003 ..: Addendum to the Regulatory Impact Analysis of the Phase III Land Disposal Restriction Final Rule: Revised Risk Assessment for Spent Aluminum Potliners	PS	PO	C	N
52	DOCID..: F-1996-PH3F-S0003.A Appendix A: Central Tendency Risk Calculations and High End Risk Calculations - Tables	PS	PO	C	N
53	DOCID..: F-1996-PH3F-S0007 ..: Background Document for Capacity Analysis for Land Disposal Restrictions Phase III - Decharacterized Waste-waters, Carbamate Wastes, and Spent Potliners (Final Rule); Volume 1: Capacity Analysis Methodology and Results	PS	PO	C	N
54	DOCID..: F-1996-PH3F-S0008 ..: Background Document For Capacity Analysis For Land Disposal Restrictions Phase III - Decharacterized Wastewaters, Carbamate Wastes, And Spent Potliners (Final Rule); Volume 2: Appendix A (Part 1)	PS	PO	C	N
55	DOCID..: F-1996-PH3F-S0008.A Attachment A: (Part 1) Detailed Analyses of the Required Treatment Capacity for Industries Generating Ignitable, Corrosive, Reactive, And/or Organic Toxicity Characteristic Wastes Managed in Clean Water Act or Clean Water Act-equivalent Systems	PS	PO	C	N
56	DOCID..: F-1996-PH3F-S0009 ..: Background Document for Capacity Analysis for Land Disposal Restrictions Phase III - Decharacterized Waste-waters, Carbamate Wastes, and Spent Potliners (Final Rule); Volume 3: Appendix A (Part 2) - Appendix F	PS	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
57	DOCID..: F-1996-PH3F-S0009.A Appendix A: (Part 2) Detailed Analyses of the Required Treatment Capacity for Industries Generating Ignitable, Corrosive, Reactive, And/or Organic Toxicity Characteristic Wastes Managed in Clean Water Act or Clean Water Act-equivalent Systems	PS	PO	C	N
58	DOCID..: F-1996-PH3F-S0009.B Appendix B: Data on Wastewater Treatment Capacity	PS	PO	C	N
59	DOCID..: F-1996-PH3F-S0009.D Appendix D: Additional Data Supporting the K088 Capacity Analysis	PS	PO	C	N
60	DOCID..: F-1996-PH3F-S0009.E Appendix E: Wastewater and Non-wastewater Quantities of D003 Wastes (1993 BRS)	PS	PO	C	N
61	DOCID..: F-1996-PH3F-S0009.F Appendix F: Case Study Report for Capacity Analysis of LDR Phase III Decharacterized Wastewater	PS	PO	C	N
62	DOCID... F-1996-PH3F-S0013 ..: Final; Best Demonstrated Available Technology (BDAT) - Background Document for Spent Potliners from Primary Aluminum Reduction - K088 Rorg...: U.S. EPA, Office of Solid Waste	PS	PO	C	N
63	DOCID..: F-1996-PH3F-S0013.A Appendix A: Treatment Performance Database and Methodology for Identifying Universal Treatment Standards for Constituents in Nonwastewater Forms of K088	PS	PO	C	N
64	DOCID..: F-1996-PH3F-S0013.B . Appendix B: Draft Annotated Index for the Administrative Record: Final Best Demonstrated Available Technology (BDAT) Treatment Standards, Phase III	PS	PO	C	N
65	DOCID..: F-1998-2P4F-S0015 ..: Technical Background Document: Human Health and Environmental Damages from Mining and Mineral Processing Wastes	PS	PO	C	N
66	DOCID..: F-1998-2P4F-S0015.A ..: Appendix A: Mining Waste Releases and Contaminants for Selected Facilities	PS	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
67	DOCID..: F-1998-2P4F-S0015.B ..: Appendix B: Memorandum to RCRA Docket F-95-PH4A-FFFFF Discussing Natural Resource Damages from Mining Operations	PS	PO	C	N
68	DOCID..: F-1998-2P4F-S0015.C ..: Appendix C: Documentation Regarding Releases from Mineral Processing Phosphogypsum Storage	PS	PO	C	N
69	DOCID..: F-1998-2P4F-S0016 ..: Final Technical Background Document: Identification and Description of Mineral Processing Sectors and Waste Streams	PS	PO	C	N
70	DOCID..: F-1998-2P4F-S0043 ..: Technical Background Document: Capacity Analysis for Land Disposal Restrictions - Phase IV: Newly Identified Toxicity Characteristic Metal Wastes and Mineral Processing Wastes, (Final Rule)	PS	PO	C	N
71	DOCID..: F-1998-2P4F-S0047 ..: Technical Background Document: Soil Treatability Analysis: Analysis of Treatability Data for Contaminated Soil Treatment Technologies, Final Report	PS	PO	C	N
72	DOCID..: F-1998-2P4F-S0063 ..: Regulatory Impact Analysis: Application of Phase IV Land Disposal Restrictions to Newly Identified Mineral Processing Wastes	PS	PO	C	N
73	DOCID..: F-1998-2P4F-S0064 ..: Regulatory Impact Analysis: Phase IV Land Disposal Restrictions - TC Metals Wastes, Final Report	PS	PO	C	N
74	Guidebook for QA/QC Procedures for Submission of Data for the Land Disposal Restrictions Program	IP	PO	I	N
75	Methodology for Developing Best Demonstrated Available (BDAT) Treatment Standards	IP	PO	I	N
76	SW-846 On-line Test Methods for Evaluating Solid Waste Physical/chemical Methods	IP	PO	I	N
77	DOCID..: F-1998-2P4F-S0044..: Technical Background Document: Background Document for Analysis of the Land Disposal Restrictions - Phase IV: Underground Injection Data and Issues.	PS	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
78	DOCID..: F-1998-2P4F-S0046..: Technical Background Report: Site-Wide Soils Remedy Report, Koppers Company, Inc., Superfund Site (Feather River Plant), Oroville, CA	PS	PO	C	N
79	DOCID..: F-1998-2P4F-S0054..: Technical Background Document: Technology Screening Guide for Treatment of CERCLA Soils and Sludges	PS	PO	C	N
80	DOCID..: F-1998-2P4F-S0058..: Technical Background Document: Application of the Phase IV Land Disposal Restrictions to Contaminated Media: Costs, Cost Savings, and Economic Impacts	PS	PO	C	N
81	DOCID..: F-1998-2P4F-S0059..: Technical Background Document: Treatability Analysis of Completed Demonstration Projects, (1995 EPA Site Program)	PS	PO	C	N
82	DOCID..: F-1998-2P4F-S0068..: Memorandum to the Record Regarding Development of Metal Treatment Standards	IP	PO	I	N
83	DOCID..: F-1998-2P4F-S00110..: Proposed Best Demonstrated Available Technology (BDAT) Background Document for Toxicity Characteristic Metal Wastes D004-D011	PS	PO	C	N
84	DOCID..: F-1998-2P4F-S00129..: Technical Resource Document: Solidification/Stabilization and its Application to Waste Materials, (EPA/530-R-93-012)	PS	ORD	C	N
85	DOCID..: F-1998-2P4F-S00146..: Treatment Technology Background Document	PS	PO	C	N

Methodology

The primary contact sent e-mails identifying, either specifically or generally, science documents she considered critical. This list was developed in consultation with a team of program office staff involved in the rulemaking. Using this information, we went to the docket and pulled the documents identified. We also met and talked on the phone with the primary contact about the rule and the critical documents.

Agency Comments and OIG Response

In commenting on the draft report, staff from the Office of Solid Waste and Emergency Response suggested specific changes related to the land disposal restrictions. In addition, they identified nine additional critical documents. We made the suggested changes to Case 4, evaluated the additional technical background documents identified by the program office, and appropriately added them to the table of critical documents.

Case 5

Reformulated Gasoline

Rule Title: Regulation of Fuels and Fuel Additives: Standards for Reformulated and Conventional Gasoline

Citation for Final Rule: 59 Federal Register 7716 (February 16, 1994)

EPA Start Action Notice: 2959

Brief description of the rule

EPA had established a National Ambient Air Quality Standard for ozone. To help achieve this standard, EPA required under section 211(k) of the amended Clean Air Act that gasoline sold in certain areas be reformulated to reduce vehicle emissions of toxic and ozone-forming compounds. These areas were the nine largest metropolitan areas with the most severe summertime ozone levels and other ozone nonattainment areas that opt into the program. In addition, the rule prohibited conventional gasoline sold in the rest of the country from becoming more polluted than it was in 1990.

The rule was implemented in phases. Retail sale of reformulated gasoline began on January 1, 1995, as did the provisions for the "simple model" certification, the anti-dumping program for conventional gasoline, and the associated enforcement procedures. During this phase (Phase I) from 1995 through 1999, either volatile organic compounds (VOC) and toxics had to be reduced by 15 percent of baseline emissions, or that of a formula fuel, whichever was more stringent. The baseline was emissions from 1990 model year vehicles. Certification of reformulated gasoline by the "complex model" began January 1, 1998. The Phase II performance standards became effective on January 1, 2000. Thus, for the year 2000 and beyond, the VOC and toxics performance standards must be no less than that of the formula fuel or a 25 percent reduction from baseline emissions, whichever is more stringent. The Phase II standards also required, under section 211(c) of the Clean Air Act, a reduction in emissions of oxides of nitrogen (i.e., NOx).

Brief description of science input to the rule

The rule was required as part of the Clean Air Act Amendments of 1990; that section of the amendments was a replacement recommended by the oil industry for language in the proposed law that would have required alternative fuel vehicles and infrastructure. The oil industry provided information that much larger emission benefits could be achieved earlier by reformulating gasoline rather than changing to alternative fuels. EPA carried out the rulemaking through a regulatory negotiation with the industry. In this process EPA, the oil industry, the auto industry, and other stakeholders provided available information on the impacts of gasoline changes on emissions, and (more importantly) committed to, throughout the rulemaking process, collecting the additional data needed to more accurately quantify the impacts.

Given the short timeline provided in the law for compliance with the reformulated gasoline provisions, the participants in the negotiations agreed that initial compliance would be based upon a model developed from the data available at the time (i.e., the "simple model"). A more "complex model" was then developed for the final rule on the basis of the much larger set of data available and required for compliance beginning in 1998. The results from this model was then further used in other models to confirm that the emission reductions from the fuel changes would in fact result in ozone level reductions. There were also studies on the relationships of various emissions to the formation of ozone. EPA pulled together the information needed to support the rule.

Description of critical documents:

One of the major technical documents supporting the rule was the regulatory impact analysis. It provided background information on the rule and addressed comments received on the proposal. See Reference 1.

Which emissions should be addressed and why was considered during development of the rule. Before the rule was proposed, EPA had already done some work on the health risks associated with emissions from automobiles. See Reference 2. Further, the relationship of various emissions needed to form ozone was evaluated. See References 3 and 4.

Several organizations tested emissions from automobiles using different kinds of gasoline. The earliest were done by an industry consortium, but EPA and others also did testing. See References 5 through 11. The emission information was used to establish the baselines with which the reformulated gasoline would be compared. In addition, the information was used in models to determine how the different gasolines would effect the formation of ozone. See References 12 and 13.

EPA also used the emission information to improve the Mobile Source Emission Factor Model (see Reference 14); it can estimate the impact of the reformulated gasoline program on emissions and is used by states to prepare emission inventories.

Furthermore, EPA used the emission information for developing the models to determine compliance with the law during the two phases in which the rule would be implemented. During the first phase, which took effect in 1995, the "simple model" would be used to certify that a gasoline met applicable emission reduction standards. The simple model allowed certification based on a fuel's oxygen, benzene, heavy metal and aromatics content and Reid Vapor Pressure (RVP). In accordance with the regulatory negotiation agreement, EPA proposed the "complex model" to supplant the simple model for certifying compliance with these standards. Certification under the complex model took effect in 1998. EPA considered the “simple” and “complex models” more accurate, faster, cheaper, and more practical to use than actual vehicle testing in predicting the emission effects of fuel modifications.

The emission information showed that NOx emission reductions could be achieved through fuel changes. Consequently, although section 211(k) only required that NOx not increase because of the reformulated gasoline, the rule required a reduction in NOx.

Finally, the cost of using reformulated gasoline was considered. See References 15 through 19. This information became part of the regulatory impact analysis.

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	U.S. EPA, December 1993, "Final Regulatory Impact Analysis For Reformulated Gasoline"	IP	PO	I	U
2	Adler, J.A., Carey, P.M., 1989, "Air Toxics Emissions and Health Risks from Mobile Sources", In: Air & Waste Management Associations 82nd Annual Meeting and Exhibition, Anaheim, CA, June 25-30, 1989.	IP	PO	I	ENP
3	Milford, J.B., Russell, A.G., and McRae, G.J., 1989, "A New Approach to Photochemical Pollution Control: Implications of Spatial Patterns in Pollutant Responses to Reductions in Nitrogen Oxides and Reactive Organic Gas Emissions," Environment Science Technology, vol. 23, pp. 1290-1301	AC	O	G	ENP
4	Finlayson-Pitts, B.J. and J.N. Pitts, Jr., 1993, "Atmospheric Chemistry of Tropospheric Ozone Formation: Scientific and Regulatory Implications," Air and Waste, Vol. 43, August, pp. 1091-1100	AC	U	U	ENP
5	Auto/Oil Air Quality Improvement Research Project (AQIRP), 1990, 1991, 1992, various technical bulletins showing results of emission testing	PS	O	O	ENP
6	Boekhaus, K.L. et al, 1991, Society of Automotive Engineers, Technical Paper 911628, "Reformulated Gasoline for California: EC-Premium Emission Control Gasoline and Beyond", In: Future Transportation Technology Conference and Exposition, Portland, OR, August 5-7, 1991, Warrendale, PA	PS	O	O	ENP
7	California Air Resources Board, July 1991, "Evaluation Of The Effects Of Lowering Gasoline Volatility From 7.8 RVP to 7.0 RVP: A Work Plan"	OG	O	O	U
8	U.S. EPA, November 1992, "Emission Testing of Reformulated Gasoline" (Note: Also published as SAE Technical Paper 941973.)	PS	PO	C	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
9	“Exhaust VOC Emission Inventory By Vehicle Emitter Class Following Implementation of an Enhanced Inspection and Maintenance (I/M) Program", Memorandum from EPA staff (Christian Lindhjem and David Brzezinski) to EPA Air Docket A-92-12, June 24, 1993	IP	PO	I	U
10	Society Of Automotive Engineers, 1994, "Reformulated Gasoline Effects on Exhaust Emissions: Phase II: Continued Investigation of the Effects of Fuel Oxygenate Content, Oxygenate Type, Volatility, Sulfur, Olefins and Distillation Parameters", SAE Technical Paper 941974	PS	PO	C	ENP
11	Society Of Automotive Engineers, 1995, "Reformulated Gasoline Effects on Exhaust Emissions: Phase II: Investigation on the Effects of Sulfur, Olefins, Volatility, and Aromatics and the Interactions Between Olefins and Volatility or Sulfur", SAE Technical Paper 950782	IP	PO	I	ENP
12	Systems Applications International, September 1992, "Modeling The Effects Of Reformulated Gasolines On Ozone And Toxics Concentrations In The Baltimore And Houston Areas", San Rafael, CA	PS	PO	C	U
13	Sillman, S., Samson, P.J., and Masters, J.M., 1993, "Ozone Production in Urban Plumes Transported over Water: Photochemical Model and Case Studies in the Northeastern and Midwestern United States," J. Geo. Res., vol. 98, number D7, pp. 12,687-12,699	AC	O	CA	ENP
14	U.S. EPA, May 1994, "Mobile Source Emission Factor Model"	IP	PO	I	U
15	Auto/Oil AQIRP, January 1992, "Estimated Costs Of Modifying Gasoline Properties", Economic Bulletin No. 2	PS	O	O	ENP
16	Turner, Mason & Company, April 1992, "Costs Of Alternate Gasoline Reformulations Results Of U.S. Refining Study"	PS	O	O	U
17	U.S. EPA, October 1992 "Draft Report, Evaluation and Costing of NOx Controls for Existing Utility Boilers in the NESCAUM Region"	PS	PO	C	U

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
18	Bonner & Moore Management Science, December 1992, rough draft, "Study of the Effects of Sulfur and Olefins on the Cost of Producing Reformulated Gasoline"	PS	PO	C	U
19	Bonner & Moore Management Science, June 1993, "Study of the Effects of Fuel Parameter Changes on VOC Emissions and on the Cost of Producing Reformulated Gasoline"	PS	PO	C	U

Methodology

The primary contact, a program scientist, and an ORD scientist sent e-mails identifying, either specifically or generally, science documents they considered critical. Using this information, we went to the docket (A-92-12) and pulled the documents identified. In addition, we identified a few other documents from the docket that we thought might be critical, and pulled them.

We were unable to find in the docket some of the documents identified by the scientists, particularly the program scientist; he had listed some of the references we had seen in the Regulatory Impact Analysis. After contacting both the ORD and program scientist, the program scientist sent the team copies of some of these documents.

Miscellaneous Other Information

Several of the critical documents referenced in the regulatory impact analysis were not in the docket for the rule. However, we were able to get copies from the EPA staff.

Case 6
Great Lakes Water Quality

Rule Title: Water Quality Guidance for Great Lakes System

Citation for Final Rule: 60 Federal Register 15366 (March 23, 1995)

EPA Start Action Notice: 3203

Brief description of the rule

In 1986, the Governors of the eight Great Lakes States signed the Great Lakes Toxic Substances Control Agreement, pledging the States' cooperation in studying, managing and monitoring the Great Lakes as an integrated ecosystem. EPA and the Great Lakes States initiated the Great Lakes Water Quality Initiative in 1989 to address the environmental concerns identified in the Governors Agreement, and to provide a forum to develop uniform water quality criteria and implementation procedures for the basin. The participants planned to use the results of this effort as a basis for revising State water quality standards and permit programs pursuant to sections 303(c) and 402 of the Clean Water Act (CWA). The Great Lakes Critical Programs Act (CPA) of 1990 (P.L. 101-596) codified the ongoing Initiative effort into the CWA. Section 101 of the CPA (CWA section 118(c)(2)) required EPA to publish water quality guidance for the Great Lakes System which conformed with the objectives and provisions of the Great Lakes Water Quality Agreement (GLWQA) and was no less restrictive than provisions of the CWA and National water quality criteria and guidance.

Section 118(c)(2) required EPA to publish proposed and final water quality guidance on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System. The Guidance consisted of water quality criteria for 29 pollutants to protect aquatic life, wildlife, and human health, and detailed methodologies to develop criteria for additional pollutants; implementation procedures to develop more consistent, enforceable water quality-based effluent limits in discharge permits, as well as total maximum daily loads of pollutants that could be allowed to reach the Great Lakes and their tributaries from all sources; and antidegradation policies and procedures. Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin had to adopt provisions consistent with the Guidance into their water quality standards and NPDES permit programs by March 1997, or EPA would promulgate the provisions for them.

Brief description of science input to the rule

Three committees were formed under the Initiative. A Steering Committee, consisting of directors of water programs from EPA's National and Regional offices and the Great Lakes States' environmental agencies, discussed policy, scientific and technical issues and directed the work of the Technical Work Group. The Technical Work Group, consisting of technical staff from the Great Lakes States environmental agencies, EPA, the U.S. Fish and Wildlife Service and the U.S. National Park Service, prepared proposals on scientific guidance for submission to the Steering Committee. A Public Participation Work Group, consisting of representatives from environmental groups, municipalities, industry and academia, observed the deliberations of the other two groups, advised them of the public's concerns, and kept its various constituencies apprized of Initiative activities. In 1992, internal EPA teams actually wrote the rule language and technical support documents.

The rule covered a wide range of pollutants, including the "bioaccumulative chemicals of concern" (BCCs) that were widely believed to be causing poor reproductive success and deformities in gulls and increased risk of cancer and the potential for systemic or non-cancer effects such as kidney damage in people consuming fish from the lakes (risks as high as 2.5×10^{-3}). Toxicological data from more than 100 contaminants found in the lakes showed the potential for acute of chronic effects on aquatic life, wildlife, or human health, including PCBs, DDT, dioxin, chlordane, and mirex.

Against this background, ambient water quality criteria for the six Great Lakes States differed by as much as an order of magnitude for many of the pollutants of concern. Wide variation also existed in procedures for translating water quality criteria into discharge permits, e.g., in procedures for the granting of mixing zones, interpretation of background levels of pollutants, consideration of pollutants present in intake waters, controls for pollutants present in concentrations below the level of detection, and determination of appropriate levels for pollutants discharged in mixtures with other pollutants. Also, when addressing accumulation of chemicals by fish some States considered accumulation through multiple steps in the food chain (bioaccumulation), while others considered only the single step of concentration from the water column (bioconcentration). Further disparities existed in deriving numeric values for implementing narrative water quality criteria, different practices in deciding what pollutants need to be regulated in a discharge, what effect detection limits have on compliance determinations, and how to develop whole effluent toxicity limitations.

The guidance provided numeric criteria (both acute and chronic) to protect aquatic life for 15 pollutants and a two-tier methodology to derive criteria or values for new pollutants. Tier I criteria (similar to the existing 304(a) CWA guidance), were to be based on laboratory toxicology data for at least eight families representing different habitats and taxonomic groups. Tier II values could be derived from acceptable toxicity tests on a single family, but must use uncertainty factors. States were allowed to substitute whole effluent toxicity (WET) testing in lieu of Tier II values, if they could show that the parameter will attain the narrative water quality standard that protects aquatic life. On finalization, the aquatic criteria for metals were changed from total recoverable metals to dissolved metals, using conversion factors to convert the former to the latter (59 FR 44678).

