ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[WH-FRL-2819-4(b)]

National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action under the Safe Drinking Water Act (42 USC 300f *et seq.*) promulgates Recommended Maximum Contaminant Levels (RMCLs) for the following eight volatile synthetic organic chemicals (VOCs) in drinking water: tricloroethylene, carbon tetrachloride, 1,1,1,-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1,-dichloroethylene, and p-dichlorobenzene. In the **Federal Register** notice of June 12, 1984, EPA proposed RMCLs for these eight compounds and tetrachloroethylene.

New data on the toxicology of tetrachloroethylene has recently become available and the public comment period on the RMCL for tetrachloroethylene is being reopened for 45 days in a separate Notice of Availability published in today's **Federal Register.** In this final rule notice, EPA examines the available data on tetrachloroethylene, including the new data together with the other eight VOCs. However, EPA will not promulgate an RMCL for tetrachloroethylene until after the close of the 45 day comment period.

RMCLs are *non-enforceable health goals* which are to be set at levels which would result in no known or anticipated adverse health effects with an adequate margin of safety. In this final rule, RMCLs for substances considered to be probable human carcinogens are set at zero and RMCLs for substances not treated as probable human carcinogens are based upon chronic toxicity or other data.

Maximum Contaminant Levels (MCLs) are *enforceable standards* and are to be set as close to the RMCLs as is feasible. MCLs are based upon treatment technologies, costs (affordability) and other feasibility factors, such as availability of analytical methods, treatment technology and costs for achieving various levels of removal. MCLs are being proposed for these eight VOCs in a separate **Federal Register** notice published today.

EFFECTIVE DATE: This rule is effective December 13, 1985.

ADDRESSES: Supporting documents cited in Section V will be available for inspection at the Drinking Water Supply Branches in EPA's Regional Offices.

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Copies of the health effects and occurrence documents are available for a fee from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll free number is 800/336–4700; local: 703/487–4650. Other information on health effects and occurrence are included in the public docket.

The public docket for this final RMCL rule is part of the public docket for the National Primary Drinking Water Regulation proposed elsewhere in today's **Federal Register.** It is available for viewing at the address described in that notice. Comments are not solicited on this final rule.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH–550), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, telephone (202) 382–7575.

SUPPLEMENTARY INFORMATION:

I. Statutory Requirements and Regulatory Framework

The Safe Drinking Water Act (42 U.S.C. 300f, *et seq.*) ("SDWA" or "the Act") requires the EPA to establish primary drinking water regulations which: (1) Apply to public water systems; (2) specify contaminants which in the judgment of the Administrator, may have any adverse effect on the health of persons; (3) specify for each contaminant either (a) MCLs or (b) treatment techniques. See section 1401(1), 42 U.S.C. 300f. A treatment technique requirement would only be set if "it is not economically or technologically feasible" to ascertain the level of a contaminant in drinking water.

The SDWA includes provisions for interim and revised regulations. See section 1412, 42 U.S.C. 300g–1. Interim regulations were to be established within 180 days of enactment of the SDWA. Revised regulations are to be developed in two steps: the Agency is to establish RMCLs and then establish MCLs as close to the RMCLs as feasible. MCLs are to be proposed at the time of promulgation of the RMCLs.

RMCLs are non-enforceable health goals. RMCLs are to be set at a level at which, in the Administrator's judgment, "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety". Section 1412(b)(1)(B). The House Report on the SDWA provides Congressional guidance on developing RMCLs:

> . . . the recommended maximum level must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at zero level.

House Report No. 93–1185, July 10, 1974, at 20. In addition, a list of contaminants is to be included in the regulations for "any contaminant the level of which cannot be accurately enough measured in drinking water to establish a Recommended Maximum Contaminant Level and which may have any adverse

effect upon the health of persons". Section 1412(b)(1)(B).

MCLs are the enforceable standards. MCLs must be set as close to RMCLs as is "feasible". Feasible means "with the use of the best technology, treatment techniques and other means, which the Administrator finds are generally available (taking costs into consideration)." Section 1412(b)(3).

RMCLs of themselves have no legal impact on public water systems or the public. By promulgating RMCLs, no system is forced to remove contaminants to this level or to take other action regarding contaminants. RMCLs only serve as goals for the Agency in the course of setting MCLs and are therefore initial steps in the MCL rulemaking. In some cases, the MCLs will be set very close to the RMCLs; in other cases control processes or economic considerations may dictate an MCL that is not as close. In any case, it is the MCLs that must be met by public water systems. Non-compliance with an RMCL cannot be the basis of an enforcement action under Section 1414 of the Safe Drinking Water Act. Under Section 1413 of the Act, to receive and maintain primary enforcement responsibility, States must adopt MCLs that are no less stringent than EPA requirements. States are not required to adopt RMCLs to receive or maintain primary enforcement responsibility.

II. Background and Summary of Comments

EPA has received significant comment and advice on these final RMCLs. Over the last 10 years, EPA has consulted the National Academy of Sciences, industry groups, chemical trade associations, the National Drinking Water Advisory Council, other Federal Agencies, and the public. EPA published an Advance Notice of Proposed Rulemaking and a Proposal and received a substantial volume of comments. All of these views and information have been carefully weighed in developing this final rule.

On June 12, 1984, EPA proposed RMCLs for nine VOCs in drinking water: trichloroethylene, tetrachloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene, and p-dichlorobenzene. The RMCLs for those chemicals considered to be carcinogens were proposed at zero, and the RMCLs for the non-carcinogens were proposed based upon chronic toxicity data. This proposal was preceded by an Advanced Notice of Proposed Rulemaking (47 FR 9350) which discussed regulatory and non-regulatory approaches to limiting exposure to VOCs in drinking water.

EPA received 95 public comments on the June 12, 1984, RMCL proposal. The three major issues discussed in the public comments were:

1. Should RMCLs for carcinogens be set at zero?
2. How should the strength of evidence of carcinogenicity be factored into the RMCL determinations?
3. What is the appropriate RMCL for chemicals with limited evidence of carcinogenicity (i.e., trichloroethylene, tetrachloroethylene and 1,1-dichloroethylene)?

The following is a discussion of the major public comments received on these key issues:

Seventy-three commenters addressed the issue of whether RMCLs for carcinogens should be set at zero, as was proposed in the RMCL proposal. Twenty-six of the commenters stated that RMCLs for carcinogens should be set at zero, while forty-seven commenters did not agree.

The primary basis for the commenters favoring a zero level was the legislative history of the SDWA which stated that the RMCLs s for contaminants for which there is no safe threshold should be set at zero. In addition, many of these commenters expressed the opinion that carcinogens should not be present in drinking water at any level and RMCLs at zero were an appropriate expression of this philosophy.

The major reasons why the commenters did not favor setting the RMCLs at zero were that zero is not measureable or attainable and it is scientifically undefinable. These commenters generally felt that RMCLs should be achievable levels which would provide actual guidance on levels attainable in public water systems.

EPA believes that zero is the appropriate RMCL goal for substances assumed to be non-threshold toxicants in the absence of countervailing data. This approach is consistent with the legislative history of the SDWA. Substances with sufficient evidence to be regulated as probable carcinogens have been assigned RMCLs of zero.

EPA concluded that the two other suggested approaches for setting RMCLs for carcinogens, limit of detection or target risk, were inappropriate as regulatory methods for establishing a health goal. Detection limits are not a function of health risk. EPA rejected target risk (e.g., 10^{-6}) for probable human carcinogens because it believed that an RMCL of zero was more consistent with the SDWA mandate and legislative history.