The final Guidance contained numeric human health criteria for 18 pollutants, as well as methodologies to derive cancer and non-cancer human health criteria for additional pollutants (two pollutant were dropped from the proposal because they did not meet the more restrictive minimum data requirements for bioaccumulation factors (BAFs) used in the final Guidance). Chronic criteria were derived to reflect long-term consumption of food and water from the Great Lakes System. The proposed and final Guidance established 10^{-5} as the risk level to be used for carcinogens. The final Guidance included a Great Lakes-specific fish consumption rate of 15 g/day, based upon several fish consumption surveys from the Great Lakes, including a study by West et al. (59 FR 44678). This rate differed from the national average consumption value of 6.5 g/day rate used in the National water quality criteria guidelines.

Commenters argued that a 15 g/day assumption would not adequately protect populations that consume greater than this amount (e.g., low-income minority anglers and Native Americans), and that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (59 FR 7629). EPA held that the human health criteria methodology, including the fish consumption rate, would provide adequate health protection for the public, because if fish are contaminated at the level permitted by criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected at the 10^{-4} risk level. Available data indicated that, even among low-income minorities who as a group consume more fish than the population on average, the overwhelming majority (approximately 95 percent) consume less than 150 grams per day (West, et al.). The final Guidance required that States and Tribes modify the human health criteria on a site-specific basis to provide additional protection appropriate for highly exposed sub-populations greater than 10^{-4}. The final Guidance also requires States and Tribes to adopt provisions to protect human health from the potential adverse effects of mixtures of pollutants in effluents, specifically including mixtures of carcinogens.

In developing bioaccumulation factors, the final Guidance used BAFs predicted from biota-sediment accumulation factors (BSAFs) in addition to field-measured BAFs, and used a food chain multiplier (FCM) to account for biomagnification when using measured or predicted bioconcentration factors (BCFs). The final Guidance uses a 3.10 percent lipid value for trophic level 4 fish and 1.82 percent for trophic level 3 fish. These values are based on an analysis of the West et al. study and data from State fish contaminant monitoring programs. The final Guidance placed a cap of 30,000 on the combined product of uncertainty factors that may be applied in the derivation of non-cancer Tier II values and a combined uncertainty factor of 10,000 for Tier I criteria. The likely maximum combined uncertainty factor for Tier I criteria in most cases is 3,000. The proposed Guidance used an 80 percent relative source contribution (RSC) from surface water pathways for BCCs and a 100 percent RSC for all other pollutants in deriving noncancer criteria. The RSC concept is applied in the National drinking water regulations and is intended to account, at least in part, for exposures from other sources for those bioaccumulative pollutants for which surface water pathways are likely to be major contributors to human exposure. The final Guidance used the more protective 80 percent RSC for all pollutants in deriving noncancer criteria. This change was made because of concern that for non-BCCs as well as BCCs, there may be other sources of exposures for noncarcinogens.

The final Guidance contained numeric criteria to protect wildlife from four pollutants and a methodology to derive Tier I criteria for additional BCCs. They were EPA's first water quality criteria specifically for the protection of wildlife. The methodology was based largely on the noncancer human health paradigm, but focused on reproduction and population survival rather than the survival of individuals. The methodology incorporated pollutant-specific effect data for a variety of mammals and birds and species-specific exposure parameters for two mammals and three birds representative of mammals and birds resident in the Great Lakes basin. The decision to restrict wildlife criteria to BCCs was consistent with comments made by the EPA Science Advisory Board (EPA-SAB-EPEC-ADV–94–001). Commenters were concerned that the mercury criterion for wildlife was not scientifically appropriate. After review of all comments and a reevaluation of all the data, the mercury criterion for wildlife was increased from 180 pg/L to 1300 pg/L. EPA believed the 1300 pg/L would be protective of wildlife in the Great Lakes System. In developing bioaccumulation factors, the proposed Guidance used a 7.9 percent lipid value for fish consumed by wildlife. The final Guidance used a 10.31 percent lipid value for trophic level 4 fish and 6.46 for trophic level 3 fish. These values were based on the actual prey species consumed by the wildlife species specified in the methodology, and are used to estimate the BAFs for the trophic levels which those species consume, and were based on the preferential consumption patterns of wildlife and cross-referenced with fish weight and size and appropriate percent lipid. This approach was believed to be a more accurate reflection of the lipid content of the fish consumed by wildlife species than the approach used in the proposal.

EPA guidelines for the derivation of human health water quality criteria use BCFs, which measure only uptake from water, when field-measured BAFs are not available. EPA believed, however, that the BAF is a better predictor of the concentration of a chemical in fish tissues in the Great Lakes because it considered uptake of contaminants from all routes of exposure. The proposed Guidance included a hierarchy of three methods for deriving BAFs for non-polar organic chemicals: field-measured BAFs; predicted BAFs derived by multiplying a laboratory-measured BCF by a food-chain multiplier; and BAFs predicted by multiplying a BCF calculated from the log K_{OW} by a food-chain multiplier. For inorganic chemicals, the proposal would have required either a field-measured BAF or laboratory-measured BCF. Based on comments received, the final Guidance modified the proposed hierarchy by adding a predicted BAF based on a BSAF as the second method in the hierarchy. BSAFs may be used for predicting BAFs from concentrations of chemicals in surface sediments. In addition, the final Guidance used a model to assist in predicting BAFs that includes both benthic and pelagic food chains, thereby incorporating exposures of organisms to chemicals from both the sediment and the water column. The model used in the proposal only included the pelagic food chain, and therefore did not account for exposure to aquatic organisms from sediment.

The proposed Guidance used the total concentration of a chemical in the ambient water when deriving BAFs for organic chemicals. EPA requested comments on deriving BAFs in terms of the freely dissolved concentration of the chemical in the ambient water. Based on comments received from the proposal and the document, the final Guidance uses the freely dissolved concentration of a chemical instead of the total concentration in the derivation of BAFs for organic chemicals in order to improve the accuracy of extrapolations between water bodies.

The proposed Guidance would have required that pollutants with human health BAFs greater than 1000 receive increased attention and more stringent controls within the Great Lakes System. These pollutants are termed BCCs. EPA identified 28 BCCs in the proposed Guidance. The additional controls for BCCs are specified in certain of the implementation procedures and the antidegradation procedures, and are discussed further in the SID. The final Guidance identified 22 BCCs to be targeted for special controls instead of the 28 in the proposed Guidance. Six BCCs were deleted from the proposed list because of concern that the methods used to estimate the BAFs may not account for metabolism or degradation of the pollutants in the environment.

EPA has traditionally developed numeric water quality criteria on a single pollutant basis, but most potential environmental hazards involve mixtures of two or more pollutants. The individual pollutants in such mixtures can act or interact in various ways which may affect the magnitude and nature of risks or effects on human health, aquatic life, and wildlife. WET tests address interactive effects of mixtures on aquatic organisms. EPA's 1986 ''Guidelines for the Health Risk Assessment of Chemical Mixtures'' set forth principles and procedures for human health risk assessment of chemical mixtures, but there were no technical guidelines on how to assess effects on wildlife from chemical mixtures. Regulatory language was proposed for two options, each with separate provisions for aquatic life, wildlife and human health. One approach was developed by the Initiative Committees, modified to delete the application of toxicity equivalency factors (TEFs) for PCBs to wildlife; the other was developed by EPA. Neither approach addressed the possible toxicologic interactions between pollutants in a mixture (e.g., synergism or antagonism) because of the limited data available on these interactive effects. In the absence of contrary data, both approaches recommended that the risk to human health from individual carcinogens in a mixture be considered additive, and that a 10^{-5} risk level be adopted as a cap for the cancer risk associated with mixtures. Both approaches also proposed using TEFs to assess the risk to humans and wildlife from certain chemical classes. The TEF approach converts the concentration of individual components in a mixture of chemicals to an ''equivalent'' concentration expressed in terms of a reference chemical. Both approaches used the 17 TEFs for dioxins and furans. The final Guidance includes a general requirement for States and Tribes to adopt an additivity provision to protect human health from the potential additive adverse effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents and required the use of the 17 TEFs included in the proposed Guidance to protect human health from the potential additive adverse effects in effluents.

The proposal attempted to develop a single, consistent approach for developing TMDLs, but there are no critical scientific or technical references in the corresponding section of the Supplementary Information Document. The regulations allowed States and Tribes the flexibility to control for WET with either numeric or narrative criteria, and allowed the States and Tribes to adopt 0.3 TUa and 1.0 TUc, either as numeric criteria or as an equivalent numeric interpretation of narrative criteria, and allowed the use of acute mixing zones for the application of the acute criteria, but again without citing scientific references.

Critical science inputs thus involved available toxicology data on humans and aquatic life for the pollutants for which criteria were established by the final rule; new criteria and a methodology developed by the Initiative Committees to specifically protect wildlife; incorporation of new data on the bioavailability of metals into the aquatic life criteria and methodologies; incorporation of Great Lakes-specific data on fish consumption rates and fish lipid contents into the human health criteria; and a methodology to determine the bioaccumulation properties of individual pollutants.

Description of critical documents

The major supporting documents underlying the rule fall into two groups. EPA prepared the Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID) [Reference 1] to provide a detailed discussion (with references) of EPA's reasons for issuing the final Guidance, analysis of comments and issues, description of specific changes made to the proposed Guidance, and further description of the final Guidance. EPA also prepared the Regulatory Impact Analysis (RIA) [Reference 2], which documents in Chapter 6 the risk levels faced by populations consuming fish and other aquatic biota in the region (the risk levels were key to setting the criteria). The RIA is heavily scientifically referenced. Finally, the Response to Comments [Reference 64] was identified by one of the Region scientists as explaining the critical science issues.

Other major supporting documents were developed by teams of EPA staff from the Office of Water, ORD, and the Regions, and they provide the detailed treatments of each issue summarized in the SID. The first three cover the development of criteria for wildlife and aquatic life, respectively: Great Lakes Water Quality Initiative Criteria Technical Support Document for Wildlife Criteria [Reference 3], Great Lakes Water Quality Initiative Criteria Documents for the Protection of Wildlife - DDT, Mercury, 2,3,7,8-TCDD, PCBs [Reference 4], and Great Lakes Water Quality Initiative Criteria Document for the Protection of Aquatic Life in Ambient Water [Reference 5]. The Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors. [Reference 6] develops the approach to bioaccumulation factors that serve as the core of a common approach for the Great Lakes States. The Great Lakes Water Quality Initiative Criteria Document for the Protection of Human Health. [Reference 7] sets forth the basis for the human health criteria for people eating fish and wildlife from the Great Lakes basin.

Several papers and reports about specific compounds of concern were identified by various respondents as critical “early mover” science. Because the documents were dated *after* the CPA, they could not have played a critical role in passage of the Act that required the guidance to be issued. That said, several of these documents stand out in the Background chapter of the SID as creating or sustaining concern about toxics in the Great Lakes. A report by Environment Canada. (1991) Toxic chemicals in the Great Lakes and associated effects. Vols I & II. [Reference 8] summed up the information then known about toxics problems in the Great Lakes Basin. Papers by Colborn (1991), Gilbertson et al. (1991), Giesey et al. (1994), Mora et al. (1993), and Tillet et al. (1992) all showed evidence of harm to birds from various toxics in the Great Lakes [References 9-13]; Colborn at al (1990) showed that the primary route of human exposure was fish consumed from the lake [Reference 14], and Swain (1991) and Fein et al.. (1984) [References 15-16] showed some potential for adverse pregnancy outcomes in the Basin using epidemiological studies. Also, a series of papers by Devault et al. [References 17-21] pointed to the fact that declining contaminant residues in fish tissue had been leveling off by the early 1990s.

Respondents identified a large number of critical references in support of development of fish and wildlife criteria. Respondents indicated that the rule relied heavily in its approach on EPA’s 1992 Framework for Ecological Risk Assessment [Reference 22]. Respondents identified several papers as being critical to the development of a model to establish bioavailability factors, which also were cited in the SID (Eadie 1990, Thomann and Conneley 1984, Thomann 1989, Gobas 1993, MacKay 1992) [References 23-27], and Oliver and Niimi (1983, 1988) and Niimi (1985) [References 28-30], who provided real-world lake data against which to test the model. Niimi (1988) also was used to derive composite DDT and metabolite BAF values for aquatic trophic levels 3 and 4, based on weighting the BAF for DDT, DDE, and DDD (derived for the dissolved fraction), in accordance with the fraction of each compound in the Great Lakes fish species. A paper by DeWolf et al. (1992) [Reference 53] was cited by ORD scientists as introducing a critical lipid-normalizing adjustment for BCFs, and another by Chin and Gschwand (1992) [Reference 54] that developed a critical equation for determining the fraction of the chemical that is freely dissolved in the water. Both were cited in Reference 6, but not the SID. A report by Host et al. (1991) [Reference 60] was cited by program scientists as important in establishing the basis for "adjustment factors" to be used to develop aquatic life criteria when a limited suite of toxicological data for the chemical in question was available. The model development is unique in that it appears to have been developed through a collaboration of researchers working at a number of institutions funded through diverse funding sources. The EPA report, Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlordibenzo-p-dioxin Risks to Aquatic Life and Associated Wildlife [Reference 31] was cited as the conceptual basis for the definitions, derivation methods, and application methods for BAFs.

Program and ORD scientists identified two critical papers that provided the background for guidance on the Tier I and Tier II water quality criteria. The Tier I approach was based on Stephan et al. (1985) [Reference 56]. The Tier II approach was cited as Host, GE, Regal, RR, and Stephan, CE. Analyses of Acute and Chronic Data for Aquatic Life. 3-16-95., and although it was referred to in the SID, it was not cited in the references. The Program office scientist also cited a draft report, Results of simulation tests concerning the percent dissolved metal in freshwater toxicity tests (Stephan 1994) [Reference 57] as critical in determining the percent dissolved metal in freshwater toxicity tests. This draft paper is cited in the SID.

Of the 24 references in the Human Health Chapter of the SID, respondents identified only two reports by West et al (1989, 1993). While two other papers on fish consumption and the West (1989) paper were used to identify a regional fish consumption estimate in the proposal, the West 1993) study [Reference 32], because it included an entire year of data and split fish into trophic levels, proved definitive. This report increased the estimates of fish consumption in the Great Lakes region by a factor of two (and thus reduced the allowable contamination levels by a factor of two), and also was used to specify the mix of trophic level fish in the diet (higher trophic level fish have higher tissue values for bioaccumulative contaminants).

The evaluator carefully read the Health Effects Chapter of the SID and identified several other references that appear to be critical. Dedrick (1973), Freirich et al. (1986), and Pinkel (1958) [References 33-35] are cited in support of a 2/3 surface area scaling factor for converting effects on test organisms to humans (against a proposal to use a 3/4 body weight scaling factor). EPA’s Exposure Factors Handbook (1989) [Reference 36] is cited several times, in support of default body weights and water consumption. Although several papers are cited, the tap water study of Ershow and Cantor (1989) [Reference 37] seems to have done the most to persuade EPA that the 2.0 L/day default value was appropriate. The program office scientist also said, “we used several data sources such as the Ceasars and Acquire databases, to develop aquatic life criteria. We used information in the IRIS database to develop Human Health criteria. We also used several state databases to determine percent lipid values of fish (needed to develop BAFs).” These databases were from the fish contaminant monitoring programs in Michigan, Wisconsin, Ohio, Indiana, New York and Minnesota. No explicit sources were identified in the Health Document; the sources were in the TSD for bioaccumulation factors.

Responding to comments on various criteria values for human health, the SID cited Norback and Weltman (1985) [Reference 38] in support of the slope factor for cancer risk from PCBs, Bowman et al. (1989) [Reference 39] on non-cancer risks from TCDD, and the Sauer (1990) reevaluation of the data of Kociba et al. (1978) [References 40 and 41] on TCDD cancer criteria. Although not identified by respondents, the SID references the EPA Risk Assessment Forum report, Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans and 1989 Update (EPA 1989) [Reference 53] in support of the additivity approach for toxic equivalency factors for human health.

ORD scientists working on the Technical Committee identified a number of documents critical to the development of Wildlife criteria. Many, but not all, were referenced in the Wildlife Chapter of the SID. Allometric equations from Nagy (1987) [Reference 42] were used to determine food and water ingestion rates when species-specific data were not available, but also allowed the use of the approach in EPA (1993) [Reference 36]. A study by Dunning (1984) [Reference 60], cited in Reference 5, was used to adjust the factors for body weights in different bird species, and a study by Calder and Braun (1983) [Reference 61] cited in Reference 3 provided a critical allometric equation for estimating drinking water ingestion rates in different species. The dose/response curve for the avian TD for mercury depended on data from a series of studies by Heinz, of which three were cited by the ORD scientists (1976a, 1976b, and 1979) [References 43-45], and Wobeser et al. (1976) [Reference 46] was cited to defend the uptake factor for mercury in mammals. A study by Anderson (1975) [Reference 47] was cited by the ORD scientists and the SID in defense of deriving water quality criteria for DDT and its metabolites, and as was Baune and Norstrum (1989) and Aulerich and Ringer (1977) [References 48 and 49] for biomagnification factors for PCBs and 2,3,7,8 TCDD, and Nosek et al. (1992) [Reference 50] for avian uptake factors for 2,3,7,8 TCDD. ORD scientists identified a pheasant study by Dahlgren et al. (1972) [Reference 58] that was used to derive the avian wildlife value for PCBs, and a study by Murray et al. (1979) [Reference 59], that was used to develop the mammalian wildlife value for 2,3,7,8-TCDD.

ORD scientists cited two reports by EPA's Science Advisory Board (EPA 1992, 1994) [References 51 and 52] as being critical. The 1992 SAB evaluation of the then nascent guidance indicated concern with the wildlife criteria concepts being formulated around the perceived requirements of the noncancer human health paradigm, which might be inadequate for wildlife. EPA made several changes in response to the SAB's commentary in the proposed Guidance (58 FR 20882). The 1994 SAB commentary (EPA1994) found that, with the changes, it promised to be an innovative and valuable new method for understanding the fate and effects of contaminants in the environment, which led to EPA believing the approach to be appropriate.

Finally, the primary contact for the region identified two reports as particularly important in independently confirming the ability of the States in the region to afford the rule, which is important because water quality criteria do consider costs. The reports are, Great Lakes Water Quality Initiative: Cost Effective Measures to Enhance Environmental Quality and Regional Competitiveness (1993) and Great Lakes Water Quality Initiative, Cost Effectiveness Update (1995) [References 62 and 63].

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID). EPA-820-B-95-001, U.S. EPA Office of Water. March 1995	IP	PO	I	FACA
2	RCG/Hagler Bailly. 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance - Final Report. Prepared by R.S. Raucher, E. Trabka, and A. Dixon for the U.S. EPA. April 15.	PS	PO	C	N
3	Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria. EPA-820-B-95-009. U.S. EPA Office of Water. March 1995	IP	PO	C	FACA
4	Great Lakes Water Quality Initiative Criteria Documents for the Protection of Wildlife DDT, Mercury, 2,3,7,8-TCDD, PCBs. EPA-820-B-95-008. U.S. EPA Office of Water. March 1995	IP	PO	C	U
5	Great Lakes Water Quality Initiative Criteria Document for the Protection of Aquatic Life in Ambient Water. EPA-820-B-95-004. U.S. EPA Office of Water. March 1995	IP	PO	C	U
6	Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors. EPA-820-B-95-005. U.S. EPA Office of Water. March 1995	IP	PO	C	U
7	Great Lakes Water Quality Initiative Criteria Document for the Protection of Human Health. EPA-820-B-95-006. U.S. EPA Office of Water. March 1995	IP	PO	C	U
8	Environment Canada. (1991) Toxic chemicals in the Great Lakes and associated effects. Vol. II. Effects. Canada. Department of Fisheries and Oceans, Health and Welfare.	OG	O	U	U
9	Colborn, T.I. 1991. Epidemiology of Great Lakes bald eagles. J. Toxicol. Environ. Health Toxicol. 33:395-453.	PS	U	U	ENP
10	Gilbertson, M., T. Kubiak, J. Ludwig, and G. Fox. 1991. Great Lakes embryo mortality, edema, and deformities syndrome (GLEMEDS) in colonial fish--eating birds: similarity to chick-edema disease. J. Toxicol. Environ. Health, 33: 455-520.	OF	OF	O	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
11	Giesy, J.P., J.P. Ludwig, and D.E. Tillitt. 1994. Deformities in birds of the Great Lakes region: Assigning causality. Environ. Sci. Technol., 28(3): 128A-135A.	AC	O	U	N
12	Mora, M.A., H.J. Auman, J.P. Ludwig, J.P. Giesy, D.A. Verbrugge, and M.E. Ludwig. 1993. Polychlorinated biphenyls and chlorinated insecticides in plasma of Caspian terns: relationships with age, productivity, and colony site tenacity in the Great Lakes. Arch. Environ. Contam. Toxicol. 24: 320-331.	AC	O	U	ENP
13	Tillitt, D.E., G.T. Ankley, J.P. Giesy, J.P. Ludwig, H. Kurita-Matsuba, D.V. Weseloh, P.S. Ross, C.A. Bishop, L. Sileo, K.L. Stromborg, J. Larson, and T. Kubiak. 1992. Polychlorinated biphenyl residues and egg mortality in double-crested cormorants from the Great Lakes. Env. Toxicol. Chem. 11: 1281-1288.	AC	O	U	ENP
14	Colborn, T.E., Davidson, A., Green S.N., Hodge, R.A., Jackson, C.I., and Liroff, R.A. 1990. Great Lakes, Great Legacy? Washington, D.C.: The Conservation Foundation; and Ottawa, Ontario: The Institute for Research on Public policy; 174.	PS	O	U	U
15	Swain, W.R. 1991. Effects of organ-chlorine chemicals on the reproductive outcomes of humans who consumed contaminated Great lakes fish: an epidemiologic consideration. J. Toxicol. Environ. Health 33: 587-639.	PS	O	G	ENP
16	Fein, G.G., J.L. Jacobson, S.W. Jacobson, P.M. Schwartz, and J.K. Dowler. 1984b. Prenatal exposure to polychlorinated biphenyls: Effects on birth size and gestational age. J. Pediatr. 105(2): 315-320.	AC	ORD	CA	ENP
17	DeVault, D.S., W.A. Willford, R.J. Hesselberg, D.A. Nortrupt, D.A. Rundberg, A.K. Alwan, and C. Bautista. 1986. Contaminant trends in lake trout (Salvelinus namaycush) from the upper Great Lakes. Arch. Environ. Contam. Toxicol. 15:349-356	IP	PO/OF	I	ENP
18	DeVault, D.S., J.M. Clark, G. Lahvis, and J. Weishaar. 1988. Contaminants and trends in fall run coho salmon. J. Great Lakes Res. 14:23-33.	IP	PO	I	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
19	DeVault, D.S. 1993a. Data on contaminant trends in Lake Trout (Unpublished). Contains data for 1984-1990.	IP	PO	I	U
20	DeVault, D.S. 1993b. Data on contaminant trends in fall run coho salmon (Unpublished). Contains data for 1986-1990	IP	PO	I	U
21	DeVault, David S., and R. Hesselberg. 1994. Contaminant trends in lake trout and walleye from the St. Lawrence Great Lakes. (Final Draft	IP/OF	PO	I	U
22	U.S. Environmental Protection Agency. 1992. Framework for Ecological Risk Assessment. Washington D.C. EPA/630/R-92/001.	IP/IO	ORD	I	FACA
23	Eadie, B.J., N.R. Morehead, and P.F. Landrum. 1990. "Three-phase partitioning of hydrophobic organic compounds in Great Lakes waters." Chemosphere, 20, 161-178.	OF	OF	O	ENP
24	Thomann, R.V. and J.P. Connolly. 1984. Model of PCB in the Lake Michigan lake trout food chain. Environ. Sci. Technol. 18: 65-71.	AC	ORD	CA	ENP
25	Thomann, R.V. 1989. Bioaccumulation Model of Organic Chemical Distribution in Aquatic Food Chains. Environ. Sci. Technol. 23:699-707	AC	OF	G	ENP
26	Gobas, F.A.P.C. 1993, "A model for predicting the bioaccumulation of hydrophobic organic chemicals in aquatic food-webs: application to Lake Ontario." Ecological Modelling, 69, 1-17.	AC	O	U	ENP
27	Mackay, D. 1982. Correlation of bioconcentration factors. Environ. Sci. Technol. 16:274-278.	AC	PO/O	U	ENP
28	Oliver, B.G. and A.J. Niimi. 1983. Bioconcentration of chlorobenzenes from water by rainbow trout: correlations with partition coefficients and environmental residues. Environ. Sci. Technol. 17:287-291.	OG	O	O	ENP
29	Oliver, B.G. and A.J. Niimi. 1988. Trophodynamic analysis of polychlorinated biphenyl congeners and other chlorinated hydrocarbons in the lake Ontario ecosystem. Environ. Sci. Technol. 22:388-397.	OG	O	O	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
30	Niimi, A.J. 1985. Use of laboratory studies in assessing the behavior of contaminants in fish inhabiting natural ecosystems. Water Poll. Res. J. Canada 20:79-88.	OG	O	O	ENP
31	U.S. EPA. 1993. Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlordibenzo-p-dioxin Risks to Aquatic Life and Associated Wildlife. EPA/600/R-93/055	IO	ORD	I	ENP
32	West, P., M. Fly, R. Marans, F. Larkin and D. Rosenblatt. 1993. 1991-1992 Michigan Sport Anglers Fish Consumption Study. Final report to the Michigan Great Lakes Protection Fund, Michigan Dept. of Natural Resources. University of Michigan, School of Natural Resources. Natural Resources Sociology Research Lab. Technical Report #6. May 1993.	AC	O	C	U
33	Dedrick, R.L. 1973. Animal Scale Up. J. Pharamcokin. Biopharm. 1:435-461.	OF	OF	O	ENP
34	Freireich, E.J., E.A. Gehan, D.P. Rall, L.H. Schmidt, and H.E. Skipper. 1966. Quantitative comparison of toxicity of anticancer agents in mouse, rat, hamster, dog, monkey and man. Cancer Chemother. Rep. 50:219-244.	OF/AC	OF	U	ENP
35	Pinkel, D.. 1958. The use of body surface area as a criterion of drug dosage in cancer chemotherapy. Cancer Res. 18:853-856.	AC	OF	G	ENP
36	U.S. Environmental Protection Agency. 1989. Exposure Factors Handbook, Washington, DC, Office of Health and Environmental Assessment. EPA/600/8-89/043.	IO	ORD	I	U
37	Ershow, A.G. and K.P. Cantor, 1989. Total Water and Tapwater Intake in the United States: Population-Based Estimates of Quantities and Sources, National Cancer Institute, Bethesda, MD.	OF	OF	O	U
38	Norback, D. and R.H. Weltman. 1985. Polychlorinated biphenyl induction of hepatocellular carcinomas in the Sprague-Dawley rat. Environ. Health Perspectives. 60:97-105	AC	OF	G	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
39	Bowman, R.E., et al. 1989. Chronic dietary intake of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) at 5 or 25 parts per trillion in the monkey: TCDD kinetics and dose-effect estimate of reproductive toxicity. Chemosphere. 18(1-6); 243-252.	AC/PS	ORD/OF	G	ENP
40	Sauer, R.M. 1990. Pathology Working Group: 2,3,7,8-Tetrachlorodibenzo-p--dioxin in Sprague-Dawley rats. Pathco, Inc. Submitted to the Maine Scientific Advisory Panel	PS	U	U	U
41	Kociba, R.J. et al. 1978. Results of a two-year chronic toxicity and oncogenicity study of 2,3,7,8-tetrachlorodibenzo-p-dioxin in rats. Toxicol. Applied Pharmacol. 46:279-303.	PS	O	O	ENP
42	Nagy, K. A. 1987. Field Metabolic Rate and Food Requirement Scaling in Mammals and Birds. Ecological Monographs. 57(2): 111-128.	AC	OF	C/G	ENP
43	Heinz, G.H. 1976a. Methylmercury: second-year feeding effects on mallard reproduction and duckling behavior. J. Wildl. Manage. 40(1): 82-90.	OF	OF	O	ENP
44	Heinz, G.H. 1976b. Methylmercury: second-year reproductive and behavioral effects on mallard ducks. J. Wildl. Manage. 40(4): 710-715	OF	OF	O	ENP
45	Heinz, G.H. 1979. Methylmercury: reproductive and behavioral effects on three generations of mallard ducks. J. Wildl. Manage. 43: 394-401.	OF	OF	O	ENP
46	Wobeser, G., N.D. Nielsen, and B. Schiefer. 1976. Mercury and mink: II. Experimental methyl mercury intoxication. Can. J. Comp. Med. 40: 34-45	AC	O	O	ENP
47	Anderson, D.W., J.R. Jehl, R.W. Risebrough, L.A. Woods, L.R. Deweese, and W.G. Edgecombe. 1975. Brown pelicans: improved reproduction off the southern California coast. Science 190: 806-808.	OF	OF	O	ENP
48	Braune, B.M. and R.J. Norstrom. 1989. Dynamics of organochlorine compounds in herring gulls: III. Tissue distribution and bioaccumulation in Lake Ontario gulls. Environ. Toxicol. Chem. 8: 957-968	OG	O	O	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
49	Aulerich, R.J. and R.K. Ringer. 1977. Current status of PCB toxicity to mink, and effect on the reproduction. Arch. Environ. Contam. Toxicol. 6: 279-292.	AC	O	G/O	ENP
50	Nosek, J.A., S.R. Craven, J.R. Sullivan, J.R. Olson, and R.E. Peterson. 1992. Metabolism and disposition of 2,3,7,8-tetrachlorodibenzo-p-dioxin in ring-necked pheasant hens, chicks, and eggs. J. Toxicol. Environ. Health. 35: 153-164.	AC	O	G	ENP
51	U.S. Environmental Protection Agency. 1992. An SAB report: Evaluation of the guidance for the Great Lakes Water Quality Initiative. Washington D.C. EPA-SAB-EPEC/DWC-93-005.	OF	O	O	FACA
52	U.S. Environmental Protection Agency. 1994. Advisory on the development of a national wildlife criteria program. Washington D.C. EPA-SAB-EPEC-ADV	OF	O	O	FACA
53	EPA 1989. Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of	IP	O	O	FACA
54	DeWolf W, de Bruijn JHM, Seinen W, Hermans JLM. 1992. Influence of biotransformation on the relationship between bioconcentration factors and octanol-water partition coefficients. Environ. Sci. Technol. 26:1197-1201.	AC	O	U	ENP
55	Chin, Y., and P.M. Gschwend. 1992. "Partitioning of polycyclic aromatic hydrocarbons to marine porewater organic colloids." Environ. Sci. Technol., 26, 1621-1626.	AC	OF/ORD	G	ENP
56	Stephan C.E., D.I. Mount, D.J. Hansen, J.H. Gentile, G.A. Chapman, and W.A. Brungs. 1985. Guidelines for deriving numerical National water quality criteria for the protection of aquatic organisms and their uses. Office of Research and Development.	IO	ORD	I	N
57	Draft Report: Results of Simulation Tests Concerning the Percent Dissolved Metal in Freshwater Toxicity Tests (Stephan, 8/1994	IO	ORD	I	N
58	Dahlgren, R.B., R.L. Linder, and C.W. Carlson. 1972. Polychlorinated biphenyls: their effects on penned pheasants. Environ. Health Perspectives 1:89-101.	AC	O	G	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
59	Murray, F.J., F.A. Smith, K.D. Nitschke, C.G. Huniston, R.J. Kociba and B.A. Schwetz. 1979. Three-generation reproduction study of rats given 2,3,7,8-tetrachlorodobenzo-p-dioxin (TCDD) in the diet. Toxicol. Appl. Pharmacol. 50:241-252.	PS	O	O	ENP
60	Dunning, J.B. 1984. Body Weights of 686 North American Birds. Monograph #1. Western Bird Banding Association.	PS	O	O	U
61	Calder III, W. A. and E. J. Braun. 1983. Scaling of Osmotic Regulation in Mammals and Birds. American Journal of Physiology. 244:601-606.	AC	OF	G	ENP
62	The Great Lakes Water Quality Initiative: Cost Effective Measures to Enhance Environmental Quality and Regional Competitiveness (DRI/McGraw-Hill, September 1993)	PS	O	C	U
63	Great Lakes Water Quality Initiative, Cost Effectiveness Update (DRI/McGraw-Hill, June 1995)	PS	O	C	U
64	Great Lakes Water Quality Guidance: Response to Comments	IP	PO	I	N

Methodology

We had an excellent response from the ORD scientists involved in the rule, who identified a large number of very specific documents, mostly associated with the fish and wildlife criteria. We also had very helpful responses from the primary contacts from the program and regional offices who identified additional documents pertaining to health risks and economics, and who also vetted the ORD scientists' responses. It is noteworthy however that all of the respondents failed to identify two of the major technical support documents. In any case, all of the technical support documents were available in electronic format. This allowed easy searching of the TSDs for the references provided by the respondents, which in turn not only made the significance of these documents clear, but also helped the evaluator to identify additional critical documents. Of all the rules in the pilot study, this one is probably is the most complete of the scientifically complex rules.

Case 7
Municipal Solid Waste Landfills

Rule Title: Standards of Performance for New Stationary Sources and Guidelines for Control of Existing Sources: Municipal Solid Waste Landfills

Citation for Final Rule: 61 Federal Register 9905 (March 12, 1996)

EPA Start Action Notice: 2535

Brief description of the rule

The standards and emission guidelines implemented section 111 of the Clean Air Act and were based on the Administrator's determination that municipal solid waste (MSW) landfills caused, or contributed significantly to, air pollution that may reasonably be anticipated to endanger public health or welfare. The intended effect of the standards and guidelines was to require certain MSW landfills to control emissions to the level achievable by the best demonstrated system of continuous emission reduction, considering costs, nonair quality health, and environmental and energy impacts.

The emissions of concern were methane and non-methane organic compounds (NMOC), which include volatile organic compounds (VOC), hazardous air pollutants (HAPs), and odorous compounds. VOC emissions contribute to ozone formation which can result in adverse effects to human health and vegetation. The health effects of HAPs can include cancer, respiratory irritation and damage to the nervous system. Methane emissions contribute to global climate change and can result in fires and explosions when they accumulate in structures in or off the landfill site.

The requirements varied depending on the size of the new or existing landfill. Landfills less than 2.5 million megagrams (Mg) or 2.5 million cubic meters must file a design capacity report. Those landfills bigger than that must calculate the annual NMOC emission rate. If the emission rate is greater than 50 Mg/yr, the landfill must install controls that are to remain in effect until the emission rate drops below that level. Specifically, using the best demonstrated technology, these landfills must have a well-designed and well-operated gas collection system and a control device capable of reducing NMOC in the collected gas by 98 weight-percent. In addition, there were record keeping and reporting requirements for these landfills.

Brief description of science input to the rule

To prepare the rule, EPA needed information about: the universe of landfills; what they emit and how much; the effect of the emissions; and the options and costs related to controlling the emissions. In addition, using some of the above information, the Agency developed a model to estimate emissions.

Description of critical documents

The key support for the final rule summarized the regulatory and cost impacts, alternatives, and comments that were the basis for changes to the rule between the proposal and promulgation. See Reference 1. However, an earlier Report to Congress was the basis for the decision that a rule was needed. See Reference 2. The proposed rule was supported by a regulatory impact analysis and an economic impact analysis. These analysis considered alternatives and related costs. See References 3 and 6.

Absent actual information on emissions, facility operators must use a model to determine if controls are necessary. Thus, developing the model was essential to the rule. Early studies evaluated the decomposition of waste material to determine the type and amount of gas generated. See References 7, 8, 9, 10 and 17. Such information was pulled together (Reference 12) and a rate of generation was calculated (References 13 and 16). This rate was needed to project either overall emissions or those from a particular landfill.

Actual emission information was needed for the model. EPA collected such information from various sources and put it into a database (Reference 14). Information about the actual number of landfills was also needed; in fact such a survey was required by a 1984 law and conducted. See Reference 15. From such information the national impacts of the proposed standards and guidelines could be estimated, justifying the need for the rule.

The model was developed by EPA, through contractors. They fine-tuned and tested it. See References 18 and 19. The result was the Landfill Gas Emissions Model (LandGEM), Reference 20.

Because the emission controls required by the rule had to be the best demonstrated technology, the Agency needed information on the available technology. This came mostly from the industry. See References 21 through 25. However, EPA evaluated the effects of some options, such as identifying the emissions from burning the collected gas. See Reference 11.

Some health information (see Reference 4) and other cost information was also collected (see Reference 5). The latter further supported the need for the rule and the former that cost was considered.

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	U.S. EPA, December 1995, "Air Emissions from Municipal Solid Waste Landfills Background Information for Final Standards and Guidelines", RTP, NC, EPA-453/R-94-02	PS	PO	C	U

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
2	U.S. EPA, October 1988, "Report to Congress Solid Waste Disposal in the United States, Volume II (Chapter 4)", Washington, DC, EPA/530-SW-88-O11B	IP	PO	I	U
3	U.S. EPA, April 1994, "Regulatory Impact Analysis of Air Pollutant Emission Standards and Guidelines for Municipal Solid Waste Landfills"	IP	PO	I	U
4	Hang, W.L., Rogers, S., 1982, "Environmental and Public Health Implications of the Port Washington Landfill", New York Public Interest Research Center, Inc.	PS	O	U	U
5	Jansen, G.R., May 1986, "The Economics of Landfill Gas Projects", In: Proceedings from the GRCDA 9th International Landfill Gas Symposium, Publication #GLFG-13	PS	O	U	U
6	Research Triangle Institute, October 1993, "Economic Analysis of Air Pollution Regulations: Landfills", RTP, NC	PS	PO	C	U
7	U.S. EPA, 1977, "Recovery of Landfill Gas at Mountain View, Engineering Site Study", EPA-530/SW-587d	PS	PO	G	U
8	DeWalle, F.B., Chain, E.S.K., Hammerberg, E., June 1978, "Gas Production from Solid Waste in Landfills", Journal of the Environmental Engineering Division	AC	ORD	G	ENP
9	South Coast Air Quality Management District, July 1982, "Landfill Gas Emissions, Report of the Task Force"	OG, PS	U	U	U
10	Emcon Associates, 1982, "Methane Generation and Recovery from Landfills", Ann Arbor Science	PS	O	U	U
11	U.S. EPA, September 1985, "Compilation of Air Pollutant Emission Factors, Volume 1: Stationary Point and Area Sources", AP-42, Fourth Edition, RTP, NC	IP	PO	I	U
12	U.S. EPA, August 1986, "Critical Review and Summary of Leachate and Gas Production from Landfills", Cincinnati, OH, EPA-600/S2-86-073	PS	ORD	CA	U
13	J. Hargrove, W. G. Vogt, and E. T. Conrad, SCS Engineers, to A. Geswein, OSWER:OSW, November 17, 1986, "Gas emission rates from solid waste landfills"	PS	PO	C	U

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
14	P. Carrico, W. G. Vogt, and E. T. Conrad, SCS Engineers, to A. Geswein, OSWER:OSW, October 6, 1986, "Data base for landfill gas trace constituents"	PS	PO	C	U
15	U.S. EPA, September 1988, "National Survey of Solid Waste (Municipal) Landfill Facilities", Washington, DC, EPA/530-SW88-034,	PS	PO	C	U
16	R. Pelt, Radian Corporation, to Municipal Solid Waste Landfill Project File, May 6, 1991, "Calculation of the Methane Generation Rate Constant, k"	PS	PO	C	U
17	R. Pelt, Radian Corporation, to MSW Landfills Project File, May 6, 1991, "Selection of Nonmethane Organic Compound Concentrations"	PS	PO	C	U
18	Radian Corporation, undated, "Development of an Empirical Model of Methane Emissions from Landfills", RTP, NC	PS	ORD	C	U
19	Radian Corporation, undated, "Analysis of Factors Affecting Methane Gas Recovery From Six Landfills", RTP, NC	PS	ORD	C	U
20	Radian International & Eastern Research Group, 1998, "User's Manual Landfill Gas Emissions Model" (LandGEM)	PS	PO	C	U
21	Van Heuit, R.E., August 1983, "Extraction, Metering and Monitoring Equipment for Landfill Gas Control and Recovery Systems", In: Proceedings of the GRCDA 6th International Landfill Gas Symposium	PS	O	U	U
22	Love, D.L., May 1986, "Overview Of Process Options And Relative Economics", In: Proceedings from the GRCDA 9th International Landfill Gas Symposium, Publication #GLFG	PS	O	U	U
23	Schell, W.J., Houston, C.D., May 1986, "Membrane Systems for Landfill Gas Recovery", In: Proceedings from the GRCDA 9th International Landfill Gas Symposium, Publication #GLFG-13	PS	O	U	U
24	Air Products and Chemicals, Inc., 1987, "Landfill Gas Treatment Experience with the GEMINI-S System"	PS	O	U	U
25	U.S. EPA, June 1992, "Landfill Gas Energy Utilization: Technology Options and Case Studies", EPA-600/R-92-116	PS	ORD	C	U

Methodology

Through e-mail or an interview with a member of the pilot study team, the primary contact and a program scientist (now with ORD) described some of the critical documents. According to the scientist, all critical documents were in the docket. Using these descriptions, we went to the docket (A-88-09) and pulled the documents described. We also pulled some documents we believed might be critical. The primary contact did not disagree with those chosen as critical when she reviewed the initial summary.

Miscellaneous Other Information

The emission standards and guidelines for municipal solid waste landfills was not as high a priority for the Agency, unlike the similar limits for municipal waste combustors. The Agency's Report to Congress on solid waste disposal was released in October 1988. However, the notice on the proposed standards and guidelines for landfills was not published until May 1991, which was 32 months later. On the other hand, the proposed rule on the combustors was published in July 1987, immediately following the related Report to Congress in June 1987. A program official credited the Agency's Landfill Methane Outreach Program as the motivation for the landfill emission rule.

The program office and ORD both contributed to the science needed for the rule, with research from as early as the late 1970s. At that time, ORD's Municipal Environmental Research Laboratory in Cincinnati had an ongoing program to evaluate municipal waste, landfill leachate, and gas management. In 1990 ORD's Air and Energy Engineering Research Laboratory began a program to improve global landfill emission estimates, which contributed to the emission model.

Case 8

Biotechnology

Rule Title: Microbial Products of Biotechnology

Citation for Final Rule: 62 Federal Register 17910 (April 11, 1997)

EPA Start Action Notice: 2326

Brief description of the rule

This rule establishes a part in the Code of Federal Regulations for microbial products of biotechnology subject to the Toxic Substances Control Act (TSCA), 40 C.F.R. Part 725. This rule establishes procedures the Agency will use to conduct premanufacture review of certain new microbial products of biotechnology. The procedures are comparable to those for traditional chemical substances but are tailored to address the specific characteristics of these microorganisms. Microorganisms subject to this rule are used commercially for such purposes as production of industrial enzymes and other specialty chemicals; agricultural practices (e.g., biofertilizers); and break-down of chemical pollutants in the environment, but not as foods, drugs, or pesticides, which are regulated under different statutes. The rule was designed to ensure that EPA can adequately identify and regulate risk associated with microbial products of biotechnology without unnecessarily hampering the biotechnology industry.