Seven comments were received in which strategies for factoring the strength of evidence of carcinogenicity in the RMCL determinations were presented. The majority of these commenters suggested that RMCLs be set at varying risk levels depending on the strength of evidence; for example, RMCLs would be set at the 10^{-6}) risk level for known carcinogens and at a 10^{-5}) risk level for compounds with limited evidence of carcinogenicity. One commenter presented an alternate approach in which VOC scores based upon the quantitative and qualitative evidence of carcinogenicity were assigned to each chemical. Arbitrary concentration levels were then to be assigned to each letter score and an Adjusted Acceptable Daily Intake (AADI) was calculated for each chemical. The AADI was compared to the arbitrary concentration level and the lower value was used as the RMCL.

An additional eighteen coments were received which addressed how strong the strength of evidence should be to justify regulating a substance. Thirteen commenters suggested that strength of evidence should be used to determine which chemicals should be regulated and five of these commenters stated that EPA should establish minimum criteria for regulating a substance as a carcinogen, based upon the International Agency for Research on Cancer (IARC) criteria.

EPA agrees with the comments suggesting that strength of evidence of carcinogenicity be considered in setting the RMCLs. EPA also agrees with those commenters who suggested that those substances with sufficient evidence to be considered probable human carcinogens should be regulated in a more stringent manner than those contaminants with less carcinogenic evidence. EPA is using a three-category approach for setting RMCLs in which chemicals are classified based upon their strength of evidence of carcinogenicity. This approach is based upon the EPA Proposed Guidelines for Carcinogen Risk Assessment (49 FR 46294).

The EPA Guidelines were proposed subsequent to the June 12, 1984 proposal and contain a categorization scheme based upon the IARC criteria. This scheme divided chemicals into five groups, ranging from strong evidence of carcinogenicity to humans to no evidence of carcinogenicity, based upon a qualitative evaluation of the available data. EPA is using this categorization scheme to divide the chemicals based upon their strength of evidence. The top two rankings, human carcinogen or animal carcinogen (A, B), are being treated as probable human carcinogens with RMCLs of zero. RMCLs for the

third rank, limited evidence of animal carcinogenicity (C), are computed non-zero values determined by the quality of data, and RMCLs for the lower two ranks, inadequate or no evidence of carcinogenicity (D and E), are computed by classical Acceptable Daily Intake (ADI) procedures.

Several comments were received which addressed the RMCLs for specific chemicals. The majority of comments regarding trichloroethylene, tetrachloroethylene and 1,1-dichloroethylene stated that these chemicals should not be regulated as confirmed carcinogens and the RMCLs should be set based uponi chronic toxicity data.

EPA has evaluated these chemicals using the EPA proposed guidelines for carcinogen risk assessment. EPA agrees that there is insufficient evidence at this time to consider 1,1-dichloroethylene as a probable human carcinogen and this compound has been ranked in EPA's Guideline Level C (limited evidence of animal carcinogenicity). In the three-category approach, the RMCLs for Category II chemicals (EPA's Guideline C) are set based either upon chronic toxicity data with an extra uncertainty factor or by use of risk extrapolation methods. The decision whether to use chronic toxicity data with an uncertainty factor of risk extrapolation methods is made on a case-by-case basis depending upon the adequacy of the data.

EPA has evaluated the data for trichloro-ethylene and tetrachloro-ethylene and has concluded that there is sufficient evidence to consider the compounds as probable human carcinogens. Thus, the RMCL for trichloroethylene will remain at zero, based upon its classification in EPA's Proposed Guidelines. The final RMCL for tetrachloroethylene will be promulgated after the close of 45-day comment period.

Appendix A presents more a detailed summary and discussion of the principal comments with EPA's responses to the comments. Additional comment and responses are contained in the background document, "Summary of Comments and EPA Responses on **Federal Register** Notices on Volatile Organic Chemicals in Drinking Water".

III. Volatile Synthetic Organic Chemicals in Drinking Water

The June 12, 1984, **Federal Register** notice summarized the available information on the occurrence of VOCs in drinking water, population exposure estimates and toxicology data. Detailed information was presented in the Health Criteria and Occurrence Documents. The following information is intended to briefly summarize available occurrence data and health considerations.

A. Occurrence of VOCs in Drinking Water

The EPA has conducted six national surveys since 1975: the National Organics Reconnaissance Survey (NORS), the National Organics Monitoring Survey (NOMS), the National Screening Program (NSP), the Community Water Supply Survey (CWSS), the Ground Water Supply Survey (GWSS) and the Rural Water Survey (RWS).

The NORS and NOMS were initiated in 1975 and primarily examined the presence of trihalomethanes in U.S. drinking water supplies. The NSP, which examined 166 water supplies between 1977 and 1981, and the CWSS, which was conducted in 1978, have demonstrated the presence in surface waters of organic contaminants in drinking water, generally at levels less than 10 μg/l.

The GWSS was conducted in 1982 and consisted of a survey of approximately 100 drinking water supplies which used ground water as a source. Five hundred supplies were selected at random and 500 were selected by States as having high potential for contamination by organic chemicals. The results showed that in the random portion of the survey, approximately 21 percent of the systems had one or more volatile organic chemicals at detectable levels (primarily in the low μg/l range). Approximately 16 percent of the smaller systems (<10,000 people) in the random sample contained some concentrations of the VOCs at levels above the quantitation limit and less than 1 μg/l, while approximately 28 percent of the large supplies (>10,000 people) contained these levels of VOCs. In the non-random portion of the survey, higher frequencies of occurrence were found at all levels. Table 1 presents a summary of occurrence data.

TABLE 1.—OCCURRENCE OF VOCS IN DRINKING WATER

Compound	Summary of GWSS occurrence data (random sample: n=466)		Summary of State occurrence data[1]	
	Positives		Number of samples	Number of positives
	Number	Percent		
Tetrachloroethylene	34	7.3	3,636	628
Trichloroethylene	30	6.4	4,228	624
1,1,1-Trichloroethane	27	5.8	3,330	715
1,1-Dichloroethane	18	3.9	2,628	177
1,2-Dichloroethylenes	16	3.4	1,249	197
Carbon tetrachloride	15	3.2	2,646	368
1,1-Dichloroethylene	9	1.9	.....	.....
p-Dichlorobenzene	5	1.1	.....	.....
Vinyl chloride	1	0.2	1,793	126

[1] The State data represent a collection of available data from various State agencies, are normally in response to contamination incidents, and are not considered to be statistically representative of national occurrence.

The nine VOCs have been detected in public drinking water supplies at various concentration levels. The following is a summary of the occurrence information based upon combined data from the national surveys.

Compound	Concentration range (μg/l) in public drinking water systems
Benzene	0.2–22
Carbon tetrachloride	0.5–30
p-Dichlorobenzene	0.1–30
1,2-Dichloroethane	0.2–21
1,1-Dichloroethylene	0.2–6.3
Tetrachloroethylene	0.1–69
1,1,1-Trichloroethane	0.8–142
Trichloroethylene	0.2–160
Vinyl chloride	0.2–66

Available data on the use, release, and occurrence of halogenated volatile organics strongly suggests the widespread *in situ* transformation of a number of 2 carbon halogenated compounds. The compounds involved include trichloroethylene, tetrachloroethylene, cis- and trans-1,2-dichloroethylene, vinyl chloride, 1,1,1-trichloroethane and 1,1-dichloroethylene. Transformations of some of the above chemicals have been demonstrated in laboratory and field studies.

A limited number of laboratory studies have shown that trichloroethylene and tetrachloroethylene can be sequentially dechlorinated to form cis- and trans-1,2-dichloroethylene, vinyl chloride and finally Cl^- and CO_2. There is some suggestion that 1,1-dichloroethylene, may also be produced in the same

degradation process. Other studies have shown that 1,1,1-trichloroethane can be dechlorinated to form 1,1-dichloroethane and chloroethane. The evidence for degradation falls into two categories: first, the low commercial production and release of a number of compounds with widespread occurrence, and second, the high degree of co-occurrence of compounds with their suspected degradation products.