The rule implements EPA’s screening program for new microorganisms under Section 5 of TSCA, creates a number of exemptions for their general commercial use, and codifies EPA's approach to related research and development (R&D).

For screening purposes, the rule continues the interpretation of "new" microorganism first put forth by EPA in 1986 (51 FR 23302), i.e., “a microorganism that is formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera[1]. The term ...includes a microorganism which contains a mobile genetic element which was first identified in a microorganism in a genus different from the recipient microorganism, [but not] a microorganism which contains introduced genetic material consisting of only well-characterized, non-coding regulatory regions from another genus." EPA believes that intergeneric microorganisms have a sufficiently high likelihood of expressing new traits or new combinations of traits to be termed "new" and warrant review. Microorganisms that are not intergeneric would not be "new", and thus would not be subject to reporting under this rule.

The rule creates a reporting vehicle specifically designed for microorganisms, the Microbial Commercial Activity Notice (MCAN). Persons intending to use intergeneric microorganisms for commercial purposes in the United States must submit an MCAN to EPA at least 90 days before

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[1] A genus (pl. genera) is a level in a classification system based on the relatedness of organisms.

such use. In general, EPA has 90 days to review the submission in order to determine whether the intergeneric microorganism may present an unreasonable risk to human health or the environment.

This rule establishes two exemptions from the requirement to submit a MCAN under Section 5(h)(4) of TSCA for new microorganisms introduced into general commerce. In the Tier I exemption, if three criteria are met, manufacturers are only required to notify EPA that they are manufacturing a new microorganism that qualifies for this exemption 10 days before commencing manufacture, and to keep certain records (i.e., they are not required to wait for EPA approval). To qualify for the Tier I exemption, a manufacturer must use one of the ten recipient organisms listed in the rule, and must implement specific physical containment and control technologies. In addition, the DNA introduced into the recipient microorganism must be well-characterized, limited in size, poorly mobilizable, and free of certain sequences. A manufacturer, who otherwise meets the conditions of the Tier I exemption, may modify the specified containment restrictions, but must submit a Tier II exemption notice. The Tier II exemption requires manufacturers to submit an abbreviated notice describing the modified containment, and provides for a 45–day period, during which EPA would review the proposed containment. The manufacturer may not proceed under this exemption until EPA approves the exemption.

Rather than submitting a MCAN during research and development, manufacturers may qualify for one of several exemptions under section 5(h)(3) if they are conducting research and development activities solely within a contained structure. For contained research conducted by researchers who are required to comply with the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant DNA Molecules* (1994), EPA has established a complete exemption from EPA review and reporting and recordkeeping requirements. For all other manufacturers conducting contained research and development activities EPA has established a parallel exemption. The exemption specifies factors which the technically qualified individual must consider in selecting the appropriate containment. The manufacturer is required to keep records to document compliance with the containment requirements, but is exempt from almost all other TSCA section 5 reporting requirements.

If the research involves testing of microorganisms in the environment, the organization may choose to submit to EPA a TSCA Experimental Release Application (TERA). EPA's review period is 60 days, although EPA may extend the period for good cause. EPA must approve the test before the researcher may proceed, even if the 60-day period expires. EPA's approval is limited to the conditions outlined in the TERA notice or approval. For researchers conducting small-scale field tests with *Bradyrhizobium japonicum* and *Rhizobium melilot*i, the final rule creates an exemption from EPA review, providing certain conditions are met. The field testing must occur on no more than 10 terrestrial acres; the introduced genetic material must comply with certain restrictions; and appropriate containment measures must be selected to limit dissemination.

Brief description of science input to the rule

There was a great deal of attention paid to the safety of genetically engineered organisms in the two decades preceding finalization of this rule. In 1976, the National Institutes of Health published its Guidelines for Research Involving Recombinant DNA Molecules. The Biotechnology Science Coordinating Committee (BSCC) of the Domestic Policy Council Working Group on Biotechnology announced a coordinated policy for dealing with biotechnology across the various agencies with a regulatory role (e.g., FDA, USDA, and EPA) in the *Federal Register* as 51 FR 23302, on June 26, 1986. The policy, while not a science document, adopted the government-wide definition of intergeneric microorganisms adopted under this rule. The Committee also published Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms With Modified Hereditary Traits, as 55 FR 31118, on July 31, 1990

EPA's FACA, the Biotechnology Science Advisory Committee (BSAC), began holding meetings in 1986 to brainstorm or review BSCC or EPA proposals on topics including substantially changing the approach to identifying the "scope" of organisms that might trigger the need for review, clarifying the types of transfers of genetic material and scale of release that would trigger a pre-manufacturing review, definitions of pathogens (gene transfers to or from pathogenic microorganisms were considered to be riskier than those among non-pathogens), and more generally what factors should be considered in assessing the risks from "new" microorganisms. Review of the minutes and from these meetings reflects a deep understanding of the potential issues involved by arguably the best microbiologists and microbial ecologists in the country, and they also illustrate the complexity of coming up with a scientifically sound approach that is effective and legally defensible.

The National Institutes of Health Recombinant DNA Advisory Committee considered the safety of release of genetically modified organisms into the environment (see Sharples, F.E. , 1987. Regulation of products of biotechnology. *Science* 235: 1329-1332, and Davis, B.D. 1987. Bacterial domestication. *Science* 235: 1329, 1332-1335 for points of view of two of the committee members). The Ecological Society of America (ESA) also convened a panel of scientists to consider the issue. Their report is summarized in Tiedje, et al. 1989. ``The planned introduction of genetically engineered organisms: Ecological considerations and recommendations." *Ecology* 70(2):298-315.

ORD also had a substantial research program in biotechnology in the 1980s. In a presentation to the BSAC in April 1987, the Assistant Administrator for Research and Development indicated that ORD had a budget of $7 million for R&D in biotechnology, approximately 80% of which was in external research grants, primarily directed at developing "widely accepted methods in ... microbial ecology." ORD projects aimed at evaluating monitoring strategies for planned field releases were presented to the BSAC at the July 1987 and January 1988 meetings. ORD reported on several biotechnology workshops at the January 1989 meeting. At the December 1989 meeting, ORD presented a progress report on 53 projects that had been conducted under the program. The "primary foci of these studies [were] on detection and enumeration, survival and colonization, and genetic exchange." Several studies funded by ORD were included in the docket for the proposed rule.

EPA from the start indicated that it intended to regulate microorganisms as chemicals under TSCA, to screen "new" microorganisms under section 5(a)(1)(A), and to use the intergeneric definition of new organisms put forward in the 1986 BSSC Coordinated Framework. There was considerable debate about this definition. Sharples (1987), Davis (1987), and Tiedje et al (1989) considered the issue of whether microorganisms that involved *intra*generic transfers of coding DNA, or transfers of "well-characterized, non-coding sequences" were inherently low-risk, and thus not worthy of screening by EPA or other Departments, and concluded that there was inadequate science to support that assumption. At the February 1987 BSAC meeting, a manufacturer presented an issue paper recommending that well-characterized, non-coding regulatory sequences be exempt, but a microbial ecologist on the committee who had been studying genetic exchange in soil dwelling Bacillus species said that manipulation of these elements may be the most powerful capability of biotechnology and there was no reason to assume they were safe. At the April 27 meeting, a different member said "microbial taxonomy is somewhat arbitrary and is a weak regulatory instrument, because it is based on phylogeny rather than evolutionary relatedness. It is questionable that taxonomic classification is related to risk." The BSAC Chair agreed. At the July 17, 1987, meeting, the BSAC decided to review an issue paper on the exemption of "genetic material consisting of well-characterized, non-coding regulatory sequences" because it "raised interesting ecological issues which should be fully considered."

However, under section 5(a)(1)(A), there is no presumption of risk associated with "new" chemicals or microorganisms. Existing microorganisms under the proposed rule would have been regulated under the Significant New Use Rule (SNUR) provisions of section 5(a)(1)(B), which involves a determination of any increase or change in the type, magnitude, or duration of exposure to humans or ecosystems. In the final rulemaking, however, EPA reserved but did not promulgate new SNUR language for microorganisms. Consequently, much of the discussion and debate involving the risks of intrageneric gene transfers or the comparative safety of well-characterized non-coding DNA in the aforementioned activities had no direct impact on the final rulemaking. What counted was novelty, not risk.

EPA dealt with this issue explicitly in determining that for this final rule, it would not reconsider, as requested by commenters #8 and 18, whether EPA should continue to exclude microorganisms that result from the addition of material that is well-characterized and contains only non-coding regulatory regions. Under section 5 of TSCA, EPA determines whether a chemical substance is "new", independently of the determination that the chemical substance or microorganism may present risks. In defining "new microorganism", EPA focused on the potential for expression of new traits or new combinations of traits. Where only well-characterized, non-coding regulatory material is transferred, no distinctly new traits are likely to be introduced. Instead, quantitative changes in existing traits in the recipient microorganism may occur. EPA recognized that the insertion of well-characterized, non-coding regulatory regions may result in expression of previously cryptic regions, but the genetic material in cryptic regions is present in the recipient and could be expressed in other members of the recipients species at any time naturally. A microorganism expressing such material as a consequence of the insertion of well-characterized, non-coding regulatory regions would thus not be "new" under TSCA.

There are only two documents cited in support of the idea of the science behind defining “new” microorganisms under the rule. One of those simply serves to identify the taxonomy of microorganisms (as opposed to the novelty of intergeneric organisms as defined), and the other deals with the taxonomy of viruses. During a presentation on ORD’s research program, one reviewer commented that, although “much progress had been made in the considering genetic, ecologic, and evolutionary issues, ... the information was still insufficient to give a definitive answer on what merited review.” The preamble acknowledges that some genera of bacteria are much more diverse than others, so that in a diverse genus, species may be as genetically different as different genera in other groups of bacteria. The rulemakers argued in response to comments that advances in bacterial taxonomy would reduce this problem over time. As the Environmental Defense Fund commented (while acknowledging that there are problems with an intergeneric scope), "no one has proposed a clearly superior scope, despite years of discussion and debate. Adoption of the intergeneric scope by EPA at this time is logical." The BSAC also commented favorably on the entire proposed rule package.

Some of the science debates and research findings undoubtedly informed the data requirements associated with an MCAN, but there are no references to any particular science sources in the preambles of the proposed or final rules. For example, EPA responded to a comment on the proposed rule: “EPA's MCAN requirements at 725.155 and 725.160 were based entirely on TSCA 5(b) and 5(d)(1),” and “The MCAN information requirements closely parallel those for PMNs and differ only to the extent necessary to accommodate the specific characteristics of microorganisms.”

For an example of how the Premanufacture Notices were modified for microorganisms:

> Section 725.155(d) requires submission of microorganism identity information. This corresponds to TSCA 8(a)(2)(A) which requires chemical identity and molecular structure information. For intergeneric microorganisms, the equivalent of chemical identity would include the taxonomic designations (genus and species) of the recipient microorganism and the donor(s) of the introduced genetic material as well as certain phenotypic and genotypic information. Many taxonomic designations at the species level define phenotypically and genotypically diverse groups of microorganisms. Therefore, supplemental information on phenotypic and genotypic traits is necessary to identify as precisely as possible a specific microorganism for Inventory listing.

The response later added:

> The purpose of the MCAN is to supply EPA with information necessary to identify and list the new microorganism on the TSCA Inventory and to determine whether the microorganism would pose an unreasonable risk to human health or the environment. In keeping with that objective, EPA has revised 725.155(b) to explicitly include the statement that the submitter include all reasonably ascertainable information that will permit EPA to make a reasoned evaluation of the human health and environmental effects of the microorganism. If EPA finds that the information submitted in the MCAN is insufficient for EPA to complete

> its review, it may request the submitter to provide the additional information during the 90-day review period, or EPA will take action under TSCA 5(e), where appropriate, to regulate the substance pending submission of the information.

Based on interviews with program staff, much of the science that would be relied upon in determining safety or risk of intergeneric microorganisms would be brought to bear in the application and review process. Although this science was not specifically identified in the rulemaking, it is clear that the part of the rulemaking creating subsections 725.155 (Information to be included in the MCAN) and 725.160 (Submission of health and environmental effects data) required substantial scientific input.

By far the major science inputs to the rulemaking itself involved specifications for the exemptions for new microorganisms in section 5(h)(3) and section 5(h)(4). These exemptions involved the conditions under which new microorganisms would be exempt from notification, depending on whether they were used in contained facilities or released to the environment, and whether they were used for commercial purposes or for research and development. The rationale for the exemptions is best laid out in the preamble to the proposed rule (59 FR 45526).

The approach for research exemptions under 5(h)(3) was modified from that used for traditional new chemicals, which covers "small quantities" of a chemical used for research. Whereas small quantities of traditional chemicals are diluted in the environment, a small innoculum (initial "dose") of microorganisms that escaped from a research experiment could establish itself and grow to a larger size or amount. For R&D in confined structures, EPA developed performance-based standards for containment and record-keeping and notification of employees aimed at understanding the number of microorganisms used in a particular setting and the efficacy of various control measures in reducing this number to a number with a reduced probability of establishment in the natural environment, and thus would not be expected to result in unreasonable risk if they should escape. The science cited to support 5(h)(3) concerned the general experience of plant and animal ecologists with the size of population determining probability of establishment.

Section 5(h)(4) exemptions allow EPA to exempt a new chemical substance from all or part of the requirements of section 5 if it is determined that the activities involving the substance will not present an unreasonable risk of injury to health or the environment. Although reasonable risk is not defined, section 6(c) provides that consideration be given to factors such as harmful effects, degree of exposure, potential benefits of the substance, substitutability, and ascertainable economic consequences of regulatory action. EPA established five types of exemptions for R&D and one for commercial use. Science is cited in support of two of the R&D situations: allowing researchers to follow the NIH guidelines in one case, and field tests of two new microorganisms, *Bradyrhizobium japonicum* and *Rhizobium meliloti*, as an example of a finding of no unreasonable risk for microorganisms proposed for exemption from TERA reporting. There are a substantial number of science citations in support of Tiered exemptions for commercial applications, relating both to ten specific recipient microorganisms exempted in the rule, the characteristics of genetic material that may be exempted from transfer to exempted recipient microorganisms, and the standards for limiting releases from the facility.

Description of critical documents

There is no specific technical support document for the rule, and the scientific arguments in support of the rule are contained in the preamble to the proposed rule (Reference 1), the preamble to the final rule (Reference 2), and in EPA (1997) *Microbial Products of Biotechnology Final Regulation under the Toxic Substances Control Act - A Summary of the Public's Comments And The Agency's Response*. (Reference 3). These three documents explain and defend the intergeneric and non-coding criteria for "new" microorganisms triggering the need for an MCAN, the reasons for the information requirements in the MCAN, and the exemptions for research and certain other microorganisms for use in general commerce. Review of the regulatory impact analysis for the rule did not reveal any technical content not contained elsewhere in the preambles and Response to Comments.

The preamble to the proposed rule cites six documents to support the idea that successful establishment of new organisms in the environment generally increases with the size of innoculum (i.e., the number of initial invaders). Of these documents four refer to higher organisms, in which the size of the initial population is suggested to depend on greater genetic variability in the invaders, which would not be the case with carefully maintained culture of microorganisms. We have included Tiedje et al (Reference 5), which references the aforementioned documents in the preamble, as well as some references dealing with microorganisms, and Schroth (Reference 6), which deals specifically with bacteria.

Tiered exemptions for organisms in general commercial use require introduced genetic material to be (1) limited in size, (2) well-characterized, (3) free of certain sequences, and (4) poorly mobilizable. The first criterion is defined as only "those segments required to perform the intended function," and the second by identifying certain characteristics of the genetic sequences, but no specific science document is cited. With respect to the third criterion, the preamble specifies that genes known to code for certain toxins classified by Gill (References 7 and 8) as being of high potency would preclude an exemption. The preamble also states that genes that might contribute to multigenic toxins or pathogenicity would not preclude exemption, because a large number of genes would be required to express the trait, but no specific science document is cited. Several science documents are brought to bear on the fourth criterion. Poorly mobilizable is defined as having a transfer frequency of 10^{-8} transfer events per donor or less. Sayre et al (1991), Kokjohn (1989), Stotsky (1989), Sayre et al. (1989), and Jeffrey et al. (1990) (References 9-13) are cited as evidence that transfers of genes among microorganisms in the environment through processes such as conjugation, transformation, and transduction occur at this frequency or higher, and Lewin (1987) and Maki et al. (1983) (References 14 and 15) are cited to show that spontaneous mutations also occur at least this rate. Basically, this limit not only represents a baseline frequency at which change occurs in genetic material in nature, but it also sets a technical limit for measurability. Finally, Ippen-Ihler (1989) (Reference 16) is cited as supporting that this frequency is attainable with current techniques.

The NIH Guidelines for Research Involving Recombinant DNA Molecules (USDA 1994) (Reference 17) provided the framework for research in contained facilities in the rule. Radian Corporation (1996) and EPA (1991) (References 18 and 19) were cited to support the requirement for a six order of magnitude reduction of microbes in waste and other materials leaving a contained research facility. Battelle 1988 (Reference 20) was cited to support EPA's position that "features known to be effective in minimizing viable microbial populations in aerosols and exhaust gases" was a more appropriate requirement than specifically requiring HEPA filters. The requirement for six log reduction of microbial populations in waste, and features known to minimize microbial populations in aerosols and exhaust gases are both among the criteria that have to be satisfied for an organism used in a contained facility to be exempt from the MCAN review (in addition to the recipient organism being on the approved list and conditions placed upon the type of genetic material introduced).

The original PMNs for *Bacillus japonicum* and *Rhizobium meliloti* are cited in support of the exemption for field testing involving these microorganisms, and we have included one as an example (Reference 21). For each of the ten microorganisms identified for tiered exemptions in the rulemaking, there is a decision document that ties all of the science together to support the exemption. An example for *A. niger* is included for the rule (Reference 4). Each of these decision documents is supported by a risk assessment, also prepared by the program office staff. Each risk assessment in turn is supported by four additional documents, a health risk assessment, an environmental hazard assessment (dealing with plant and animal effects), an exposure assessment, and an organism profile. We have included examples of these documents for *A. niger* in the critical documents for this rule (References 22-25). Each of these secondary documents contains references to the scientific literature, which we were unable to include due to time constraints.

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	Microbial Products of Biotechnology - 59 FR 45526 - Proposal Preamble	IP	PO	I	FACA
2	Microbial Products of Biotechnology - 62 FR 17910 - Final Preamble	IP	PO	I	N
3	Microbial Products of Biotechnology Final Regulation under the Toxic Substances Control Act - A Summary of the Public's Comments And The Agency's Response. US EPA. March 26, 1997	IP	PO	I	N
4	Final Decision Document: TSCA Section 5(h)(4) Exemption for Aspergillus niger.	IP	PO	I	FACA

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
5	Tiedje, J., Colwell, R.K., Grossman, Y.L., Hodson, R.E., Lenski, R.E., Mack, R.N., Regal, P.J. 1989. The planned introduction of genetically engineered organisms: Ecological considerations and recommendations. Ecology 70(2):298-315.	AC	O	C	ENP
6	Schroth, M.N. 1983. Bacteria as biocontrol agents of plant disease. Pages 362-369 in Klug, M.J. Reddy, C.A., eds. Current Perspectives in Microbial Ecology. American Society for Microbiology, Washington, DC.	AC	U	U	U
7	Gill, D.M. 1982. Bacterial toxins: a table of lethal amounts. Microbiological Reviews 46(1): 86-94.	AC	U	U	ENP
8	Gill, D.M. 1987. ``Bacterial Toxins: description. Laskin, A.I. Lechevalier, H.A., eds. pp. 3-18 in CRC Handbook of Microbiology, 2nd edition, Volume VIII, Toxins Enzymes. CRC Press, Boca Raton, FL.	AC	O	C	N
9	Sayre, P.G. and Miller, R.V. 1991. Bacterial mobile genetic elements: Importance in assessing the environmental fate of genetically engineered sequences. Plasmid 26:151-171.	IP, AC	PO, U	I, U	ENP
10	Kokjohn, T.A. 1989. Transduction: mechanism and potential for gene transfer in the environment. pp 73-97 in Levy, S.B. and Miller, R.V., eds. Gene Transfer in the Environment. McGraw-Hill: New York	AC	ORD	CA	N
11	Stotzky, G. 1989. ``Gene transfer among bacteria in soil. pp. 165-222 in Levy, S.B. and Miller, R.V., eds. Gene Transfer in the Environment. McGraw-Hill: New York	AC	ORD	CA	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
12	Saye, D.J. Miller, R.V. 1989. ``The aquatic environment: consideration of horizontal gene transmission in a diversified habitat. Pages 223-259 in Levy, S.B. and Miller, R.V., eds. Gene Transfer in the Environment. McGraw-Hill: New York	AC	ORD	CA	N
13	Jeffrey, W., Paul, J., and Stewart, G. 1990. ``Natural transformation of a Marine Vibrio Species by Plasmid DNA. Microbial Ecology 19:259-268.	AC	ORD, OF	G, CA	ENP
14	Lewin, B., ed. 1987. Pages 55-56 in ``Genes, Third Edition. John Wiley Sons, New York	AC	O	C	N
15	Maki, H., Horiucki, T., and Sekiguchi, M. 1983. ``Structure and expression of the DNAQ mutator and RNase H genes of Escherichia coli: Overlap of the promoter regions. Proceedings of the National Academy of Sciences 80:7137-7141	AC	O	G	ENP
16	Ippen-Ihler, K. 1989. ``Bacterial Conjugation. Pages 33-72 in Levy, S.B. and Miller, R.V., eds. 1989. Gene Transfer in the Environment. McGraw-Hill: New York.	AC	U	U	N
17	U.S. Department of Health Human Services, National Institutes of Health (NIH). 1994. Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) (59 FR 34496, July 5, 1994)	OF	OF	U	U
18	Radian Corp. 1996. Review of past premanufacture notices for potential containment criteria for the 5(h)(4) exemptions in the proposed biotechnology rule. U.S. EPA, Office of Pollution Prevention and Toxics, unpublished. Washington, D.C.	PS	PO	C	U
19	U.S. EPA Office of Toxic Substances. 1991. Analysis of environmental releases and occupational exposure in support of proposed TSCA 5(h)(4) exemption.	IP	PO	I	N

Ref .	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
20	Battelle. 1988. Final Report on Biosafety in Large-Scale rDNA Processing Facilities. 4 volume set. U.S. EPA, Risk Reduction Engineering Laboratory, Cincinnati, OH.	OF	ORD	IAG	U
21	PMN Application for Rhizobium melitoli	PS	O	O	FACA
22	Dynamac. 1991. Human health assessment of the possible risk for use Aspergillus niger as a recipient microorganism, Unpublished	PS	PO	C	U
23	Kough, J. 1991. Environmental assessment for the use of A. niger as a recipient microorganism. Unpublished, U.S. EPA	IP	PO	I	U
24	Versar. 1991. Screening level exposure assessment of Aspergillus species for 5(h)(4) exemption under the proposed biotech rule. Unpublished	PS	PO	C	U
25	Dynamac. 1990. Organism Profile: *A. niger.* Unpublished	PS	PO	C	U

Methodology

OIG had no response from any of the respondents during the development of this case study. The information was developed by reading the rule and preamble, the major technical support documents, the ESA report (Tiedje 1989), the regulatory impact analysis, the response to comments report, and the reports and minutes from the BSAC meetings in the docket. The reference lists for the major technical support document and response to comments, as well as research papers cited in the docket table of contents were identified, and scanned for content, funding sources, etc. Research funded by ORD and identified by acquisition number were tracked back to the original decision memos in the Grants Administration Division files (most turned out to be competitively awarded).

Agency Comments and OIG Response

During the internal agency review, the primary contact and other program officials involved in the rule identified some significant misunderstandings of the screening (MCAN) process in the original draft, and pointed out additional areas where science played a critical role in exclusions under section 5(h)(4). The scientific underpinnings for the exclusions were identified only in the preamble to the proposed rule, which we had not examined earlier. Consequently, we made substantial changes to the list of critical documents during finalization of this report.

Case 9

Pulp and Paper (Air)

Rule Title: National Emission Standards for Hazardous Air Pollutants for Source Category: Pulp and Paper Production

Citation for Final Rule: 63 Federal Register 18504 (April 15, 1998)

EPA Start Action Notice: 3105

Brief description of the rule

EPA promulgated effluent limitations guidelines and standards under the Clean Water Act (CWA) for a portion of the pulp, paper, and paperboard industry, and national emission standards for hazardous air pollutants (NESHAP) under the Clean Air Act (CAA) as amended in1990 for the pulp and paper production source category. This summary deals only with the NESHAP.

Prior to 1990, the Clean Air Act directed EPA to regulate toxic air pollutants based on the risks each pollutant posed to human health. The Act directed EPA to identify all pollutants that caused "serious and irreversible illness or death," and to develop standards to reduce emissions of these pollutants to levels that provided an "ample margin of safety" for the public. During the 1970s and 1980s, EPA became involved in many legal, scientific, and policy debates over which pollutants to regulate and how stringently to regulate them. In 20 years, EPA regulated only seven pollutants (asbestos, benzene, beryllium, inorganic arsenic, mercury, radionuclides, and vinyl chloride).

In 1990, Congress amended section 112(b) of the Clean Air Act to mandate a more practical approach to reducing emissions of toxic air pollutants. It lists 189 HAPs and directs EPA to develop rules to control all new and existing major sources of HAP (facilities that emit 10 tons of any single HAP or 25 tons of total HAPs). In the first phase, EPA develops regulations, MACT standards, requiring sources to meet specific emissions limits that are based on emissions levels already being achieved by many similar sources in the country. In the second phase, EPA applies a risk-based approach to assess how these technology-based emissions limits are reducing health and environmental risks. This rule reflect the first phase of the NESHAP process for the pulp and paper sector, which was identified in a list published by EPA in 1992 as a major source of 14 major HAPs, including methanol, chlorinated compounds, formaldehyde, benzene, and xylene

When developing a MACT standard for a particular source category, EPA looks at the level of emissions currently being achieved by the best-performing similar sources through clean processes, control devices, work practices, or other methods. These emissions levels set a baseline (referred to as the “MACT floor”) for the new standard. At a minimum, a MACT standard must achieve, throughout the industry, a level of emissions control that is at least equivalent to the MACT floor (EPA can establish a more stringent standard if it makes economic, environmental, and public health sense). This NESHAP was expected to reduce baseline emissions of HAPs by 65 percent or 139,000 Mg/yr.

Brief description of science input to the rule

The MACT floor is established differently for existing sources and new sources. For *existing sources*, the MACT floor must equal the average emissions limitations currently achieved by the best-performing 12 percent of sources in that source category, if there are 30 or more existing sources. If there are fewer than 30 existing sources, then the MACT floor must equal the average emissions limitation achieved by the best-performing five sources in the category. For *new sources*, the MACT floor must equal the level of emissions control currently achieved by the best-controlled similar source. Wherever feasible, EPA writes the final MACT standard as an emissions limit (i.e., as a percent reduction in emissions or a concentration limit that regulated sources must achieve) to provide flexibility for industry to determine the most effective way to comply with the standard.

The (engineering) science involved in this first phase of a NESHAP thus involves gathering data on emissions of each HAP from the various potential emissions points in the pulp and paper production process, making some determination of how to classify these processes to determine if different MACTs are appropriate for different processes, identifying the best-performing source and the best-performing 12% sources (for existing-source MACTs); determining whether to set the MACT as a technology or an emissions limit; identifying appropriate compliance monitoring methods; and determining whether a more stringent MACT is justified. There is no requirement to either show a harmful effect (HAPs are designated in the CAAA of 1990, and there is a separate process for revising the list), or to show achievement of an ambient standard downwind of the source.

With respect to monitoring, EPA had proposed that method 308 be used to monitor methanol emissions, but commenters held that EPA should not use an un-validated method. EPA validated the method before finalization

Description of critical documents

One of the major technical support documents was the original background information document (BID), *Pulp, Paper, and Paperboard Industry -Background Information for Promulgated Air Emission Standards, Manufacturing Processes at Kraft, Sulfite, Soda, Semi-Chemical Mills, Mechanical, and Secondary and Non-wood Fiber Mills,* EPA-453/R-93-050a 1973 [Reference 1]. This document characterized and classified the industrial sources in this category and their background emissions; identified the applicable control technologies; proposed model process units, control options, and their corresponding environmental impacts and control costs; and presented the database system used to calculate the environmental impacts. The revision of this BID for the final rule [Reference 2] is essentially a response to comments, and presents changes to the rule since proposal, rather than re-presenting the material in the proposal BID. Another major support document was the *Economic Analysis for the National Emission Standards for Hazardous Air Pollutants for Source Category: Pulp and Paper Production; Effluent Limitations Guidelines, Pretreatment Standards, and New Source*

Performance Standards: Pulp, Paper, and Paperboard Category—Phase 1 EPA Contract No. 68-C3-0302 1997 [Reference 3], which laid out the cost-benefit analysis for the rule. This is critical for a NESHAP, which allows a MACT lower than the typical 12% floor if justified by the cost-benefit ratio.

Several of the critical documents centered around development of the emissions factors for the industry (emissions factors are critical, because they are the basis for setting the MACT floor). The *Chemical Pulping Emission Factor Development Document* [Reference 4], prepared by ERG for EPA's Office of Air Quality Planning and Standards (OAQPS), represents the integration data from a number of studies conducted by contractors working for EPA or the regulated industry. Rather than cite these individually, they include five reports on the EPA "five mill" study, one by Entropy Environmentalists and four by Roy F. Weston working under contract to OAQPS [Reference 4]; a memo from J.L. Shumaker, International Paper, to P. Lassiter, July 27, 1994, [Reference 5] summarizing HAP emissions test data for 11 International Paper mills, conducted by Roy F. Weston under contract to International Paper; NCASI Technical Bulletins 701 and 702 [References 6 and 7], which summarized test data from chemical wood pulp mills and kraft mill condensates; a ten-volume summary of test data from the NCASI "16 mill study" [Reference 8]; and a report by Roy F. Weston on the Texas Mill study conducted under contract to the Texas Paper Industry [Reference 10]. Two additional reports by Radian under contract to EPA [References 9 and 10] document the chemical recovery combustion sources at kraft and sulfite mills, respectively.

The technical arguments in Reference 2 are difficult for the non-specialist to follow, but the key issue is that many changes were made to the proposed rule based on data submitted by industry, and many of the references in Reference 2 are to memoranda from Radian and ERG, to the primary contact or to the OAQPS person identified as the recipient of comments on the rule. For purposes of the science pilot, we did not feel it necessary to go into detail on these, since the critical technical inputs all fall into the same categories (private sector firms under contract either to EPA or industry).

<u>Table of critical documents</u>

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	Pulp, Paper, and Paperboard Industry - Background Information for Promulgated Air Emission Standards, Manufacturing Processes at Kraft, Sulfite, Soda, Semi-Chemical Mills, Mechanical, and Secondary and Non-wood Fiber Mills, EPA-453/R-93-050a, October 1993	IP	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
2	Pulp, Paper, and Paperboard Industry - Background Information for Promulgated Air Emission Standards, Manufacturing Processes at Kraft, Sulfite, Soda, Semi-Chemical Mills, Mechanical, and Secondary and Non-wood Fiber Mills, EPA-453/R-93-050b, October 1997	IP	PO	C	N
3	Economic Analysis for the National Emission Standards for Hazardous Air Pollutants for Source Category: Pulp and Paper Production; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Pulp, Paper, and Paperboard Category—Phase 1 EPA Contract No. 68-C3-0302 . October 27, 1997	PS	PO	C	N
4	Chemical Pulping Emission Factor Development Document. Revised Draft Report, July 1997. Eastern Research Group.	IP	PO	C	N
5	EPA Five Mill Study - Five reports (docket II-A -17 to 21)	PS	PO	C	N
6	J.L. Shumaker, International Paper, to P. Lassiter, EPA:CPB. July 27, 1994. HAP emissions test data for 11 International Paper mills. (Docket IV)	PS	O	C	N
7	NCASI Technical Bulletin, No. 701. Compilation of `Air Toxic' and Total Hydrocarbon Emissions Data for Sources at Chemical Wood Pulp Mills. Volumes I and II. October 1995	PS	O	O	N
8	NCASI Technical Bulletin No. 702. Acetaldehyde, Acetone, Methanol and Methyl Ethyl Ketone Contents of Kraft Mill Condensates. October 1995.	PS	O	O	N
9	NCASI ten volume summary of test reports (16-mill study) Various NCASI Technical Bulletins (Docket IV)	PS	O	O	N
10	Texas mill study (6 volumes) conducted by Roy F. Weston under contract to the Texas Paper Industry (Docket II)	PS	O	C	N

Methodology

We received no detailed responses to the questionnaires, but the primary contact directed us to the docket and made a few general comments about how NESHAPs are developed. This summary was developed by reading the major support documents and other documents identified on the pulp and paper rule web page. We then considered whether the documents referenced in these documents were also critical.

Case 10
Pulp and Paper (Water)

Rule Title: Effluent Limitation Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pulp, Paper, and Paperboard Point Source Category

Citation for Final Rule: 63 Federal Register 18504 (April 15, 1998)

EPA Start Action Notice: 3105

Brief description of the rule

The EPA Office of Water, in 1988, initiated a revision of the effluent limitations guidelines for the pulp and paper industry under authority of the Clean Water Act (CWA) in response to a Consent Decree on regulating dioxins. The intent of the Consent Decree with the Environmental Defense Fund/National Wildlife Federation was for EPA to address discharges of toxic pollutants from pulp mills and to conduct a multiple pathway risk assessment considering sludges, water effluent, and products made from pulp products. The Clean Water Act requires periodic reviews of existing effluent guidelines and Section 304(m) drives the process for selecting both new and previously regulated industries. Early in the process EPA decided to integrate the development of the effluent guidelines with standards under the Clean Air Act (CAA) for controlling emissions of hazardous air pollutants (HAPs) by maximum achievable control technology (MACT). The integrated rules became known as the pulp and paper air and water Cluster Rules.

The water rule limits the discharge of pollutants into navigable waters of the U.S. and the introduction of pollutants into publicly owned treatment works by existing and new pulp, paper, and paperboard mills in the subpart B and E subcategories. The pollutants of concern are chlorinated organic compounds from chlorine bleaching, particularly dioxins and furans, adsorbable organic halides (AOX), chloroform, and chlorinated phenolics. These pollutants have been determined to be human carcinogens and human system toxicants, and many are extremely toxic to aquatic life.

The primary focus of this rule is to eliminate or reduce the formation of the pollutants by pollution preventing process changes and internal controls. For this rule, EPA determined that the effluent limitations and standards based on Best Available Technology Economically Achievable (BAT) should be complete substitution of chlorine dioxide for elemental chlorine as the key process technology. EPA also determined that the technology basis for New Source Performance Standards for toxics and non-conventional pollutants is the BAT Model Technology with the addition of oxygen delignification and/or extended cooking. Finally, the rule includes a voluntary advanced technology incentives program to move mills well beyond the rule’s regulatory baseline toward the minimum impact mill of the future. These process changes also contribute to controlling emissions of HAPs.

Brief description of science input to the rule

To prepare the rule, EPA needed information about: the universe of pulp and paper mills; what pollutants the mills discharge in effluents; available technologies to eliminate or reduce the formation of pollutants; data on the cost and performance of these technology options; and analyses to determine the effluent reduction benefits and economic impacts of these options.

Description of critical documents

The key support for the final rule summarized the technologies tested, the analysis for determining pollutants in effluent discharges, and cost impacts. [See References 1 - 6]. Another key support was the summarization of field sampling results of technologies other than pulping and bleaching technologies, sampling effluents and analyses of 365 specific compounds. [See References 1,8]. Another key support was a document on the technical support for the voluntary advanced technology incentives program. [See Reference 7].

Additional information that was important to the development of the rule was background information on dioxin releases from pulp and paper mills. Additional technical information on pulp and paper mill discharges and treatment techniques and treatment results was used for rule development. [See references 9 - 14]. The rule itself summarized data gathering activities and reasons for changes after proposal in response to comments.

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	Supplemental Technical Development Document for Effluent Limitations Guidelines and Standards for the Pulp, Paper, and Paperboard Point Source Category	IP	PO	C	N
2	Economic Analysis for the National Emissions Standards for Hazardous Air Pollutants for Source Category: Pulp and Paper Production; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pulp, Paper, and Paperboard Industry-Phase I	IP	PO	C	N
3	Analytical Methods for the Determination of Pollutants in Pulp and Paper Industry Wastewater	IP	PO	C	N
4	Assessment of Final Effluent Limitations Guidelines for the Papergrade Sulfite and Bleached Papergrade Kraft and Soda Subcategories of the Pulp, Paper, and Paperboard Industry	IP	PO	C	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
5	Statistical Support Document for the Pulp and Paper Industry: Subpart B	IP	PO	C	N
6	Technical Support Document for Best Management Practices for Spent Pulping Liquor Management, Spill Prevention, and Control	IP	PO	C	N
7	Technical Support Document for the Voluntary Advanced Technology Incentives Program	IP	PO	I	N
8	Summary Report for Pulp and Paper Mill Sampling Program. June 1996.	IP	PO, ORD	C	II
9	U.S.E.P.A./Paper Industry Cooperative Dioxin Study. March 1988	IP	PO	O	N
10	U.S.E.P.A/Paper Industry Cooperative Dioxin Study: The 104 Mill Study. May 1990. Technical Bulletin No. 590.	PS	O	U	N
11	NCASI Report: Examination of Data Relevant to EPA's Proposed Effluent Limitations Guideline for Chloroform at Bleached Papergrade Kraft Subcategory Mills. February 1996.	PS	O	O	N
12	NCASI Technical Bulletin No. 711: Loading and Treatability of Adsorbable Organic Halide (AOX) in Kraft Bleach Plant Effluents. April 1996.	PS	O	O	N
13	ERG Memo to EPA on Docket References to the Relationship Between AOX and Concentrations of Other Pollutants; and to AOX as an Appropriate Measure of BAT Performance. July 29, 1996.	PS	PO	C	N
14	NCASI Report: Progress in Reducing the TCDD/TCDF Content of Effluents, Pulps, and Wastewater Treatment Sludges from the Manufacturing of Bleached Chemical Pulp. 1996 NCASI Dioxin Profile. May 1997.	PS	O	O	N

Methodology

The primary contact e-mailed us a detailed response on the rule and generally identified science documents he considered critical. Using the information provided by the primary contact, we went to the docket and pulled documents that we thought were critical. We met with the primary contact to get a better understanding of the rule. The primary contact did not disagree with those chosen as critical when he reviewed the summary.

Miscellaneous Other Information

According to the primary contact, the Cluster Rules were not "peer reviewed" within the structure of the process for which ORD has the Agency lead responsibility. However, the entire rule-making project from start to finish, including data and information sources, underwent in-depth scrutiny by the industry and many other stakeholders inside and outside of government, primarily through our notice and comment process driven by the Administrative Procedures Act (APA). Moreover, the Cluster Rules (and all of the effluent guidelines) were developed through an open process. For the Cluster Rules, in addition to extensive coordination with the industry on all data gathering, five public meetings were held prior to proposal, and two public meetings after proposal. Innumerable individual meetings also were held with industry, environmentalists, and other stakeholders throughout the process. EPA also published a notice of availability of additional information between proposal and promulgation for both the air and water rules. EPA received thousands of public comments (many linear feet). All of these comments have responses in the record included in many volumes.

The primary contact believed this rulemaking process must be substantially more rigorous than the Agency's "peer review" process. Among the most important reasons why it must be substantially more rigorous is that the primary product of this process is enforceable numerical permit limitations and standards, implemented under a statute (CWA) with provision for penalties, which therefore must be firmly grounded on fact and science. In addition, the rules are often litigated. Without a very strong record including comments and responses, EPA risks remands by the courts. At this writing the effluent guideline portion of the Cluster Rules is in the final stages of litigation.

Case 11

Disinfectants and Byproducts

Rule Title: National Primary Drinking Water Regulations: Stage1 Disinfectant and Disinfection Byproducts

Citation for Final Rule: 63 Federal Register 69389 (December 16, 1998)

EPA Start Action Notice: 2772

Brief description of the rule

The Stage I Disinfection Byproducts Rule finalized maximum residual disinfectant level goals (MRDLGs) for chlorine, chloramines, and chlorine dioxide; maximum contaminant level goals (MCLGs) for four trihalomethanes, two haloacetic acids, bromate, and chlorite. The rule also established National Primary Drinking Water Regulations (NPDWRs) which consist of maximum residual disinfectant levels (MRDLs) or maximum contaminant levels (MCLs) or treatment techniques for the above mentioned disinfectants and their byproducts. Monitoring, reporting, and public notification requirements for these compounds are also included in the NPDWRs. Potential health risks of people exposed to disinfectants and disinfection byproducts (DBPs) include cancer and adverse reproductive and developmental effects. EPA believed that the rule would provide public health protection for households not covered by previous drinking water rules for disinfection byproducts. The rule also provided first time protection from exposure to haloacetic acids, chlorite (a major chlorine dioxide byproduct) and bromate (a major ozone byproduct).

EPA's most significant concern in developing regulations for disinfectants and DBPs was the need to ensure that adequate treatment be maintained for controlling risks from microbial pathogens. EPA initiated a negotiated rulemaking which included representatives of State and local health and regulatory agencies, public water systems, elected officials, consumer groups, and environmental groups. The Regulatory Negotiation (Reg. Neg.) Committee had as one of its major goals to develop an approach that would reduce the level of exposure from disinfectants and DBPs without undermining the control of microbial pathogens. The Committee's intention was to ensure that drinking water is microbiologically safe at the limits set for disinfectants and DBPs and that these chemicals do not pose an unacceptable health risk at these limits. EPA subsequently established the Microbial and Disinfectants/Disinfection Byproducts (M-DBP) Advisory Committee which resulted in the collection, development, evaluation, and presentation of substantial new data related to key elements of this proposed rule.

The Safe Drinking Water Act (SDWA) requires EPA to publish a MCLG for each contaminant which, in the judgement of the EPA Administrator, "may have any adverse effect on the health of persons and which is known or anticipated to occur in public water systems" (Section 1412(b)(3)(A). MCLGs are to be set at a level at which "no known or anticipated adverse effect on the health of persons occur and which allows an adequate margin of safety" (Section

1412(b)(4). The Act also requires that at the same time EPA publishes an MCLG, which is a non-enforceable health goal, it also must publish a National Primary Drinking Water Regulation (NPDWR) that specifies either a MCL or treatment technique. The final Stage 1 rule applied to community water systems and nontransient noncommunity water systems that treat their water with a chemical disinfectant for either primary or residual treatment. Certain requirements for chlorine dioxide applied to transient noncommunity water systems.