In summary, the available data on occurrence supports the hypotheses that the major source of ground water contamination for vinyl chloride, 1,2-dichloroethylene, and 1,1-dichloroethylene is the decomposition of trichloroethylene and tetrachloroethylene and that the major source of 1,1-dichloroethane is the degradation of 1,1,1-trichloroethane. The data also suggest that chloroethane may also be a contaminant of ground water. Since trichloroethylene, tetrachloroethylene, and 1,1,1-trichloroethane are widely released in the environment, their degradation products are also expected to have a wide occurrence. The occurrence documents referenced in Section V summarize available data to support these hypotheses.

B. Human Health Considerations

Exposure at very high levels to the VOCs for which RMCLs are proposed has been shown to result in a variety of acute and chronic toxic effects in animals. These levels are usually much higher than those found in public drinking water supplies. Damage to the liver and kidneys is a common effect demonstrated in animals from high exposure to several VOCs, as well as central nervous system effects and cardiovascular changes.

Carcinogenic effects have also been demonstrated from exposure to certain of these VOCs. Two of these compounds are demonstrated human carcinogens, while others have exhibited carcinogenic effects in animal studies. The evidence of carcinogenicity for these nine compounds ranges from sufficient evidence in humans to very limited or no evidence in animals.

Excess cancer risk rates have been calculated for the VOCs using a variety of models including the one-hit model, the Weibull model and the multi-stage model. Table 2 presents various risk estimates (95% confidence limit) using the multistage model, as calculated by EPA's Carcinogen Assessment Group (CAG) and the National Academy of Sciences (NAS).

TABLE 2.—CANCER RISK ESTIMATES FOR VOCs

Compound	Concentration in drinking water (μg/1) corresponding to a 10^{-5} risk	
	NAS	CAG[1]
Trichloroethylene	45	26
Tetrachloroethylene	35	6.7
Carbon tetrachloride	45	2.7
1,2-Dichloroethane	7.0	3.8
Vinyl chloride	10	0.15
1,1-Dichloroethylene	NC	0.61
Benzene	NC	13

[1] These calculations represent the most recent calculations by CAG.
NC=Not calculated.

In the June 12, 1984, RMCL proposal, chemicals were divided into two groups (carcinogens and non-carcinogens) and the RMCLs were proposed on a separate basis for each group. Based upon comments received, in this final action, chemicals are divided into three groups (probable human carcinogens, equivocal evidence of carcinogenicity and non-carcinogens) and the RMCLs set on different basis for each group. Section IV (Determination of RMCLs) discusses the methodology and basis for determining the RMCLs in this notice.

Acceptable Daily Intakes (ADIs) have been calculated for these nine compounds, following the procedure outlined in the RMCL proposal (49 FR 24330). In the proposal and this final rule, these ADIs are converted to solely represent drinking water intake (i.e., mg/l) and termed Adjusted ADIs (AADIs).

IV. Determination of RMCLs

The SDWA authorizes EPA to establish RMCLs for "each contaminant which, in [the Administrator's] judgment . . . may have any adverse effect on the health of persons" Section 1412(b)(1)(B). RMCLs are to be set at a level to prevent known or anticipated adverse effects and which allows an adequate margin of safety. Presented below are discussions of (1) the factors used to select the VOCs for regulation and (2) the methodology and basis for determining what levels are appropriate for the RMCLs.

A. Selection of Contaminants for Regulation

The June 12, 1984, **Federal Register** notice discussed the major factors considered in determining which VOCs should be regulated. This section provides a further discussion of the factors used to select the specific VOCs for which RMCLs are being promulgated at this time.

The three primary criteria for selection of contaminants for MCL regulations under the SDWA are: (1) The analytical ability to detect a contaminant in drinking water, (2) the potential health risk, and (3) the occurrence or potential for occurrence in drinking water.

General selection criteria have been developed which essentially expand the three primary factors listed above. Use of a specific formula to apply the selection criteria is appropriate because of the many unquantifiable variables; however, a decision-making "logic train" has been developed which incorporates the selection criteria and provides a framework from which to make appropriate determinations. Given the variability associated with exposure and human health aspects of drinking water contaminants and the directives of the SDWA, the decision criteria must remain flexible such that a case-by-case decision can be made for each contaminant. Nevertheless, the decision criteria do set forth an operative framework. For each contaminant, the essential factors in the analysis are as follows:

- Is it possible to detect the contaminant in drinking water at any level by analytical methods? If not, a drinking water regulation is probably inappropriate.
- Are there sufficient health effects data upon which to make a judgment on an RMCL? Are there potential adverse health effects of exposure to the contaminant via ingestion?
- Does the contaminant occur in drinking water?

—Has the contaminant been detected in significant frequencies and in a widespread manner in drinking water?

—If data are limited on the frequency and nature of contamination, is there a significant potential of drinking water contamination?

From the list of VOCs in the March 4, 1982, ANPRM (47 FR 9350), nine contaminants were selected for inclusion in the June 12, 1984, **Federal Register** notice as proposed RMCLs. Available data on each of the chemicals on analytical methods, health effects, occurrence, and potential occurrence were evaluated using the selection criteria and framework outlined above. The following chemicals were proposed for regulation: trichloroethylene, tetrachloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene and p-dichlorobenzene.

Three EPA approved analytical methods are available for measurement

of all nine VOCs at approximately $150 per sample.

Trichloroethylene, tetrachloroethylene and 1,1,1-trichloroethane were proposed for regulation based upon: (1) Occurrence data which showed these compounds to be present at significant frequencies in drinking water supplies; and (2) evidence of toxic effects. The random portion of the Ground Water Supply Survey (GWSS) reported that trichloroethylene was detected in 6.4 percent of the supplies, tetrachloroethylene in 7.3 percent of the supplies and 1,1,1-trichloroethane in 5.8 percent of the supplies sampled.

Carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethylene, vinyl chloride and benzene were also detected in the GWSS but at lower frequencies. RMCLs were proposed for these compounds based upon their occurrence and toxicology. Vinyl chloride and benzene are known human carcinogens, while carbon tetrachloride and 1,2-dichloroethane have strong evidence of carcinogenicity in animals.

An RMCL was proposed for p-dichlorobenzene based upon its detection in a limited number of drinking water systems, its potential for further drinking water contamination and toxic effects.

RMCLs were not proposed for cis- and trans-1,2-dichloroethylene, chlorobenzene, trichlorobenzene and methylene chloride in the June 12 proposal. RMCLs were not proposed for cis- and trans-1,2-dichloroethylene and chlorobenzene because toxicology evaluations were not complete at the time of the proposal; however, these evaluations have since been completed and RMCLs are included in the Phase II RMCL proposal. Occurrence data were not available for trichlorobenzene due to analytical difficulties in obtaining samples in the Ground Water Supply Survey. The toxicology data available for methylene chloride at the time of proposal did not permit a determination of health risks. However, new toxicology data has recently become available and is presently being evaluated. In addition, the available occurrence data were not considered reliable due to problems with laboratory contamination and quality assurance. Both of these chemicals will be considered in later phases of the Revised Regulations.

B. Basis for RMCLs

The June 12, 1984, **Federal Register** notice discussed three main options for setting RMCLs for carcinogens and requested comment on these options. These options were: (1) Set RMCLs at zero, (2) set RMCLs at the analytical detection limit, or (3) set RMCLs at a non-zero level based upon a calculated negligible contribution to lifetime risk. In addition, comment was requested on the strength of evidence needed to justify regulating a compound as a carcinogen, and on factoring the degree of evidence of potential carcinogenicity into the RMCL determinations. Several options were suggested.