Brief description of science input to the rule

To prepare the rule, EPA needed information on the national occurrence in drinking water of (1) the chemical byproducts that form when disinfectants used for microbial control react with the naturally occurring compounds present in source water and (2) disease-causing microorganisms. EPA also needed information on how to minimize the risk from DBP's and, at the same time, still maintain adequate control over microbial contaminants. In addition, EPA needed to assess risks associated with DBP occurrence levels and to evaluate best available technologies for reducing such risks to feasible levels (while not compromising microbial protection). Using scientific and technological information gathered, EPA defined best available technologies, criteria by which total organic carbon (naturally occurring organic precursors to DBP formation) should be removed, and how various DBPs and disinfectants should be measured and monitored.

Description of critical documents

As stated earlier, this rule required extensive data gathering and analysis by EPA. An information collection rule was established after the Reg. Neg. Committee determined that a rule for DBPs was necessary. The rule evolved from many Federal Register notices, public comments, and Advisory Committee meetings from which EPA established MCLs and MRDLs based on scientific research. [See References 1-3]. Occurrence and exposure data was needed to understand the extent of DBPs in drinking water and to determine the extent of the population that is exposed to DBPs. Various studies and research documents detailed the occurrence and exposure data and EPA analyzed and compiled the information in an occurrence assessment document. [See References 4, 8, 13, 15]. Toxicity and epidemiological studies were key to establishing MCLs and MRDLs. [See References 5, 6, 7, 9, 10, 11, 12, 14, 16-22, 58].

Treatment technology information and methods and standards documents were used for reviewing drinking water and wastewater and the relationship between DBPs and organic compounds. [See References 23-34]. MCLGs and MRDLGs were established based on criteria and assessment documents. EPA compiled criteria information on the various DBPs in a series of health criteria documents. [See References 44-45, 49-57, 59]. The final rule also contained a detailed discussion for chloroform, DCA, chlorite, chloride dioxide, and bromate because significant new data was received after the proposal. The final rule also contained a summary of the major public comments on the MCLGs and MRDLGs. [See Rule Preamble]. Treatment technologies and best available technologies documents were used to determine treatment requirements and alternative treatments for meeting the new effluent guidelines. [See References 46-48]

EPA used numerous scientific articles and reports for occurrence and exposure information and criteria and assessment information. [See References 35-44].

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	U.S.E.P.A. 1994. National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts. Proposed Rule. 59 FR 38668. July 29, 1994.	IP	PO	I	OEP
2	U.S.E.P.A. 1997. National Primary Drinking Water regulations; Disinfectants and Disinfection Byproducts; Notice of Data Availability; Proposed Rule. 62 FR 59388. November 3, 1997.	IP	PO	I	OEP
3	U.S.E.P.A. 1998. National Primary Drinking Water Regulations; Disinfectants and Disinfection Byproducts; Notice of Data Availability; Proposed Rule. 61 FR 15606. March 31, 1998.	IP	PO	I	OEP
4	U.S.E.P.A. 1998. Occurrence Assessment for Disinfectants and Disinfection Byproducts in Public Drinking Water Supplies. Office of Groundwater and Drinking Water. EPA 815-B-98-004	PS	PO	C	ENP
5	U.S.E.P.A. 1998. Quantification of Cancer Risk from Exposure to Chlorinated Water. Office of Science and Technology, Office of Water. November 9, 1998.	IP, IO	PO	I	ENP
6	Cantor, K.P., et al. 1987. Bladder cancer, drinking water source and tap water consumption: a case control study. J. National Cancer Inst. 79: 1269-1279	OF	PO, ORD, OF	O	ENP
7	DeAngelo, A.B., et al. 1991. The carcinogenicity of dichloroacetic acid in the male B6C3F1 mouse. Fund. Appl. Toxicol. 16:337-347.	IO	ORD	I	ENP
8	Krasner, S.W., et al. 1989. The occurrence of disinfection by-products in U.S. drinking water. Journal AWWA	OG, PS	PO, O	CA	ENP
9	Kurokawa et al. 1986. Dose-response studies on the carcinogenicity of potassium bromate in F344 rats after long-term oral administration. J. National Cancer Inst. 77: 977-982.	OG	O	O	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
10	Morris, R.D., et al. 1992. Chlorination, chlorination by-products, and cancer: a meta- analysis. Am. J. Public Health. 82: 955-963	AC	O	U	ENP
11	National Toxicology Program 1987. Toxicology and carcinogenesis studies of bromodichlorommethane in F344/N rats and B6C3F1 mice (gavage studies). Technical Report Series No. 321. NIEHS.	OF	OF	O	OEP
12	Stevens, et al. 1989. Formation and control of non-trihalomethane disinfection by-products. Journal AWWA. Aug:55-60	IO	ORD	I	ENP
13	Bellar, et al. 1974. The occurrence of organohalides in chlorinated drinking water. Journal AWWA, Dec:703-706.	IO	ORD	I	ENP
14	CMA. 1996. Sodium chlorite: drinking water rat two-generation reproductive toxicity study. Quintiles Report Ref. CMA/17/96.	PS	O	O	ENP
15	Cantor, et al. 1998. Drinking water source and chlorination byproducts. I. Risk of bladder cancer. Epidemiology. 9:21-28	OF	OF	C, O	ENP
16	DeAngelo, et al. 1998. Carcinogenicity of potassium bromate administered in the drinking water to male B6C3f1 mice and F344/N rats. Toxicologic Pathology. (draft in press)	IO	ORD	I	U
17	Freedman, M., et al. 1997. Bladder cancer and drinking water: a population-based case-control study in Washington County, Maryland. Cancer Causes and Control. 8:738-744.	OF	OF	O	ENP
18	King, W.D., and Marrett, L.D. 1996. Case-control study of bladder cancer and chlorination by-products in treated water (Ontario, Canada). Cancer Causes and Control. 7:596-604.	AC	O	O	ENP
19	McGeehin, M.A. et al. 1993. Case--control study of bladder cancer and water disinfection methods in Colorado. Am. Jour. Epidemiology. 138:492-501.	OG, AC	O	O	ENP
20	Bull, R.J. and Cupflower, F.C. 1991. Health Effects of Disinfectants and Disinfection Byproducts. Prepared for the American Water Works Research Foundation.	AC	O	U	U

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
21	Waller, et al. 1998. Trihalomethanes in drinking water and spontaneous abortion. Epidemiology 9:134-140.	OG	PO	CA	ENP
22	Reif, et al. 1996. Reproductive and developmental effects of disinfection by-products in drinking water. Environmental Health Perspectives 104:1056-1061.	OG, AC	ORD	CA	ENP
23	Amy, et al. 1987. Developing models for predicting trihalomethane formation potential and kinetics. Journal AWWA. July: 89-97.	AC	ORD	G	ENP
24	Glaze, et al. 1993. Evaluating the formation of brominated DBPs during ozonation. Journal AWWA. Jan.:96-103	AC	O	O	ENP
25	Krasner, S.W., et al. 1993. Formation and control of bromate during ozonation of waters containing bromide. Journal AWWA. Jan: 73-81	OG	O	C	ENP
26	Harrington, et al. 1992. Developing a computer model to simulate DBP formation during water treatment. Journal AWWA. Nov: 78-87.	AC	PO, O	O	ENP
27	Owen, et al. 1993. Characterization of Natural Organic Matter and Its Relationship to Treatability. AWWA Research Foundation	PS	O	O	U
28	Summers, R.S., et al. 1997. Analyzing the Impacts of Predisinfection Through Jar Testing, Proceedings, AWWA Water Quality Technology Conference, Denver, CO.	AC	O, PO	U	U
29	APHA. 1995. Method 4500-C102 E for chlorite daily monitoring; Method 6251B for HAA5 monitoring. Std. Methods for the Examination of Water and Wastewater, 19th Ed. American Public Health Association, Washington, D.C.	PS	O	U	ENP
30	APHA. 1996. Methods 5310B, 5310C, and 5310D - for TOC monitoring. Std. Methods for the Examination of Water and Wastewater, 19th Ed. Supplement. American Public Health Association, Washington, D.C.	PS	O	U	ENP
31	U.S.E.P.A. 1992. Methods 524.2, 552.1. Methods for the Determination of Organic Compounds in Drinking Water--Supplement II. EPA/R-92/129.	IO	ORD	C	II

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
32	U.S.E.P.A. 1993. Method 300.0. Methods for the Determination of Inorganic Substances in Environmental Samples. EPA/600/R/93/100.	IO	ORD	C	II
33	U.S.E.P.A. 1995. Methods for the Determination of Organic Compounds in Drinking Water. Supplement III. EPA-600/R-95/131.	IO	ORD	C	II
34	U.S.E.P.A. 1997. Method 300.1. Determination of Inorganic Anions in Drinking Water by Ion Chromatography. Revision 1.0. US EPA Nat. Exposure Research Laboratory, Cincinnati, OH.	IP, IO	ORD	C	II
35	Amy, et al. 1993. National Survey of Bromide Ion in Drinking Water Sources. Progress reports to AWWA Research Foundation, U. of Colorado at Boulder, Dept. of Civil, Environmental, and Architectural Engineering, Boulder, Colo. 1992--1993.	AC	O	O	U
36	McGuire, M.J., Meadow, R.G. 1988. AWWA Research Foundation trihalomethane survey. Journal AWWA. Jan:61-68	PS	O	G	ENP
37	Shorney, et al. 1996. The influence of raw water quality on enhanced coagulation and softening for the removal of nom and DBP formation potential. Proc. 1996 AWWA Annual Conference, Toronto, Ontario, Canada.	AC	O	O	U
38	Singer, P.C., et. al. 1996. Enhanced Coagulation and Enhanced Softening for the Removal of Disinfection By--Product Precursors: An Evaluation, Report to AWWA Disinfectants/Disinfection By-Products Technical Advisory Workgroup of the Water Utility Council. December 1996.	AC	O	O	U
39	Westrick, et. al. 1983. The Ground Water Supply Survey Summary of Volatile Organic Contaminant Occurrence Data. Technical Support Division, Office of Drinking Water, U.S. EPA., Cincinnati, OH	IP	PO	I	U
40	Edwards, M.. 1997. Predicting DOC removal during enhanced coagulation. Journal AWWA. 89:78-89	AC	ORD	G	ENP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
41	Edzwald, J.K., et. al. 1990. Aluminum coagulation of natural organic matter. Proc. Fourth Int'l. Gothenberg Symposium on Chemical Treatment, Madrid, Spain.	AC	U	O	U
42	Randtke, S.J., et. al. 1994. Comprehensive assessments of DBP precursor removal by enhanced coagulation and softening. Proc. AWWA Ann. Conf. (Water Quality), New York, NY.	AC	O	O	U
43	Singer, P.C., et al. 1995. Enhanced Coagulation and Enhanced Softening for the Removal of Disinfection By-Product Precursors: An Evaluation. Report prepared for the AWWA Government Affairs Office, Washington, D.C., Dept. of Environmental Sciences and Engineering, UNC, Chapel Hill, NC.	AC	O	O	U
44	White, M.C., et al. 1997. Evaluating criteria for enhanced coagulation compliance. Journal AWWA.	PS	O	O	ENP
45	Cromwell, J.E., et al. 1992. Analysis of potential tradeoffs in regulation of disinfection by-products. Office of Ground Water and Drinking Water Resource Center. Washington, D.C., EPA-811-R-92-008.	PS & IP	PO	C	U
46	U.S.E.P.A. 1994. Regulatory Impact Analysis for NPDWR: Disinfectant/Disinfection By-Products Regulations. Washington, D.C.	PS	PO	C	U
47	U.S.E.P.A. 1998. Technologies and Cost for Control of Disinfectant and Disinfection By-products. Office of Ground Water and Drinking Water Resource Center. Washington, D.C.	PS	PO	C	ENP
48	U.S.E.P.A. 1998. Regulatory Impact Analysis for the Stage 1 Disinfectant/Disinfection By-Products Regulations. Washington, D.C. EPA 815-B-98-002.	PS	PO	C	ENP
49	U.S. EPA 1993. Draft Drinking Water Health Criteria Document for Bromate. Office of Science and Technology, Office of Water.	PS	PO	C	U
50	U.S. EPA 1994. Final Draft Drinking Water Health Criteria Document for Chlorine Dioxide, Chlorite and Chlorate. Office of Science and Technology, Office of Water.	PS	PO	C	U

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
51	U.S. EPA 1994. Draft Drinking Water Health Criteria Document for Chlorine, Hypochlorous Acid and Hypochlorite Ion. NCEA Office and Research and Development.	U	ORD	I	ENP
52	U.S. EPA 1994. Final Draft for the Drinking Water Criteria Document on Trihalomethanes. Health and Ecological Criteria Div., OST.	PS	PO	C	U
53	U.S. EPA 1994. Draft Drinking Water Health Criteria Document for Chlorinated Acetic Acids /Alcohols /Aldehydes and Ketones. Office of Science and Technology, Office of Water.	PS	PO	C	U
54	U.S. EPA 1994. Draft Drinking Water Health Criteria Document for Chloramines. ECAO. Office of Research and Development.	IO	ORD	I	ENP
55	U.S. EPA 1998. Dichloroacetic acid: Carcinogenicity Identification Characterization Summary. NCEA. Office of Research and Development. EPA 815–B–98–010	IO	ORD	I	ENP
56	U.S. EPA 1998. Health Risk Assessment /Characterization of the Drinking Water Disinfection Byproduct Chlorine Dioxide and the Degradation Byproduct Chlorite. Office of Science and Technology, Office of Water. EPA815–B–98–008.	PS	PO	O	ENP
57	U.S. EPA 1998. Health Risk Assessment /Characterization of the Drinking Water Disinfection Byproduct Bromate. Office of Science and Technology, Office of Water. EPA 815–B–98–007.	PS	PO	O	ENP
58	U.S. EPA 1998. Panel Report and Recommendation for Conducting Epidemiological Research on Possible Reproductive and Developmental Effects Exposure to Disinfected Drinking Water. Office of Research and Development.	U	ORD	U	U
59	U.S. EPA 1998. Health Risk Assessment/ Characterization of the Drinking Water Disinfection Byproduct Chloroform. Office of Science and Technology, Office of Water. EPA 815–B–98–006.	PS	PO	C	ENP

Methodology

The program scientist and ORD scientist sent e-mails identifying, either specifically or generally, science documents they considered critical. Using this information, we went to the docket and pulled the documents identified. We also selected additional critical documents from the preamble references. In addition, we met and talked on the phone with the program scientist about the rule and the critical documents.

Agency Comments and OIG Response

In commenting on the draft report, the Office of Water's Office of Ground Water and Drinking Water suggested specific changes related to disinfectants and by-products. Because these changes improved the factual accuracy of the report, we changed Case 11 as suggested. The Office of Ground Water and Drinking Water also recommended that we reassess the peer review status of critical documents that appeared in scientific journals, and believed that certain document should have been categorized as primary documents instead of as secondary documents. We did reassess the peer review category for journal articles related to all the cases, and changed the category as appropriate. Finally, we removed all references to primary documents and secondary documents throughout the report and addendum.

Case 12

Polychlorinated Biphenyls

Rule Title: Disposal of polychlorinated biphenyls (PCB)

Citation for Final Rule: 63 Federal Register 35383 (June 29, 1998)

EPA Start Action Notice: 2878

Brief description of the rule

EPA amended its rules under the Toxic Substances Control Act (TSCA) that address PCB. The changes were intended to: simplify the disposal options; make clean-ups more like those of the Resource Conservation and Recovery Act and Superfund programs; and make the regulations as self-implementing and flexible as possible since the PCB program did not have much funding. The specific areas of change addressed in the amendments covered all of the key TSCA components of use, manufacture, processing, distribution in commerce, and treatment/storage/disposal. The following are some of the more significant changes found in the amendments:

- Addition of provisions authorizing certain uses of PCBs.
- Authorizing the manufacture, distribution, and use of PCBs for research and development activities.
- Authorizing additional options for PCB cleanup and disposal.
- Establishing standards and procedures for managing “PCB remediation waste” (resulting largely from spill cleanup) and “PCB bulk product waste” (derived from manufactured products).
- Establishing methods for determining PCB concentration and equating surface and bulk concentration for non-porous materials.
- Specifying management controls for PCB items destined for reuse.
- Establishing a mechanism for coordinating PCB management approvals among federal programs.

Numerous other changes and clarifications apply to PCB analysis, marking, record-keeping, reporting, and requesting exemptions.

Brief description of science input to the rule

In amending the disposal rule, EPA considered more recent health-risk information and additional sources of contamination. Testing methods were also updated. Otherwise, EPA used the knowledge it had gained from years of monitoring PCB disposal practices across the country to increase the options available in resolving PCB problems.

Description of critical documents

In the major supporting document for the rule, EPA determined the cost impact of the changes, which was needed because the options must be cost-effective and environmentally protective. See Reference 1.

Since the rule must protect against unreasonable risk, evaluating risk was an important part of the process. Reference 2 is the overall risk assessment. It evaluated risk in terms of lifetime cancer probability, so the updated cancer dose-response assessment (Reference 3) was used. Other risk-related information was also available. For example, Reference 4 addressed exposures from one pound or less of PCBs. One pound was the minimum at which a spill must be reported, and the maximum amount that may be manufactured in a year without a permit. Reference 5 addressed exposure from PCB-contaminated fluff in a landfill. Fluff is the nonmetallic waste output of a shredder operation and is often contaminated by PCB.

Measuring the extent of contamination was important to disposal because the options vary with both the amount of PCB involved and whether it is integrated into a product. Reference 6 concerned testing methods.

References 7 and 8 identified two specific contamination problems for which the requirements were changed. The first concerned fluff, which was discussed above, and the second concerned natural gas pipelines. Since 1981 EPA had monitored efforts by the natural gas industry to reduce PCB contamination of it pipeline distribution system. Based on this experience, the requirement pertaining to natural gas pipelines were changed in the rule.

Because the effectiveness of clean-up affects disposal options, EPA certifies clean-up methods that can be used. Reference 9 offered an approach using kerosene to remove PCB from a surface, and Reference 10 offered an approach using less hazardous, aqueous-based cleaners for the same purpose.

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	U.S. EPA, April 1998, "Cost Impacts of the Final Regulation Amending the PCB Disposal Regulations at 40 CFR Part 761"	PS	PO	C	N
2	Versar, Inc., May 1998, "Assessment of Risks Associated with the PCB Disposal Amendments", Springfield, VA	PS	PO	C	N
3	U.S. EPA, September 1996, "PCBs Cancer Dose-Response Assessment and Application to Environmental Mixtures", EPA/600/P-96/001F, Washington, DC	IO	ORD	I	OEP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
4	U.S. EPA, October 24, 1986, Memorandum from Gregg Schweer, Exposure Assessment Branch, to Jane Kim, Chemical Regulation Branch, Re: "Conservative Estimates of Potential Exposures of PCBs Resulting from Spills of One Pound of PCBs in Mineral Oil or Askaral Fluid"	IP	PO	I	N
5	U.S. EPA, August 16, 1988, Memorandum from Pat Jennings, Exposure Assessment Branch, to Denise Keehner, Chief, Chemical Regulation Branch, Re: "Estimates of Exposure of Humans to PCBs from Disposal of Fluff"	IP	PO	I	N
6	U.S. EPA, September 1986, "Test Methods for Evaluating Solid Waste", Third Edition. SW-846, Method Number 9095 "Paint Filter Liquids Test"	IP	PO	I	U
7	U.S. EPA, April 1991, "Project Summary--PCB, Lead and Cadmium Levels in Shredder Waste Materials: A Pilot Study", EPA 560/5-90-008A, Washington, DC	PS	PO	C	N
8	U.S. EPA, February 1991, "Technical Guidance for the Declassification of Interstate Natural Gas Pipeline Systems"	IP	PO	I	N
9	Midwest Research Institute June 25, 1992, Letter from K. Boggess to J. Smith, Chemical Regulations Branch, EED, OPTS, USEPA, Re: PCB surface decontamination experiments using kerosene"	PS	PO	C	N
10	Battelle, undated, Final Report for Work Assignment 1-9, Technical Support for PCB Disposal Rulemaking", Columbus, OH	PS	PO	C	N

Methodology

The primary contact, via two e-mails, described some of the critical documents. All of them were in the docket, according to him. We went to the docket (OPPT 66009A) and identified and pulled the documents we could based on the primary contact's descriptions. In addition, we identified and pulled some documents we thought might be critical. The primary contact later disagreed with some of those we identified as critical, so we removed them from the summary.

Miscellaneous Other Information

The preamble included a list of references considered by EPA in developing the final rule.

Regional Ozone

Case 13

Rule Title: Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group (OTAG) Region for Purposes of Reducing Regional Transport of Ozone

Citation for Final Rule: 63 Federal Register 57355 (October 27, 1998)

EPA Start Action Notice: 3945

Brief description of the rule

States are required under section 110 of the Clean Air Act Amendments of 1990 to develop State Implementation Plans (SIPs) that assure control of pollution sources sufficient to attain or maintain compliance with National Ambient Air Quality Standards. Section 110(a)(2)(d)) requires that a SIP contain provisions prohibiting its sources from emitting air pollutants in amounts that would contribute significantly to non-attainment, or interfere with maintenance of NAAQS, in one or more downwind States, and Section 110(k)(5) authorizes EPA to find that a SIP is substantially inadequate to meet any CAA requirement. If EPA makes such a finding, it must require the State to submit, within a specified period, a SIP revision to correct the inadequacy. Section 184 delineates a multi-state ozone transport region (OTR) in the Northeast and requires specific additional controls for all areas (not only non-attainment areas) in that region, and established the Ozone Transport Commission (OTC) for the purpose of recommending to EPA, controls for all areas in that region.