The consideration of RMCLs set at zero for potential human carcinogens centered on the legislative history of the SDWA which stated that,

> . . . the recommended maximum (contaminant) level must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at zero level.

In the proposal, RMCLs were proposed at zero for those substances which in EPA's view had at least "limited" evidence of carcinogenicity; tetrachloroethylene, trichloroethylene, carbon tetrachloride, 1,2-dichloroethane, vinyl chloride, benzene and 1,1-dichloroethylene. The basis for proposing RMCLs at zero was that the existence of a threshold for the action of potential carcinogens cannot be demonstrated by current science; it was conservatively believed that no threshold exists, absent evidence to the contrary. EPA also concluded that there was insufficient basis to distinguish between mechanisms of carcinogenicity (e.g., genotoxicity or others). Following the guidance provided in the legislative history, the RMCLs were proposed at zero. In addition, the Agency stated that setting RMCLs at zero for carcinogens would present a general philosophy that as a goal, carcinogens should not be present in drinking water.

1. Strength of Evidence of Carcinogenicity

The questions raised in the RMCL proposal concerning strength of evidence centered on the evidentiary threshold required to conclude that a substance should be considered to be a "carcinogen" for the purpose of this regulation. Chemicals have varying degrees and qualities of evidence concerning their potential carcinogenicity. EPA requested comment on how this evidence could be used in determining the RMCLs and also on the classification of chemicals according to their strength of evidence of carcinogenicity.

The commenters generally supported the use of strength of evidence in determining the RMCLs, but disagreed over the way in which the strength of evidence should be applied. A number of commenters stated that EPA should factor strength of evidence in the RMCLs based upon the IARC criteria. Several commenters felt that a compound should only be regulated as a carcinogen if there is evidence of human carcinogenicity or strong evidence of animal carcinogenicity, while others felt that a substance with "limited" evidence of carcinogenicity should be regulated as a carcinogen. A number of commenters proposed schemes for factoring the degree of evidence of carcinogenicity in the RMCL determinations.

- Two commenters proposed an approach in which RMCLs were set at zero for known human carcinogens, at a 10^{-6} lifetime cancer risk level for compounds with strong evidence of carcinogenicity in animals and at a 10^{-5} lifetime risk level for compounds with limited evidence in animals.
- Another approach consisted of setting RMCLs for known human and animal carcinogens at the 10^{-5} to 10^{-6} lifetime risk levels and setting RMCLs for those with limited evidence of animal carcinogenicity at the 10^{-4} to 10^{-5} lifetime risk levels.

As noted above, after the RMCL proposal, EPA proposed an approach for classifying chemicals based upon the strength of evidence of carcinogenicity (Proposed Guidelines for Carcinogen Risk Assessment 49 FR 46294, November 1984). EPA proposed a categorization scheme based upon the International Agency for Research on Cancer (IARC) criteria. The categorization consists of a five category approach, as shown below. In contrast, the IARC classification consists of three categories with the primary difference being that IARC does not distinguish between those with chemicals with inadequate animal evidence of carcinogenicity and those chemicals with no evidence for carcinogenicity, while the EPA scheme makes that distinction.

EPA Proposed Categorization for Carcinogens

Group A—Human carcinogen (sufficient evidence from epidemiological studies).

Group B—Probable human carcinogen.

Group B1—At least limited evidence of carcinogenicity to humans.

Group B2—Usually a combination of sufficient evidence in animals and inadequate data in humans.

Group C—Possible human carcinogen (limited evidence of carcinogenicity in animals in the absence of human data).

Group D—Not classified (inadequate animal evidence of carcinogenicity).

Group E—No evidence of carcinogenicity for humans (no evidence for carcinogenicity in at least two adequate animal tests in different species or in both epidemiological and animal studies).

IARC Criteria

Group 1—Chemical is carcinogenic to humans (sufficient evidence from epidemiological studies).

Group 2—Chemical is probably carcinogenic to humans.

Group 2A—At least limited evidence of carcinogenicity to humans.

Group 2B—Usually a combination of sufficient evidence in animals and inadequate data in humans.

Group 3—Chemical cannot be classified as to its carcinogenicity to humans.

Both of these classification schemes are based upon a qualitative review of all available evidence. Information considered in each assessment include short-term tests, long-term animal studies, human studies, pharmacokinetic studies, comparative metabolism studies, structure—activity relationships and other relevant toxicological studies.

Other groups have also supported the concept of assessing carcinogens by degree of evidence. The National Academy of Sciences (NAS) in *Drinking Water and Health*, 1977. Vol. I, classified chemicals with carcinogenic effects into four groups: human carcinogens, suspected human carcinogens, animal carcinogens and suspected animal carcinogens.

The U.S. Office of Science and Technology Policy's recent review of the science and associated principles of chemical carcinogenic risk (50 FR 10372) generated a series of principles to be used to establish specific guidelines for assessing carcinogenic risk. The review discussed the type of tests (short- and long-term) used to assess potential carcinogens and the interpretation of data in light of the strength of evidence. A classification system for carcinogens was not provided in the report.

Table 3 classifies the VOCs based upon an assessment under the EPA and IARC criteria. These classifications will be revised if new data on the VOCs dictate reclassification. In addition, EPA will reconsider these classifications if the final EPA Guidelines for Carcinogen Risk Assessment vary significantly from the proposed EPA guidelines.

TABLE 3.—STRENGTH OF EVIDENCE OF VOCs

Compound	Evidence of Carcinogenicity	EPA guide lines	IARC classi-fication
Trichloroethylene	Carcinogenic in several strains of mice by the inhalation and oral route. Weakly mutagenic.	B2*	3
Tetrachloroethylene	Carcinogenic in mice by gavage and mice and rats by the inhalation route. Inconclusive mutagenicity data.	B2	3
Carbon Tetrachloride.	Carcinogenic in 3 species by the oral route.	B2	2B
1,2-Dichloroethane	Carcinogenic in 2 species by the oral route.	B2	2B
Vinyl Chloride	Carcinogenic in animals by the inhalation and oral route and carcinogenic in humans by inhalation.	A	1
Benzene	Carcinogenic in animals and humans by inhalation and in animals by gavage.	A	1
1,1-Dichloroethylene.	Two positive studies in mice and rats by the inhalation route and many negative studies by the inhalation and oral routes. Positive mutagenicity data.	C	3
p-Dichlorobenzene	Negative results (draft) in several animal species.	D	3
1,1,1-Trichloroethane.	Preliminary animal evidence being audited Inadequate human evidence.	D	3

*Classified by the EPA Risk Assessment Forum: an Agency-wide advisory group to the EPA Administrator.

2. Three-Category Approach for Setting RMCLs

The June 12, 1984, RMCL proposal consisted of a two-category approach to setting RMCLs; chemicals were classified as carcinogens or non-carcinogens. All chemicals with evidence of carcinogenicity ranging from limited to sufficient were classified as "carcinogens" and their RMCLs were proposed at zero. As noted, a number of commenters pointed out that this approach did not adequately take into account the varying degrees of evidence of the chemicals classified as carcinogens. In response to comment and consistent with the EPA guidelines, EPA is using this scheme in its final RMCL rule. This approach to setting RMCLs considers all of the available scientific data.

Table 4 describes this approach for setting RMCLs based upon the EPA classification system. The corresponding IARC classifications are included in the table for comparative purposes.

Table 4

Three-Category Approach for Setting RMCLs

Category I—Known or probable human carcinogens: Strong evidence of carcinogenicity.
- EPA Group A or Group B
- IARC Group 1, 2A or 2B

Category II—Equivocal evidence of carcinogenicity.
- EPA Group C
- IARC Group 3

Category III—Non-carcinogens: Inadequate or no evidence of carcinogenicity in animals.
- EPA Group D or E
- IARC Group 3

Category I includes those chemicals which, in the judgment of EPA, have sufficient human or animal evidence of carcinogenicity to warrant their regulation as known or probable human carcinogens. The approach to setting RMCLs for these compounds is not changed from the RMCL proposal; RMCLs are set at zero. These compounds are potential human carcinogens and they have not been demonstrated to exhibit a threshold; thus it is believed for the purpose of regulation that any exposure could contribute some finite level of risk.

Category II includes those chemicals for which some limited but insufficient evidence of carcinogenicity exists from animal data. These will not be regulated in the same manner as known or probable human carcinogens. However, RMCLs will reflect the fact that some experimental evidence of carcinogenicity in animals has been reported.

EPA has considered two main options for setting the RMCLs for these types of chemicals. The first option consists of setting the RMCL based upon non-carcinogenic endpoints (the AADI) if adequate data exist. To account for the equivocal evidence of carcinogenicity, an additional uncertainty factor would be applied (e.g., AADI divided by a factor of 10 or some other value). A factor of 10 would be applied in most cases because uncertainty factors have historically been applied in order of magnitude increments, with each additional ten-fold factor accounting for an added measure of uncertainty. However, uncertainty factors other than 10 would be applied if the data indicated the need for a greater or lesser extra safety margin. An example of when a greater uncertainty factor would be applied is if the AADI was based upon a weak study with a lack of supporting data. A lesser uncertainty factor would be applied in instances

when a great deal of strong epidemiology data exists. The second option consists of setting the RMCL based upon a lifetime risk calculation in the range of 10^{-5} to 10^{-6} using a conservative method (i.e., a method that may overestimate the risk) such as the linear multi-stage model. This is intended to be protective for compounds that are not being considered carcinogens, but for which questions have been raised concerning potential effects. EPA will use the first option if valid non-carcinogenic data are available upon which to base an ADI. If valid non-carcinogenic data are not available and risk levels can be calculated from adequate data, then risk calculations will be used.

EPA believes that both of these approaches reflect the primary consideration concerning Category II chemicals: RMCLs should be less conservative than those for Category I chemicals and more conservative than those for Category III chemicals. This is reflective of the quantity and quality of the toxicology data that are available. For the contaminant regulated under this category, in this rulemaking, it is clear that there is ample evidence to regulate the chemical based on evidence of adverse health effects unrelated to carcinogenicity. Thus, EPA is merely regulating this contaminant more conservatively as a result of the equivocal evidence of carcinogenicity. In regulating this contaminant, EPA is not regulating it based solely on equivocal evidence of carcinogenicity.

Category III includes those substances with inadequate or no evidence of carcinogenicity. RMCLs will be calculated based upon chronic toxicity data using ADIs as proposed. The ADI approach is well accepted in the scientific community as a method for determining acceptable exposure levels for threshold toxicants and was supported by the majority of commenters on the RMCL proposal. As proposed, an exposure factor of 20 percent contribution from drinking water is used conservatively to determine the RMCLs. This contribution factor is included because there is often an inadequate data base to precisely calculate multi-media exposure contributions for a cross section of the population. Drinking water is frequently a minor contribution to total exposure. In "Drinking Water and Health" (1977), the NAS provided projections of one percent and 20 percent as illustrations of drinking water contributions. The National Interim Primary Drinking Water Regulations also assumed that drinking water contributed 20 percent of the total daily intake for six organic chemicals. This approach was most consistently supported by commenters to both the ANPRM and RMCL proposal among those suggested.

3. RMCLs for VOCs Categorized by Three-Category Approach

Table 5 presents a distribution of the nine VOCs among the three categories.

Table 5

VOCs Using Three Category Regulatory Approach

Category I—Known or Probable Human Carcinogens: Strong evidence of carcinogenicity.
- Benzene
- Vinyl chloride
- Carbon tetrachloride
- 1,2-Dichloroethane
- Trichloroethylene
- Tetrachloroethylene

Category II—Equivocal Evidence of Carcinogenicity.
- 1,1-Dichloroethylene

Category III—Non-Carcinogens: Inadequate or no evidence of carcinogenicity in animals.
- 1,1,1-Trichloroethane
- p-Dichlorobenzene

The following are short discussions of the rationale for the placement of each VOC in its respective category. A more extensive discussion can be found in the Health Effects Criteria Documents referenced in Section V.

Benzene. Benzene has been placed in Regulatory Category I, based upon its documented carcinogenic effects in humans. Reported effects in humans include myelocytic anemia, thrombocytopenia and leukemia, particularly acute myelogenous and monocytic leukemia. Exposure to benzene has also been shown to result in carcinogenic effects in animals; several studies have shown an increase in tumors and leukemias in benzene-exposed animals. The IARC has categorized benzene in Group 1, sufficient evidence of carcinogenicity in humans. The NAS has classified benzene as a suspect human carcinogen. EPA has classified benzene in EPA's Group A, sufficient evidence from epidemiological studies.

Vinyl chloride. Vinyl chloride has been shown to have carcinogenic effects in humans and animals. In humans, exposure to vinyl chloride is associated with angiosarcoma of the liver. In animals, serveral tumor types including mammary carcinomas, liver angiosarcomas and pulmonary angiosarcomas have been reported following exposure to vinyl chloride through ingestion or inhalation. Vinyl chloride has exhibited a significant degree of DNA binding in short-term studies. The IARC has classified vinyl chloride in Group 1, sufficient evidence of carcinogenicity to humans. The NAS has classified vinyl chloride as a human carcinogen. EPA has classified vinyl chloride in EPA's Group A; sufficient evidence from epidemiological studies. Vinyl chloride has been placed in Regulatory Category I, based upon its carcinogenic effects, as described above, in humans and animals.

Carbon tetrachloride. Carbon tetrachloride has been shown to be carcinogenic in rats, mice and hamsters through oral exposure. Hepatocellular carcinomas have been observed in several animal studies as a result of carbon tetrachloride exposure. Carbon tetrachloride has been identified as an animal carcinogen by the National Cancer Institute (NCI) and has been used as a positive control in several bioassays. The IARC has concluded that sufficient evidence of carcinogenicity in animals exists for carbon tetrachloride and has classified the compound in Group B2. The NAS has classified carbon tetrachloride as an animal carcinogen. EPA has classified carbon tetrachloride in EPA's Group B2; sufficient evidence in animals and inadequate evidence in humans. EPA has placed carbon tetrachloride in Regulatory Category I, based upon its demonstrated carcinogenic effects in animals.

1,2-Dichloroethane. 1,2-Dichloroethane has been placed in Regulatory Category I, based upon its carcinogenic effects in animals through ingestion exposure. In the NCI bioassay, 1,2-dichloroethane administered by gavage to rats and mice was shown to increase the incidence of several types of tumors. 1,2-Dichloroethane has not been shown to be carcinogenic through inhalation exposure in animals. The IARC have classified 1,2-dichloroethane in Group B2; sufficient evidence of carcinogenicity in animals. EPA has classified 1,2-dichloroethane in EPA's Group B2; sufficient evidence in animals and inadequate evidence in humans.