In 1994 (the due date for serious ozone non-attainment areas to submit a demonstration of attainment of the NAAQS), it became clear that many of the Eastern Seaboard States could not achieve their 1-hour NAAQS for ozone because of upwind sources of ozone and its precursors, nitrogen oxides (NOx) and volatile organic compounds (VOCs). Together with the Ozone Transport Assessment Group (OTAG), established under the Environmental Council of States (ECOS), EPA worked with the 37 eastern-most States and the District of Columbia, industry, and environmental groups to gather technical information and identify and evaluate strategies for reducing long-range transport of ozone and its precursors. Following two years of analysis, in 1997 the OTAG States voted 32-5 to recommend that EPA reduce NOx emissions from utilities and other major sources. Reductions ranged from those already required by the Clean Air Act, up to an 85% reduction in emissions rate from 1990 utility levels in a number of States in the OTAG region.

In this rule EPA made a finding that 22 of the 37 States and the District of Columbia made significant contributions to exceedences in the NAAQS for ozone in at least one downwind State, and required them to submit SIPs that require NOx emission reductions to significantly reduce such contributions (EPA did not claim that meeting these targets would result in NAAQS being met in downwind States, but that meeting them would significantly reduce the impact on downwind States in the most cost-effective manner). The rule set NOx emissions caps for each State reflecting those reductions. The rule did not mandate which sources must reduce pollution, but utilities and large non-utility point sources were identified as highly cost-effective targets.

The final rule includes a NOx Budget Trading Program that will allow States to achieve the required emissions reductions in a cost-effective way.

EPA also proposed Federal Implementation Plans (FIPs) to reduce regional ozone transport, in the event that any of the 22 States or the District of Columbia did not submit the required State implementation plan provisions in response to the NOx State implementation plan call (NOx SIP call) or failed to submit an approvable plan. The FIPs include NOx reduction requirements for utilities and large non-utility point sources, including large industrial boilers and turbines, large internal combustion engines, and cement manufacturing.

Brief description of science input to the rule

Section 110(a)(2)(d) of the Clean Air Act Amendments likely owes its existence to scientific studies began in the late 1960s that identified ozone as a "regional" pollutant. Papers presented at a major international symposium sponsored by EPA in 1977 (the year Section 110(a)(2)(d) was added to the Clean Air Act) indicted that there was strong empirical evidence for ozone and its precursors to be transported aloft and transported for hundreds of miles in overlapping urban plumes during sustained high pressure events, resulting in high ozone concentrations downwind. The Clean Air Act Amendments of 1990 further strengthened section 110, and directed EPA to contract an expert review of the ozone problem to the National Research Council of the National Academy of Sciences, who concluded in their 1992 report, *Rethinking the ozone problem in urban and regional air pollution*, that "Given the regional nature of the ozone problem in the United States, a regional model is needed to develop the control strategies for individual urban areas." OTAG was formed three years later to develop this regional model.

The rulemaking early on relied heavily on the scientific consensus-building process in OTAG, which established technical working groups co-chaired by EPA and a representative of a State environmental agency or the regulated community. One group tested the results of an air quality model, UAM-V, against real world ozone data collected during four episodes (periods of elevated ozone concentrations over large parts of the eastern U.S.), and modified the model chemistry to bring the results into better agreement with the observations. The models were tested against each other and found to provide similar results (although the models share some of the same features, they are different in several respects, including the fact UAM-V does not actually apportion the sources of ozone explicitly to upwind sources, but must be run with and without the upwind sources included to calculate unwind contributions by difference). The group also developed consistent NOx and VOC emissions inventories for the OTAG states, which were used to drive the models. Analyses also were done using observations of air quality data during episodes to lend independent confirmatory support to the model runs, including the conclusion that upwind controls of VOC emissions would not have a significant impact on downwind air quality. OTAG work groups developed and evaluated alternative control strategies, including market trading schemes (see below). The OTAG research led to a number of voted recommendations to EPA in 1997.

The critical culmination of the scientific input to the rule itself is found in the *Air Quality Modeling Technical Support Document for the NOx SIP Call*. This report documents the results of a series of analyses employing UAM-V and CAMx, that provide quantitative estimates of the impacts of upwind sources of NOx on downwind exceedences of the 1-hour and 8-hour ozone NAAQS, under a 2007 base case, as well as under the various control options. The models simulated the meteorological conditions characteristic of four historical "episodes" in the Eastern

U.S. (extended periods of weather conducive to the regional transport and formation of ozone), using emissions estimated for the year 2007, with and without several control scenarios. These model runs differed from the OTAG runs mainly in that the emissions inventory was modified by EPA to include more recent utility emissions data for 1994-96 based on continuous emissions monitors instead of less accurate emissions factors, and the fact that the models were run for all the States in the OTAG area for all four episodes. The 2007 inventories included projected NOx and VOC emissions from stationary sources, road and non-road mobile sources, and biogenic emissions (trees produce VOC), using several EPA planning models (IPM, MOBILE5, and BEIS2, respectively), which project emissions for 2007 based on economic factors and the effects of regulatory programs expected to be in effect in that year. EPA also updated the OTAG data on the economics and feasibility of various control strategies. The results of the model runs and the underlying inventories and control strategies are the critical science link in the rule, in that they are the basis for identifying certain upwind States as significant contributors to downwind States and demonstrating that a control strategy deemed cost-effective by EPA would reduce such exceedences, thus providing justifications for the emissions caps for each State under the SIP call. The rule ran into a legal challenge, including the allegation that projected state-by-state fossil fuel heat input data were considerably different than those subsequently observed, apparently due to utility deregulation and energy trading.

The models required development of comparable emissions inventories for each State, both to drive the models and to serve as the base against which the NOx emissions cap for each State in the SIP call was calculated. The base case emissions inventory was a hypothetical inventory for the year 2007, assuming that all other regulations affecting NOx and other ozone precursors not associated with the rulemaking were having their intended result. Also critical was the determination of which controls on various emissions sources were “highly cost-effective,” defined in the rulemaking as costing less than $2000/ton of NOx reduced. Several emissions scenarios (0.25, 0.20, 0.15, and 0.12 lb NOx/mm BTU for large electric generating units and 60% reductions from baseline for large non-electricity-generating industrial boilers and turbines, 90% reduction from large internal combustion engines, and 30% reduction from cement manufacturing sources, along with both intrastate and interstate emissions trading) were evaluated in the modeling technical support document to determine that such reductions would significantly reduce upwind contributions to downwind exceedences.

EPA determined that an emissions reduction of 0.15 NOx/mm BTU for large electric generating units with interstate emissions trading and a 60% reduction in the other sources cited above were both highly cost-effective and technically feasible by 2003, and that such a reduction would “eliminate the significant amount of contribution” of the upwind states to exceedences in downwind states. The expected emissions reductions were used to set State-by-State caps for the NOx SIP call[2]. The States were allowed to meet these caps by means other than the controls used in the IPM models to set the caps. Because the air quality models represent only the meteorological conditions during the four historical episodes, and not the entire ozone season, it is not possible to forecast the probable frequency with which each State would exceed its ozone NAAQS or contribute significantly to exceedence in a downwind State after implementation of the rule.

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[2] Even though 0.12 lb/ mm BTU feel below the $2000/ton threshold, and would further reduce excedeences, EPA was not sure that the technology could be implemented by 2003

Description of critical documents

Although there were no formal responses to the questionnaires, the OIG team member responsible for this rule was able to delve more deeply into the science behind this rule, by being co-located with a team of air quality modelers familiar with the history of air quality modeling. Therefore, some of the critical science was found in the reference section of other critical documents, which had been identified in turn among the references of still other supporting documents. Some of the key science documents cited in the preamble (the numbers reference the attached table) included the*:*

- *Air Quality Modeling Technical Support Document for the NOx SIP Call* [Reference 1], or TSD, which bears the weight for identifying States as significant contributors to exceedences in downwind States and recognizing that technologies recognized by EPA as cost-effective would significantly reduce these contributions.

- *Development of Modeling Inventory and Budgets for the Ozone Transport SIP Call* [Reference 2], which describes the development of the 2007 emissions inventory.

- *Regulatory Impact Analysis of the NOx SIP Call*, [Reference 3] which contains the analyses that establish the cost-effectiveness of the various control technologies, including the emissions trading options.

- *Response to Significant Comments on the Finding of Significant Contribution and Rulemaking for Certain States in the OTAG Region for Purposes of Reducing Regional Transport of Ozone* [Reference 4], which reiterates and explains the science behind the three documents cited above.

The only other potentially key documents were published as part of the OTAG effort. The preamble clearly stated that, “The OTAG’s air quality modeling and recommendations formed basis for today’s action” (see preamble p. 57361). The proposed rule relied heavily on the scientific consensus-building process in OTAG underpinning the development and testing of the air quality models, development of the emissions inventory that underlies the model runs, and the analysis of air quality data that lends confirmatory support to the model runs, including the conclusion that upwind controls of VOC emissions would not have a significant impact on downwind air quality. The preamble directs the reader to the OTAG webpages on the Internet. However, citation of specific OTAG results in the preamble of the final rule are limited (see below).

The modeling TSD [Reference 1] reference list is short, but most of the references appear critical. It cites the manuals for the two models (UAM-V [Reference 5] and CAMx [References 6, 7, 8]); the studies conducted by OTAG testing the models against real world data in the episodes [References 9, 10, 11]; the chemical mechanism used in the models and an update to this mechanism required to bring the modeled results into better agreement with the observed data [References 12 and 13]; documents associated with the emissions inventory [References 2, 14]; the Regulatory Impact Analysis [Reference 3], and the OTAG Technical Support Document [Reference 15], which identified the four episodes used in the modeling study and set the initial conditions and boundary conditions; meteorological data; grid configurations; fine grid/coarse grid definition; and vertical layer structures for the modeling. Both UAM-V and CAMx were developed using private funding by Systems Applications International, Inc. (SAI) and ENVIRON, Inc., respectively.

The manuals for the models [References 5, 6, 7, 8] apparently are the only comprehensive descriptions, since no peer reviewed literature was cited. UAM-V is an enhancement of UAM-IV, the model that is recommended by EPA's Office of Air Quality Planning and Standards (OAQPS) for development of SIPs. None of the UAM models have source-apportionment capability, and several of the UAM-V developers left SAI to form ENVIRON and develop CAMx, which does have source apportionment capability. The two models are considered otherwise very similar. Each manual has a lengthy citation list, with many citations in common. Generally, we looked through the citations for references that seemed to represent important subroutines that would have been difficult to duplicate de novo. Interviews with modelers suggested that much of the modeling effort is a mathematical exercise, and can be done de novo. The performance of the models was reviewed in the open OTAG scientific meeting process (which we listed as Other External in Table 1).

Of the critical science cited in the model user manuals, a report by Reynolds et al. (1973) [Reference 16] reflects the birth of the UAM series of models. Early development of UAM was funded under contract to SAI by ORD. The gray literature reports documenting further model development are difficult to track, but looking at Reynolds (1977) pp795-802 In Dimitriades [Reference 25] and the UAM-V users manual [Reference 5], it is clear that UAM was developed through a combination of contracts and co-operative agreements between SAI, Inc. and ORD and later OAQPS between 1970 and 1990. Arguably, SAI, and thus UAM-V and CAMx, owe their existence to early research and development funding by EPA's Office of Air and Radiation (OAR) and ORD.

Three critical papers provided the scientific underpinning for the ozone chemistry (CB-4) mechanism. Gery, et al. (1989) [Reference 12] was cited in both manuals and in the TSD. This paper represents the culmination of a series of projects funded by ORD under contract to SAI to develop the CB-IV mechanism, the most widely used mechanism in ozone models (Dodge 2001)[3]. Whitten et al. (1996) [Reference 13] was cited in the manuals as the modification of the CB-4 mechanism to better deal with isoprene emissions from vegetation. The underlying research cited in the manuals was conducted by Carter, W. (1996) [Reference 17] working at the California Air Resource Board under a contract with ORD.

Late in the project we discovered a summary of the OTAG process by Keating and Ferrell (1999)[4]. They explained that OTAG had switched from the Biological Emissions Inventory System (BEIS), the model used to estimate emissions of VOC and NOx from vegetation and soils, to a new version, BEIS2. The newer model (Geron et al. 1994) [Reference 39] according to Keating and Ferrell,

> resulted in a 500% increase in the estimates of isoprene emissions and a 400% increase in the estimates of soil NOx emissions as compared to the estimates produced by BEIS.

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[3] Dodge, M. 2000. Chemical oxidant mechanisms for air quality modeling. Atmospheric Environment: 34: 2103-2030

[4] Transboundary Environmental Assessment: Lessons from the Ozone Transport Assessment Group. Technical Report, NCEDR/99-02. National Center for Environmental Decision-making Research: Knoxville, TN.

> These changes had a significant effect on the overall emissions inventory, the relative performance of air quality models, and the policy recommendations implied by air quality model's predictions.

BEIS2 was felt to be more accurate, but resulted in overestimation of the ozone levels when run with either UAM-V or CAMx. The addition of the Carter chemistry to the UAM-V code by Whitten et al. yielded better results, but when a researcher at one of the centers tried to use the new chemistry in a new model, it performed poorly (Jang 1997) [Reference 40]. Timin et al. (1997) [Reference 41] subsequently discovered that some of the reactivity data in UAM-V had been altered when the new isoprene code was added, and this was subsequently fixed in both UAM-V and CAMx. Without these latter papers, the modeling results could have contained substantial errors.

Two other papers cited in the CAMx manual appear critical. Sillman, S. (1995) [Reference 18], developed the mechanism used in CAMx to delineate between NOx and VOC control of ozone formation. This research was funded under a competitive cooperative agreement with the University of Michigan funded by ORD/AREAL. Wesley, M.L. (1989) [Reference 19] developed the mechanism in CAMx used to deposit ozone to vegetation surfaces, and important “sink” for atmospheric ozone. This research was conducted by Argonne National Labs under an IAG funded by ORD.

The tests of the models against real world data collected during four episodes were conducted by the four OTAG modeling centers. They were reported in Alpine Geophysics, LLC (1998) *Modeled Effects of Indiana Point Source NOx Emissions Reductions on Local and Regional 1-HR and 8-HR Ground Level Ozone Concentrations in 1995 and 2007 Using Two OTAG Oxidant Episodes* [Reference 9]; Sonoma Technology, Inc., (1997a); *Evaluation of the UAM-V Model Performance in OTAG Simulations, Phase I: Summary of Performance Against Surface Observations*," STI-996120-1605-FR [Reference 10]; Sonoma Technology, Inc.(STI), (1997b). *Comparison of CAMx and UAM-V Model Performance for Two Ozone episodes in the Eastern United States*. STI-996203-1733-FR [Reference 11]. The contracts to assemble and report on the results of the modeling studies were funded by OAQPS. Peer review was limited to OTAG process.

The data that supported the modeling evaluations included the 1988 episode in the Northeast studied intensively using EPA’s Regional Oxidant Model, the 1991 LMOS episode funded by the Great Lakes States (LADCO 1995); SOS in the 1993 episode in the Southeast (e.g., Chameides and Cowling 1995); the and the1995 NARSTO-NE study in the Northeast (Roberts et al. 1995) [References 35-38]. These references are included because they indicate who performed the research and the funding sources and mechanisms, but were not cited in the model reports.

In summary, ORD and later OAR funded under contract the majority of the research that led to development of UAM model and it’s critical components, although not the final development of UAM-V and CAMx. That was done primarily with venture capital from the SAI and ENVIRON. Model testing and evaluation was funded by OTAG, using episode data that owe their existence to a number of field studies funded by ORD, the States, and industry under the SOS, LADCO, and NARSTO programs.

The critical reports cited in the Modeling TSD are: EPA (1996) *Forecast of Average Daily NOx Emissions in July by Electric Generation Units Using OTAG 2007 Base Case and the Integrated*

Planning Model (IPM), [Reference 20], and EPA (1998a) *Development of Modeling Inventory and Budgets for the Ozone Transport SIP Call* [Reference 2]. These reports were developed by OAQPS with support from in-house contracts. These reports in turn build on reports prepared for OAQPS by E.H. Pechan & Associates, Inc: Pechan (1997a) *Ozone Transport Assessment Group (OTAG) Emissions Inventory Development Report - Volume I: 1990 Base Year Development (revised draft)* [Reference 21]; Pechan (1997b) *Ozone Transport Assessment Group (OTAG) Emissions Inventory Development Report - Volume III: Projections and Controls (draft)*; [Reference 22] and Pechan (1997c) *The Acid Rain Data Base for 1996 (ARDB96) Technical Support Document (draft)* [Reference 22]. Pechan had prepared earlier versions of the first two reports under contract to OTAG.

The final NOx emissions caps were heavily influenced by EPA's determination that an emissions cap of 0.15 lb/mm BTU for large electric generating units was both cost-effective and technically achievable by 2003 (preamble, p. 57401). The three most critical sources cited appear to be EPA, 1998b. *Regulatory Impact Analysis of the NOx SIP Call* Docket A-96-56, VI-B-09, September 1998 [Reference 3]; *Analyzing Electric Power Generation under the CAAA*, March 1998. Docket V–C–3 [Reference 24]; and *Performance of Selective Catalytic Reduction on Coal-Fired Steam Generating Units* (cited on p. 57413 of the preamble) [Reference 42].

There is a fairly clear link back to the early science that established ozone as a regional air quality problem (i.e., high-ozone episodes were not caused entirely by local sources and plumes from one upwind urban area), which led to the inclusion of Section 110(a)(2)(d) into the 1977 Clean Air Act Amendments. A major international symposium sponsored by ORD and attended by more than 1000 scientists represented a key milestone in the regional ozone transport debate. Dimitriades, B. [Ed.] International Conference on photochemical oxidant pollution and its control. Proceedings v.1&2. EPA-600/3-77-001 a&b [Reference 25]. The symposium was organized by an EPA scientist. None of the papers were peer-reviewed [B. Dimitreades, pers. com.]. Although the papers covered a wide range of topics involving photochemistry, methods, etc., two papers stand out as critical for this rule.

In the first paper, Ripperton, et al. (1977) [Reference 26] cited six Research Triangle Institute (RTI) studies conducted from 1970-1976 that led to the *hypothesis* that ozone and its precursors were transported aloft, and that new ozone was created with each diurnal cycle, and thus rural background ozone was the result of precursors transported for hundreds of miles in overlapping urban plumes during sustained high pressure events. These studies also are described by Vukovitch (1977) [Reference 27]. These studies, cited in NRC (1992) (see below) as seminal, were funded under contracts with ORD and later OAR. In the second paper, Wolff, et al. (1977) [Reference 28] reported on a high pressure episode over New England, and showed that the precursors must have been built up in the Midwest and moved to the east. Wolff was working at the Interstate Sanitation Commission, which received its funding from three NE States. Wolff et al cited two other works that used similar approaches: Coffey and Stasiuk (1975), [Reference 29] which received rigorous journal peer review, and Bach (1975) [Reference 30], which was funded under contract to OAR.

NRC (1992) *Rethinking the ozone problem in urban and regional air pollution*. [Reference 31], cited in the modeling TSD, represents the results of the deliberations of an expert panel formed by the National Research Council (NRC) under directions from Congress. Performed under contract to OAR (and rigorously peer reviewed under NRC guidelines), the report concluded that a regional model was needed to develop the control strategies for individual urban areas. It cited

Ripperton, et al. (1977), Vukovitch et al. (1977), and Logan (1989), as providing critical supporting evidence.

Logan (1989) [Reference 32], analyzed two years of data from the SURE/ERAQS monitoring network covering the states between IN, MA, and NC. The NRC report said that Logan's analysis strengthened the conclusions of the case studies cited above. Logan's work was funded by a grant to Harvard from the National Science Foundation (or NSF). The NRC report also cited Sillman et al. (1990) [Reference 33] as evidence of the necessity to treat urban ozone plumes explicitly in regional-scale air quality models. This work also was funded as a grant to Harvard from NSF.

OTAG continued to pursue the analysis of air quality data (as opposed to simulation modeling) to provide independent support for the modeling results. These results are summarized in Guinnup, D. and R. Collom, (1997) *Final Report, Volume II: Summary and Integration of Results OTAG Air Quality Analysis Workgroup* [Reference 34]. The impact of the work is summed up (although not explicitly cited) in pp. 57381-57386 of the preamble. One paragraph sums it up as follows (p. 57382):

> The EPA relied on OTAG data to develop the information necessary to evaluate the weight-of-evidence factors identified above. These data include emissions (tons) and emission density (tons per square mile), *air quality analyses, trajectory, wind vector, and ''ozone cloud'' analyses*, and subregional zero-out modeling. *In brief, EPA's proposed approach was as follows: the OTAG transport distance scale was applied to identify, based on the meteorological potential for transport, which States may contribute to ozone in downwind States*.[5]"

These references are deemed critical, even though their role is limited to their confirmatory value of the modeling. The references in the OTAG report were funded by OTAG, published on the OTAG Air Quality Analysis subgroup webpage, and subject to OTAG review as noted above. In summary, ORD and OAR funded a significant amount of the research that established ozone as a regional air quality problem under contract to Research Triangle Institute, an independent research organization. The Interstate Sanitation Commission funded Wolff's work, and grants from NSF to Harvard also proved important, as did the availability of monitoring data from the EPRI monitoring network. OTAG funding was invested in additional work that had largely only confirmative impact on the science behind the rule itself.

<u>Table of critical documents</u>

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	Air Quality Modeling Technical Support Document for the NOx SIP Call, U.S. Environmental Protection Agency, Office of Air and Radiation, September 23, 1998.	IP	PO	C	N

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[5] Only the items in italics (added) refer to the air quality analysis.