Trichloroethylene. Six completed studies investigating the carcinogenic potential of trichloroethylene have been carried out. Two of these studies revealed significant increases in the incidence of liver tumors among both sexes of $B_6C_3F_1$ mice. Several of the remaining studies were technically flawed and the data cannot be used, and the remainder of the studies reported no evidence of carcinogenicity. A recent study (Henschler, et al., 1984) concluded that trichloroethylene containing epichlorohydrin and epoxybutane causes tumors in test animals, but that

purified trichloroethylene was not carcinogenic in ICR/HA mice. However, the Henschler study used mice that are known to be less responsive to hepatocellular carcinomas than the mice in several of the other studies. Therefore, EPA is not relying only on this study in drawing its conclusions regarding carcinogenicity. Trichloroethylene has exhibited DNA binding in short-term test systems.

There is disagreement in the scientific community about the relevance of mouse liver tumors as indicators of human cancer risk. Several strains of laboratory mice appear to develop a high and variable proportion of liver tumors with or without exposure to the chemicals. This may indicate that those mouse livers contain a signficant proportion of initiated tumor cells which do not appear to be present in human liver or it may indicate bias in the test protocol currently used by the National Toxicology Program (corn oil gavage). Certain scientists believe that the increased incidence of mouse liver tumors should be treated in the same manner as the increased incidence of tumors at any other rodent organ site, while others believe that mouse liver tumors are a spurious situation which is not relevant to human hazard.

The EPA proposed guidelines for carcinogen risk assessment (49 FR 46294) examined the relationship of mouse liver tumors to human hazard and concluded that "the mouse-liver-only tumor response, when other conditions for a classification of 'sufficient' evidence in animal studies are met, should be considered as 'sufficient' evidence of carcinogenicity with the understanding that this classification could be changed to 'limited' if warranted when a number of factors such as the following are observed: the occurrence of tumors only in the highest dose group and/or only at the end of the study; no substantial dose-related increase in the proportion of tumors that are malignant; the occurrence of tumors that are predominantly benign, showing no evidence of metasteses or invasion; no dose-related shortening of the time to the appearance of tumors; negative or inconclusive results from a spectrum of short-term tests for mutagenic activity; the occurrence of excess tumors only in a single sex".

The IARC stated that substances should be classified as having limited evidence of carcinogenicity if the studies involve a single species or experiment, are restricted by inadequate protocols and, in the past, have been difficult to classify as malignant by histological criteria alone (e.g., lung and liver tumors in mice).

The Office of Science and Technology Policy's report on chemical carcinogens (50 FR 10372) stated that,

> Generally, there is consensus that the mouse liver model in principle does have significance in terms of human risk, but unambiguous diagnosis between "benign" or "hyperplastic" liver nodules and malignant neoplasia remains elusive and there is no apparent scientific consensus. A recent review of the issue has emphasized the need for judgment on a case-by-case basis and the possible relevance of other toxicological information.

Based upon the EPA guidelines, EPA's Risk Assessment Forum classified trichloroethylene in Group B2; sufficient animal evidence of carcinogenicity and inadequate human evidence. As noted above, the EPA guidelines regard mouse liver tumors as sufficient evidence unless downgraded by other factors. EPA concluded that these other factors were not present for trichloroethylene and thus the compound was classified as having sufficient evidence of carcinogenicity. The NAS has classified trichloroethylene as an animal carcinogen.

EPA's Science Advisory Board (SAB) examined the toxicology of trichloroethylene and its ranking under the IARC criteria. The majority of the Committee members felt that the compound should be classified in IARC Category 3 (compound cannot be classified as to its carcinogenicity for humans), while one member felt that IARC Category 2B (probable human carcinogen) was more appropriate. The Committee concluded that, "a definitive statement on the carcinogenicity of the compound cannot be made by this Committee at this time because the interpretation of male mouse hepatocellular carcinomas is uncertain and the animal evidence is limited at this time".

EPA is conservatively classifying trichloroethylene in Regulatory Category I, based upon the positive evidence of liver tumors in $B_6C_3F_1$ mice, as well as malignant lymphomas in mice, pulmonary adenocarcinomas in mice, mutagenicity and binding with DNA, which has resulted in EPA's Risk Assessment Forum's classification of the compound in EPA's Group B2. The evidence for Category I ranking for trichloroethylene is weaker than for the other chemicals included in that group.

Tetrachloroethylene. The principal effect in animals from acute exposure to tetrachloroethylene is on the central nervous system. Central nervous system effects include depression, ataxia and respiratory cardiac arrest. Short-term/subchronic effects in animals are manifest principally as damage to the liver and kidney, while chronic effects also include liver and kidney damage, as well as central nervous effects. In humans, central nervous system depression and hepatic toxicity are also the principal effects exhibited from exposure to tetrachloroethylene.

The classification of tetrachloroethylene for carcinogenicity is based upon the results of several studies, including: (1) The NCI bioassay (1977) in which tetrachloroethylene (administered by gavage) increased the incidence of hepatocellular carcinomas in both sexes of $B_6C_3F_1$ mice, but not in rats. Due to high level of mortality among the rats, these data are not considered adequate. Several repeat studies were carried out; however data from these studies are undergoing audit by the NTP, (2) the draft report of the recently completed NTP bioassay (1985) in which tetrachloroethylene, administered through inhalation, was shown to induce carcinogenic effects in both rats and mice under the test conditions. The bioassay demonstrated an increased incidence of mononuclear cell leukemias in male and female rats and rare renal cell neoplasms in male rats. In mice, increased incidences of hepatocellular adenomas and carcinomas in males and hepatocellular carcinomas in females were seen; (3) several studies through inhalation and intraperitoneal exposure have produced negative results; and (4) mixed results have been obtained from a number of short-term studies designed to evaluate mutagenic potential. Tetrachloroethylene has not been shown to exhibit DNA binding in short-term studies.

EPA's Risk Assessment Forum, classified tetrachloroethylene in Group C, according to the EPA guidelines. Group C is used for agents with limited evidence of carcinogenicity in animals in the absence of human data. This classification was based upon the positive results from the NCI gavage bioassay and the inconclusive mutagenicity data. However, the new NTP rat and mice inhalation bioassay has since been completed, demonstrating a positive carcinogenic response in both species. Based upon this evidence and the positive carcinogenic evidence in mice by gavage (NCI, 1977), EPA has elevated the overall evidence of carcinogenicity to the "sufficient" category, Group B2.

The SAB examined the toxicology of tetrachloroethylene and the majority of the members of the SAB concluded that there was insufficient evidence to

classify tetrachloroethylene as a probable human carcinogen and that according to the IARC criteria the chemical belongs in Group 3. One member of the Committee agreed with the classification but felt that the compound "almost belongs" in Group 2B. This classification was carried out before the results of the NTP inhalation bioassay became available. The IARC had previously concluded that tetrachloroethylene has limited evidence of carcinogenicity in animals and inadequate evidence in humans and have classified the compound in Group 3; however IARC did not have the results of the NTP inhalation bioassay.

In summary, tetrachloroethylene has been classified in Regulatory Category I based upon the available data which have shown sufficient evidence of carcinogenicity in animals. This classification considers the new NTP cancer bioassay as well as other available data. As explained above, EPA is not promulgating an RMCL for tetrachloroethylene at this time. Rather, EPA is soliciting comments on the NTP bioassay.

1,1-Dichloroethylene. 1,1-Dichloroethylene has been shown to exhibit liver and kidney damage in animals from high dose exposure. Other acute and chronic effects include central nervous system depression and sensitization of the heart.

1,1-Dichloroethylene has been classified in Regulatory Category II. This classification is based upon an evaluation of the data involving over a dozen long-term animal studies, one short-term initiator/promotor assay and a series of short-term tests designed to evaluate mutagenic potential. The positive results have been reported in the following studies: (1) Kidney adenocarcinomas in mice and mammary tumors in rats and mice following inhalation exposure (Maltoni, 1985, in press); and (2) activity as an initiator in mice. Negative results have been reported in approximately a dozen studies involving exposure via inhalation, gavage and oral exposure via drinking water.

Short-term tests evaluating mutagenic potential have shown positive responses for DNA alkylation, repair and synthesis and negative results for cell culture tests. The IARC have concluded that there is sufficient evidence for activity in short-term tests.

The SAB examined the toxicology of 1,1-dichloroethylene and agreed with EPA that 1,1-dichloroethylene should be classified in Group 3, according to the IARC criteria. The SAB also recommended that the Agency attempt to verify the results of the Maltoni, *et al.*, 1977 study. The SAB did not review the results of the final Maltoni, *et al.*, inhalation study in this analysis since the data were not peer reviewed or published at the time. However, the SAB was critical of the carcinogenic risk estimates for 1,1-dichloroethylene, based upon the final Maltoni, *et al.*, inhalation data, stating that the uncertainties regarding the values needed to be better articulated.

EPA has classified 1,1-dichloroethylene in EPA's Group C, based upon the negative NCI bioassay, marginal results from inhalation exposure in mice and rats, activity as an initiator in mice and the mutagenic potential of the compuund. EPA believes that due to the mutagenic potential of the compound, the positive results in several animal studies and the compound's structural similarity to vinyl chloride there is a sufficient basis to regulate it in Category II rather than Category III.

1,1,1-Trichloroethane. The principal non-carcinogenic effects from exposure to 1,1,1-trichloroethane in animals and humans are depression of the central nervous system, increase in liver weight and cardiovascular changes.

1,1,1-Trichloroethane has been classified in Regulatory Category III (inadequate evidence of carcinogenicity in animals). This classification was based upon the results of two animals bioassays by the NCI. The first bioassay was completed in 1977 and consisted of exposure of mice and rats to 1,1,1-trichloroethane through corn oil gavage. Only 3 percent of the animals survived to the end of the experiment and thus it was concluded that carcinogenicity could not be determined from this study. In the second carcinogenesis bioassay, preliminary results showed an increased incidence of hepatocellular carcinomas in mice but not in rats. These initial results have been questioned and the study is presently being audited.

1,1,1-Trichloroethane has shown mixed results in mutagenicity studies. The compound was not shown to be mutagenic in studies using yeast as an indicator organism, while both positive and negative results were reported in mutagenicity using various *Salmonella typhimurium* strains. 1,1,1-Trichloroethane has been shown to exhibit minimal evidence of DNA binding in test systems.

The IARC have classified 1,1,1-trichloroethane in Group 3; inadequate evidence of carcinogenicity in animals. EPA has concluded that there are insufficient data to classify 1,1,1-trichloroethane as a probable or possible human carcinogen, based upon the results of the NCI biassays. Thus, 1,1,1-trichloroethane has been classified in EPA's Group D and Regulatory Category III.

p-Dichlorobenzene. p-Dichlorobenzene has been shown to exhibit non-carcinogenic adverse effects in animals, including liver and kidney damage, porphyria, and splenic weight changes. In humans, exposure to dichlorobenzenes has been reported to result in anorexia, liver effects and blood dyscrasias.

p-Dichlorobenzene has been classified in Regulatory Category III (inadequate evidence of carcinogenicity to humans). p-Dichlorobenzene has not been shown to be carcinogenic to animals or humans. Several animal studies have shown negative results for the compound, including a bioassay undertaken by the NTP in which p-dichlorobenzene was administered by gavage to both sexes of mice and to female rats. The draft results showed no evidence of carcinogenicity from exposure to the compound.

p-Dichlorobenzene has not been found to be mutagenic when tested in the *Salmonella typhimurium* or *E. coli* systems. However, the compound has been shown to induce abnormal mitotic division in higher plants.

EPA has concluded that p-dichlorobenzene should be classified in EPA's Group D and Regulatory Category III based upon the negative results of the carcinogenicity studies.

4. Final RMCLs

The following provides a summary and basis for the final RMCLs for each VOC, based upon the three-category approach.

Category I Contaminants

The RMCLs for Category I contaminants (known or probable human carcinogens) are set at zero, using the same approach as was outlined in the June 12, 1984, RMCL proposal. Thus, final RMCLs for the following substances considered to be known or probable human carcinogens are "zero": benzene, vinyl chloride, carbon tetrachloride, 1,2-dichloroethane and trichloroethylene.

Category II Contaminants

The RMCLs for Category II contaminants (equivocal evidence of carcinogenicity) are set based upon chronic toxicity data with an additional margin of safety, or upon lifetime risk calculations if chronic toxicity data are not available. For 1,1-dichloroethylene, EPA is setting the RMCL based upon chronic toxicity data, primarily liver effects observed in animal studies. The

RMCL is based upon the ADI divided by an extra factor of 10 to account for the possible carcinogenicity of the compound and considering 20 percent drinking water contribution. The AADI in the June 12 proposal for 1,1-dichloroethylene was 350 μg/l, based upon an animal study in which liver effects were noted. Applying an extra factor of 10, and considering 20 percent exposure from drinking water, a final RMCL of 7 μg/l has been determined. An extra factor of 10 was applied because EPA believes that an additional order of magnitude is appropriate for this chemical. This is because of the conflicting bioassay data and the structural similarity to vinyl chloride. Thus, EPA believes that these data cannot be dismissed and is accounting for these data by applying an additional order of magnitude uncertainty factor.

Category III Contaminants

The RMCLs for Category III contaminants (non-carcinogens) are determined based upon chronic toxicity data. The AADI considering 20 percent drinking water contribution is the basis for the RMCLs for these contaminants. For 1,1,1-trichloroethane, the final RMCL is 200 μg/l, as proposed on June 12, 1984. For p-dichlorobenzene, the final RMCL is 750 μg/l, as proposed on June 12, 1984.

Table 6 summarizes the final RMCLs for the VOCs. In the judgment of the Administrator, the RMCLs at these levels prevent known and anticipated adverse effects with a margin of safety.

TABLE 6.—FINAL RMCLS FOR THE VOCS

Compound [1]	RMCL
Benzene	zero
Vinyl chloride	zero
Carbon tetrachloride	zero
1,2-Dichloroethane	zero
Trichloroethylene	zero
1,1-Dichloroethylene	7 μg/l
1,1,1-Trichloroethane	200 μg/l
p-Dichlorobenzene	750 μg/l

[1] A final RMCL will be published for tetrachloroethylene after the close of the 45-day comment period, to allow for the public comments on the new data.

5. Effective Dates

The final RMCLs are effective December 13, 1985. This date is 30 days after the publication of this notice. However, as explained above, the RMCLs are only health goals used by EPA in determining maximum contaminant levels.

V. Public Docket/References

All supporting materials pertinent to the development of this final rule are included in the public dockets located at EPA headquarters, Washington, D.C. The two public dockets (i.e., RMCL rulemaking docket-closed-and the MCL/Monitoring docket) are available to the public and the public should contact the Drinking Water Regulations Docket Manager for access. Materials in the public docket include such documents as the following:

- Public comments on the ANPRM and Proposed Rulemaking for RMCLs.
- Transcripts of the April 26, 1982, and August 6, 1984 public meeting.
- Report and background material for the four public workshops, Summer 1982.
- Transcripts and meeting of NDWAC meetings.
- Summaries of meetings, telephone calls from outside EPA.
- Letters to/from the public.
- Technical reports.
- Other supporting materials.

VI. Regulatory Analyses

The promulgation of an RMCL is different than the proposal of an MCL in that an RMCL is, by law, to be based only on health and safety considerations, while an MCL takes feasibility and cost into consideration. Therefore, this RMCL notice does not include an analysis of the economic impact on various possible MCLs. However, the Agency has analyzed the probable impact of the various alternatives, and this is reported in the MCL proposal.