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
2	EPA (1998a) U.S. Environmental Protection Agency, "Development of Modeling Inventory and Budgets for the Ozone Transport SIP Call," Docket A-96-56, V-E-06, March 23, 1998.	IP	PO	C	U
3	EPA (1998b) Regulatory Impact Analysis of the NOx SIP Call Docket A-96-56, VI-B-09, September 1998	IP	PO	C	U
4	EPA (1998c) Response to Significant Comments on the Finding of Significant Contribution...	IP	PO	C, I	U
5	System Application International (SAI), (1995) "User's Guide to the Variable Grid Urban Airshed Model (UAM-V)," April 1995, San Rafael, CA 94903.	PS	O	O	OEP
6	ENVIRON International (1997a) User's Guide to the Ozone Tool: Ozone Source Apportionment Technology for UAM-IV, ENVIRON: Novato, CA	PS	O	O	OEP
7	ENVIRON International (1997b) User's Guide to the Comprehensive Air Quality Model with Extensions (CAMx), ENVIRON:Novato, CA	PS	O	O	OEP
8	ENVIRON International (1997c) Assessment of the Contribution of Emissions from Northern OTAG States on Elevated Ozone Concentrations, December 1997, ENVIRON, Novato, CA.	PS	O	C	OEP
9	Alpine Geophysics, LLC (1998) Modeled Effects of Indiana Point Source NOx Emissions Reductions on Local and Regional 1-HR and 8-HR Ground Level Ozone Concentrations in 1995 and 2007 Using Two OTAG Oxidant Episodes, AGL:Covington, KY 41017	PS	O	C	OEP
10	Sonoma Technology, Inc. (1997a) “Evaluation of the UAM-V Model Performance in OTAG Simulations, Phase I: Summary of Performance Against Surface Observations," STI-996120-1605-FR, Santa Rosa, CA	PS	PO	C	OEP

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
11	Sonoma Technology, Inc. (STI), (1997b) Comparison of CAMx and UAM-V Model Performance for Two Ozone episodes in the Eastern United States. STI-996203-1733-FR, Santa Rosa, CA.	PS	PO	C	OEP
12	Gery, M.W., G.Z. Whitten, J.P. Killus and M.C. Dodge (1989) "A photochemical kinetics mechanism for urban and regional scale computer modeling," J. Geophysical Research, 94, 12925-12956,	PS	ORD	C	ENP
13	Whitten G.Z., H.P. Deuel, C.S. Burton and J.L. Haney (1996) "Overview of the implementation of an updated isoprene chemistry mechanism in CB4/UAM-V," Report of SAI, San Rafael, CA	PS	ORD	C	OEP
14	EPA (1996) U.S. Environmental Protection Agency, "Forecast of Average Daily NOx Emissions in July by Electric Generation Units Using OTAG 2007 Base Case and the Integrated Planning Model (IPM)," December 1996.	IP	PO	C	U
15	OTAG Technical Support Document, June 1997	PS	O	O	OEP
16	Reynolds, S., M. Liu, T. Hecht, P. Roth, and J. Seinfeld (1973) Urban Airshed Photochemical Simulation Study: volume 1 – Development and Evaluation. EPA -R4-73-020a-e	PS	ORD	C	U
17	Carter, W. (1996) Condensed atmospheric photooxidation mechanisms for isoprene. Atmospheric Environment 30: 4275-4290	AC	ORD, O	CA, C	ENP
18	Sillman, S. (1995) The use of NOy, H_2O_2, and HNO_3 as indicators for ozone- NOx- hydrocarbon sensitivity in urban locations, J. Geophys. Res. 100: 14,175 -14,188	AC	ORD	CA	ENP

Ref .	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
19	Wesley, M.L. (1989) Parameterization of surface resistances to gaseous dry deposition in regional-scale numeric models. Atmospheric Environment 23: 1293-1304	OF	ORD	IAG	ENP
20	EPA (1996) U.S. Environmental Protection Agency, "Forecast of Average Daily NOx Emissions in July by Electric Generation Units Using OTAG 2007 Base Case and the Integrated Planning Model (IPM)," December 1996	IP	PO	C	U
21	Pechan (1997a) Ozone Transport Assessment Group (OTAG) Emissions Inventory Development Report - Volume I: 1990 Base Year Development (revised draft) prepared for U.S. EPA, OAQPS by E.H. Pechan & Associates, Inc. February, 1997;	PS	O	C	OEP
22	Pechan (1997b) Ozone Transport Assessment Group (OTAG) Emissions Inventory Development Report - Volume III: Projections and Controls (draft) prepared for U.S. EPA, OAQPS by E.H. Pechan & Associates, Inc.,June, 1997	PS	PO	C	U
23	Pechan (1997c) The Acid Rain Data Base for 1996 (ARDB96) Technical Support Document (draft)	PS	PO	C	U
24	Analyzing Electric Power Generation under the CAAA, March 1998 .	IP	PO	C	U
42	Performance of Selective Catalytic Reduction on Coal-Fired Steam Generating Units	IP	PO	C	N
25	Dimitriades, B. [Ed.] International Conference on photochemical oxidant pollution and its control. Proceedings v.1&2. EPA-600/3-77-001 a&b	IO	ORD	I	N
26	Ripperton, L.A., J.B. Worth, F.M Vukovitch, and C.E. Decker. 1977. Research Triangle Institute Studies of High Ozone Concentrations in Urban Areas. pp. 413-424 In Dimitriades (1977)	PS	ORD, PO	U	N

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
27	Vukovitch (1977) On the relationship between high ozone in the rural surface layer and high pressure systems. Atmospheric Environment 11:967-983	PS	PO	C	ENP
28	Wolff, G.T. Lioy, P., Wright, G.D., Meyers, R.E., and R.T. Cederwell (1977) An investigation of long-range transport of ozone across the Midwestern and Eastern United States. In Dimitriades (1977)	OG	O	O	N
29	Coffey, P.E., and W. Stasiuk (1975) Evidence of atmospheric transport of ozone into urban areas. ES&T 9(1): 59-62	OG	O	O	ENP
30	Bach, Jr., W. (1975) Investigation of ozone and ozone precursor concentration in non urban locations in the eastern U.S. EPA 450-3-74-034-a	PS	PO	C	U
31	NRC (1991) Rethinking the ozone problem in urban and regional air pollution. National Research Council, National Academy Press, Washington, DC	OG	PO, OF, O	G	ENP
32	Logan, J.A. (1989) Ozone in the rural areas of the United States. Journal of Geophysical Research 94:8511-8532	AC	OF	G	ENP
33	Sillman, S., J. Logan, and S. Wofsy (1990) A regional scale model for ozone in the United States with subgrid representation of urban and power plant plumes. JGR 95:5731	AC	OF, ORD	G	ENP
34	Guinnup, D. and R. Collom (1997) Final Report, Volume II: Summary and Integration of Results OTAG Air Quality Analysis Workgroup	OG, IP	O	O	OEP
35	Dennis, R. (1990) Eulerian Model Evaluation Program, pp.5-83 to 5-102 In R. Dennis et al. Evaluation of Regional Acid Deposition Models (Part 1) National Acid Precipitation Assessment Program.	IO, PS, OF, OG	ORD, O	C, I	FACA

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
36	Chameides, W. L. and E. B. Cowling (1995) The state of the Southern Oxidants Study (SOS): N.C State University	AC	ORD	CA	U
37	LADCO (1995) Lake Michigan Ozone Study: Lake Michigan Ozone Control Program. Lake Michigan Air Directors Consortium, Des Plains, IL.	OG	O	U	U
38	Roberts, et al. NARSTO-Northeast - 1995 Summer Ozone Study. NARSTO November 1995	IO, IP, PS, AC, OF	ORD, OF, O	C	II
39	Geron, C. D., A. B. Guenther, and T. E. Pierce (1994) "An improved model for estimating emissions of volatile organic compounds from forests in the eastern United States". Journal of Geophysical Research, 99:12773	IO	ORD	I	ENP
40	Jang, C. J., S. C. Y. Lo, J. Vukovich, P. Kasibhatla, R. T. Tang, and L. Bender (1997) "Sensitivity of Ozone Predictions to Biogenic Hydrocarbon Chemistry and Emissions in Air Quality Models." (97-RA94.05). Proceedings of the 90th Annual Air and Waste Management Association Meeting and Exhibition, Pittsburgh, PA	PS	O	C	N
41	Timin, B., J. Lawrimore, C. Jang, and H. Jeffries (1997) The Effect of the Updated Isoprene Chemistry on Ozone Concentrations in OTAG, Draft Version 1.5. Raleigh, NC: North Carolina Division of Air Quality	OG	O	O	N

Methodology

We received no responses to questionnaires. We were given a broad introduction to the rule by the primary contact, who directed us to the OTAG homepage on the web and to the program scientist who led the modeling technical workgroup. That program scientist led us to the appropriate manuals and the report of the modeling group, and suggested some additional contacts. The OIG team member is co-located with ORD's air quality modeling division, so he was able to get some additional scientific background on modeling issues, even though no ORD scientists were involved in the rule-making per se. OIG also was able to interview one of the scientists who oversaw one of the OTAG modeling centers, who provided some additional insight. Primarily, however, this summary was put together by going to the key documents and working back through the reference sections in those papers to their referenced documents, and from there back to even earlier references. The OTAG references were generally available on the web, but it was very difficult to navigate among the references, as each center has it’s own webpage. The OTAG review paper by Keating and Ferrell (1999) would have been more helpful if we had been introduced to it earlier in the process.

Case 14
Nonroad Diesel Engines

Rule Title: Control of Emissions of Air Pollution from Nonroad Diesel Engines

Citation for Final Rule: 63 Federal Register 56967 (October 23, 1998)

EPA Start Action Notice: 3645

Brief description of the rule

This rule established (or revised) emission standards and emission guidelines for combined particulate matter (PM), carbon monoxide (CO), non-methane hydrocarbons (NMHC), and nitrogen oxides (NOx) from nonroad diesel engines. Under section 213(a)(2) of the Clean Air Act, the Administrator had previously determined that nonroad engine emissions were significant contributors to ambient ozone and carbon monoxide in more than one nonattainment area, and under section 213(a)(4) determined that emissions of PM and smoke from compression-ignition (i.e., diesel) nonroad engines caused or contributed to air pollution caused a range of adverse health effects for humans. NOx and PM were the emission components of the most concern for this rule.

Covered nonroad equipment and engines included: agriculture and logging, construction, general industrial, lawn and garden, utility, and material handling. The emission limits were technology based, and relied somewhat on the science used to develop on-highway heavy-duty engine emission standards. Because the standards were intended to reduce emissions by up to two-thirds from previous standards, engine manufacturers would have to build and maintain new (or rebuilt) nonroad engines that adhered to the new, stringent emissions standards. The manufacturers believed they could achieve these goals and, with the California Air Resources Board and EPA, signed a statement of principles to that effect.

The emission standards varied depending on the rated power of the engine and when the engine was built (or rebuilt). Engines were divided into five categories, engines rated under 37 kW; between 37 and 75 kW; between 75 and 130 kW; between 130 and 450 kW, and above 450 kW. Within each engine power category, the initial standards were set as tier 1; for the larger power categories, the tier 1 standards were set in a 1994 rule. For this 1998 rule, the tier 1 standards were set for the engine power category under 37kW. Tier 2 and 3 standards (more stringent standards) were also set to be effective in future years, dependent on the engine power category.

Smoke standards promulgated under a previous rule for nonroad diesel engines rated at or above 37 kW were extended to cover nonroad diesel engines rated under 37 kW, except 1-cylinder engines and marine propulsion engines, and constant speed engines. The rule revised the existing nonroad engine averaging, banking, and trading program that (because of the technological feasibility, lead time, and cost) EPA believed was an important element in reaching the new emissions standards.

Brief description of science input to the rule

To prepare the rule, EPA needed information about: the large number of engine manufacturers; the broad range of engine sizes; installation of nonroad diesel engines into the vast array of construction, industrial, agricultural, electrical generation applications; what the engines emit and how much; the effect of the emissions; the control techniques that addressed unique characteristics of nonroad applications (special engine cooling needs, dusty operating environments, etc.) and the similarities with highway heavy-duty engines; and the costs associated with controlling the emissions. In addition, a Nonroad Emissions Model (computer program) was also developed for this rule to project emissions inventories from nonroad sources.

Description of critical documents

A Report to Congress that confirmed and quantified air pollutants from nonroad engine sources was the basis for the decision that a rule was needed. [See Reference 1.] EPA, the California Air Resources Board, and engine manufacturers established a joint Nonroad Diesel Engines Statement of Principles that formed the basis for the stringent emissions standards in the rule. [See References 5 and 6.] The proposed rule was supported by two regulatory impact analyses and an economic impact analysis. These analyses considered engine technology alternatives and related costs. [See References 3, 4, and 6.]

Obtaining emission data and developing the model were important to the rule [See References 1 and 8.] The data on which the model was based included such information as: source population, annual hours of use, horsepower, engine load factor, estimated average emissions. [See References 2 and 6.] Additional information on the rebuilt engine industry and challenges in varying organizational learning rates was also collected. [See References 2 and 7.] An additional report analyzed NOx reduction benefits and health and environmental effects. [See Reference 8.]

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	Nonroad Engine and Vehicle Emission Study-Report and Appendices, EPA-21A-201, November 1991	IP, PS	PO	I, C	OEP
2	ICF Incorporated, Industry Characterization: Nonroad Heavy Duty Diesel Engine Rebuilders, January 3, 1997	PS	PO	C	U
3	Final Regulatory Impact Analysis: Control of Emissions of Air Pollution from Highway Heavy-Duty Engines, U.S.E.P.A., September 16, 1997	IP	PO	I	U

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
4	Estimated Economic Impact of New Emission Standards for Heavy-Duty On-Highway Engines, Acurex Environmental Corporation Final Report (FR-97-03), March 31, 1997, page 4-11	PS	PO	C	U
5	Nonroad Compression-Ignition Engine Statement of Principles (see 60 FR 45580, August 31, 1995, Appendix)	IP, OG, PS	PO	O	U
6	Final Regulatory Impact Analysis: Control of Emissions from Nonroad Diesel Engines	IP	PO	I	U
7	Learning Curves in Manufacturing, L. Argote and D. Epple, Science, February 1990, Vol. 247, page 920	AC	O	G	ENP
8	Benefits of Reducing Mobile Source NOx Emissions, ICF Inc., Draft Final, September 30, 1996	PS	PO	C	U

Methodology

The program scientist sent an e-mail identifying, either specifically or generally, science documents he considered critical. Using this information, we went to the docket and pulled the documents identified, as well as a few others we believed critical. We also talked on the phone with the primary contact about locating one of the older critical documents and he referred us to a website that contained the document.

Case 15
Plant-Incorporated Protectants

Rule Title: Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)

Citation for Final Rule: 66 Federal Register 37771 (July 19, 2001)

EPA Start Action Notice: Unknown

Brief description of the rule

Plants have evolved, and thus naturally possess, various mechanisms to resist pests. More recently, scientific techniques have been developed by which pest resistance traits from diverse living organisms can be introduced into plants to prevent, destroy, repel or mitigate pests. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the genetic material required to produce such pesticidal traits, and the substances produced as a result of the introduced genetic materials, are each pesticides, and thus subject to regulation under FIFRA. The pesticidal substances, along with the genetic materials necessary to produce them, are designated "plant-incorporated protectants" by EPA.

FIFRA section 3(a) provides, with some exceptions, that no person may distribute or sell in the United States any pesticide that is not registered. Section 25(b)(2) of FIFRA allows EPA to exempt, by regulation, any pesticide from some or all of the requirements of FIFRA. With one exception, under this rule EPA requires registration of plant-incorporated protectants. Thus, as with other pesticides, the applicant must show that the protectant "when used in accordance with widespread and commonly recognized practice, . . . will not generally cause unreasonable adverse effects on the environment". The exception is for protectants derived through conventional breeding from sexually compatible plants. Excluding the requirement for reporting adverse effects, requirements of FIFRA and the Federal Food, Drug and Cosmetics Act do not apply to these protectants.

In addition, the rule establishes a new part in the Code of Federal Regulations (CFR) specifically for plant-incorporated protectants, i.e., 40 CFR 174. Procedures are also set forth for Confidential Business Information (CBI); any claim of confidentiality must be substantiated when the claim is made. The rule also requires, for exempted plant-incorporated protectants, that any person who produces, for sale or distribution, a plant-incorporated protectant about which there is any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant, the producer must submit such information to EPA within 30 days.

Brief description of science input to the rule

The rule was a legal mechanism to confirm that plant-incorporated protectants were covered by FIFRA. The science aspects concerned the exemption for protectants derived through conventional breeding from sexually compatible plants. To comply with FIFRA, such protectants may not generally cause unreasonable adverse effects on the environment. EPA supported this conclusion by showing that the adverse effects of naturally-occurring protectants were already known and unlikely to get worse.

Description of critical documents

To shape the regulation, EPA (sometimes with other Federal agencies) held conferences in 1987, 1988 and 1990 dealing with plant related issues, and posed several questions about different aspects of the proposed rule to science panels; these panels had public meetings in 1992, 1993, and 1994 to discuss the questions and provided a report on their conclusions. See References 1 through 6.

In preparing the rule, EPA drew on a large body of information developed through systemic scientific study available in public literature, such as References 7 and 8. From this information, staff from the EPA program office prepared five issue papers with extensive bibliographies. Most of the cited scientific studies justified the exemption, i.e., that plant-incorporated protectants derived through conventional breeding from sexually compatible plants should be exempt from FIFRA. See References 9 through 13.

Two other major supporting documents underlying the rule were the economic analysis and summary of comments on the proposed rule. These were critical because, respectively, they summarized the options considered by the EPA (including costs and benefits) and how the rule was changed because of the comments. See References 14 and 15.

Table of critical documents

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
1	On October 19-21, 1987, a meeting on "Genetically Engineered Plants: Regulatory Considerations" at Cornell University, Ithaca, New York	IP	PO	I	U
2	Doebley, J, 1988, In: "Transgenic Plant Conference." Proceedings of a meeting held September 7-9, 1988, in Annapolis, Maryland, Frisco, Colorado: Keystone Center, Pages 137-145	AC, PS, IP	PO	I	U
3	On November 6-7, 1990, a conference on "Pesticidal Transgenic Plants: Product Development, Risk Assessment, and Data Needs" in Annapolis, Maryland	IP	PO	I	U
4	U.S. EPA, FIFRA Scientific Advisory Panel meeting in Arlington, VA on December 18, 1992	AC	PO	I	FACA
5	U.S. EPA, Biotechnology Science Advisory Committee meeting on July 13, 1993	AC, PS	PO	I	FACA

Ref.	Document/Study	Who Performed It (Category)	Who Funded It (Category)	Funding Mechanism	Peer Review?
6	U.S. EPA, joint meeting of science advisors in Arlington, VA on January 21, 1994	AC	PO	I	FACA
7	International Food Biotechnology Council, 1990, "Biotechnologies and food; Assuring the safety of foods produced by genetic modification", In: Regulatory Toxicology and Pharmacology, Vol. 12, New York, New York: Academic Press	PS	O	U	ENP
8	National Research Council, 1999, "Hormonally Active Agents in the Environment", National Academy Press, Washington DC	OG	PO, OF	CA	ENP
9	U.S. EPA, 1994, "FIFRA: Benefit and environmental risk considerations for inherent plant-pesticides" (issue paper)	IP	PO	I	U
10	U.S. EPA, 1994, "Risk considerations for outcrossing and hybridization" (issue paper)	IP	PO	I	U
11	U.S. EPA, 2000, "Dermal and inhalation exposure to plant substances" (issue paper)	IP	PO	I	U
12	U.S. EPA, 2000, "Natural toxicants in food" (issue paper)	IP	PO	I	U
13	U.S. EPA, 2000, "The glycoalkaloid class; solanine and chaconine: Mechanisms of action" (issue paper)	IP	PO	I	U
14	U.S. EPA, 2000, "Economic analysis of the plant-incorporated protectant regulations under the Federal Insecticide, Fungicide, and Rodenticide Act"	IP	PO	I	U
15	U.S. EPA, December 2000, "Summary of public comments and EPA's response on issues associated with plant-incorporated protectants (formerly plant-pesticides)	IP	PO	I	U

Methodology

The ORD scientist identified by the primary contact sent a detailed list of critical documents. However, we could not find any these documents in the docket. Therefore, we concluded they had not affected the rule so we did not include them among the critical documents. The primary contact did not identify any critical documents, but sent us several documents.

The preamble referenced various documents during the explanation of the rulemaking process. Members of the pilot study team reviewed this list and picked some items we believed might be critical. We pulled these from the docket. When the primary contact and ORD scientist reviewed the initial summary, the primary contact suggested some changes to the list, which we made.

Miscellaneous Other Information

The preamble for the final rule was written like a scientific paper in that the references were cited as the key points were made in the narrative.

The Office of Research and Development had programs pertaining to biogenics at its laboratories in Gulf Breeze and Corvallis. Staff from the Corvallis laboratory was on the work group for this rule and reviewed it before it was promulgated. However, the work done by ORD was not specifically cited to support the rule.

The 1994 proposed rule offered three categorical exemptions, of which only one was included in the 2001 rule. The other two proposed exemptions were: from FIFRA and FFDCA 408, all plant-incorporated protectants based on viral coat proteins; and from FIFRA, all plant-incorporated protectants that acted by primarily affecting the plant (e.g., thicker wax cuticle). These were omitted from the final rule because such a wide range of comments were received and because more scientific information became available since proposal. The science gaps identified related particularly to these two proposed exemptions.

Agency Comments and OIG Response

In commenting on the draft report, the Office of Prevention, Pesticides and Toxic Substances suggested changes related to plant-incorporated protectants. Because these changes improved the factual accuracy of the report, we changed Case 15 as suggested.