The report includes an analysis of the impact of the various alternatives on water supply industry vis-a-vis capital costs of technology, operating and maintenance costs and the feasibility of financing new treatment. Additionally, impact on the consumer and on the nation as a whole is presented.

Under the Regulatory Flexibility Act, 5 USC 601 et seq., I certify that this action will not have a significant impact on a substantial number of small entities. This action will have no economic impact in and of itself because this a non-enforceable health goal.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This action does constitute a "major" regulatory action because it will not have a major financial or adverse impact on the community and it is a non-enforceable action. This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

This rule contains no information collection requirements under the provision of the Paperwork Reduction Act of 1980 (44 USC 3501 *et seq.*).

List of Subjects in 40 CFR 141

Chemicals, intergovernmental relations, radiation protection, recording and recordkeeping requirements, water supply.

Dated: October 10, 1985.

Lee Thomas,

Administrator.

Appendix A. Summary of Comments

The following is a summary and discussion of the principal comments to EPA's proposed RMCLs for VOCs in drinking water and EPA's responses to them. A more detailed response to comments on the specific contaminants is contained in the background document, "Summary of Comments and Responses on **Federal Register** Notices on Volatile Synthetic Organic Chemicals in Drinking Water". In its June 12, 1984, Proposed Rulemaking, EPA specifically asked for comments on the following nine questions.

1. How strong should the scientific evidence be to justify regulating a substance, particularly for carcinogenicity?

2. How should evidence of mouse liver tumors be weighed? If evidence is limited to mouse liver tumors, is that sufficient evidence to warrant regulating that substance as a carcinogen? Conversely, what would be the scientific basis for giving mouse liver tumors less weight in the evaluation of the potential for human carcinogenicity?

3. For non-carcinogens, is the approach used for computing the AADIs scientifically acceptable? Is providing for an assumed contribution of 20 percent from drinking water appropriate when more precise data are not available?

4. Should RMCLs for carcinogens be set at zero? If RMCLs are set at zero, what guidance, if any, should be provided on the actually attainable target levels in drinking water?

5. Should RMCLs for carcinogens be set at the analytical detection limit? What would this be for each VOC considered in this proposal?

6. Should setting RMCLs for carcinogens be established at a non-zero level based upon negligible risk determinations? What non-zero level and upon what basis? Which model and which assumptions? Does an incremental lifetime risk level of 10^{-6} represent a virtually non-existent or negligible risk? Should higher or lower risk rates be considered? Would another level be more representative yet meet the needs for practical implementation of the SDWA? Would use of the linearized multi-stage model in the non-

zero RMCL calculations meet the Congressional intent to incorporate a margin of safety into the RMCLs?

7. Should a range of finite risk levels for each RMCL be selected such as 10^{-5} to 10^{-6} instead of zero or a single value?

8. How should the degree of evidence of potential carcinogenicity be factored into the RMCL determinations? It there is sufficient experimental evidence of human carcinogenicity, should the RMCL be either zero or the one in one million risk equivalent, or some other calculated value? Should the RMCL be set at a higher concentration and higher nominal risk (to indirectly reflect less concern) as the strength of evidence of carcinogenicity is reduced? For example, if there is only sufficient evidence of animal carcinogenicity, should the RMCL be in the 10^{-5} up to the 10^{-6} risk range? If less than "limited evidence" is available, should the RMCL be determined based upon and ADI calculation?

9. Should an RMCL and an MCL be set for total VOCs to address multiple exposure to VOC's? On what basis?

In all, EPA received 95 public comments; 19 from water utilities, 3 from water utility associations, 22 from industry, 13 from industry associations, 10 from State governments, 11 from public interest groups, 8 from private citizens and 7 from other groups including federal government agencies and academic institutions. The following discussion summarizes comments received on the proposed regulations and the Agency's responses to those comments.

A. Specific Questions Posed in Federal Register Notice

1. Strength of Evidence of Carcinogenicity (Questions 1 and 8 from the **Federal Register** notice RMCL proposal)

Comments: Eighteen comments were received which addressed how strong the strength of evidence should be to justify regulating a substance. Thirteen commenters suggested that strength of evidence should be used to determine which chemicals should be regulated and five of these commenters stated that EPA should establish minimum criteria for regulating a substance as a carcinogen, based upon the IARC criteria. Four of the commenters who addressed the IARC criteria stated that EPA should not regulate a substance for carcinogenicity if IARC has classified the compound in Group III and one commenter suggested that EPA could use the IARC classification to set RMCLs which incorporate strength of evidence, i.e., set RMCLs at zero for known carcinogens and at varying risk levels based upon the strength of animal carcinogenicity data.

Seven commenters suggested that minimum criteria for carcinogenicity should be set based upon an evaluation of the available data. One commenter said that a positive carcinogenic response in one animal species in a properly conducted test should be considered sufficient evidence to regulate a compound as a carcinogen, while five commenters stated that EPA should not regulate a chemical for carcinogenicity where there is only limited evidence of carcinogenicity. One commenter suggested that EPA should regulate a substance for carcinogenicity only if it has demonstrated a positive response in one or more epidemiological studies or in animal bioassays in two or more species.

Several commenters stated that a conservative approach should be taken where even sparse or limited evidence should be considered as indicative of pssible carcinogenicity and the compound should be regulated, while several other commenters said that a compound should not be regulated if there is substantial doubt as to whether it poses a significant risk to humans.

One commenter noted that it is impossible to draw a sharp line between carcinogens and non-carcinogens as there is no such thing as a non-carcinogen, only compounds which have not been tested for carcinogenicity. An additional comment addressed the significance of positive versus negative evidence, stating that positive evidence in a well-conducted study should outweigh negative evidence.

A comment was received which suggested that when evidence exists that a VOC may be harmful to health but evidence is sparse or inconclusive, the evidence should still be used in decisionmaking, providing the NAS agrees on the reasonableness of the judgment. If substantial doubt exists, this commenter suggested that EPA not set an RMCL. Several comments were received which questioned the decision to classify certain of the VOCs as carcinogens. These comments are discussed in the background document "Summary of Comments and EPA Responses on **Federal Register** Notices on Volatile Organic Chemicals in Drinking Water". One commenter felt that EPA's decision to classify several of the chemicals (unspecified) as carcinogens is questionable, due to the limited evidence of carcinogenic effects, the fact that these chemicals are not genotoxic and that the metabolites are the carcinogens.

Six commenters suggested schemes whereby RMCLs would be set at varying risk levels based upon the strength of evidence of carcinogenicity. One commenter noted that setting RMCLs at zero for human carcinogens, at a 10^{-6} risk level for animal carcinogens and at a 10^{-5} level where limited evidence of animal carcinogenicity exists is appropriate, while another commenter suggested a similar scheme with the inclusion of another category for those chemicals with limited evidence of human carcinogenicity. One comment was received which said that RMCLs should be set at a 10^{-6} risk level for known or suspect carcinogens and at a 10^{-5} risk level for compounds with limited evidence of carcinogenicity, while another commenter suggested the same strategy with a risk range of 10^{-5} to 10^{-6} for known carcinogens and 10^{-4} to 10^{-5} for compounds with limited evidence. A commenter noted a scheme in which RMCLs for known human carcinogens would be set at a 10^{-6} risk level, suspect human and known animal carcinogens at a 10^{-5} level and suspect animal carcinogens based upon chronic toxicity. An additional commenter stated a strategy of setting RMCLs for compounds with sufficient evidence of human carcinogenicity at a risk level of 10^{-6}, a risk range of 10^{-5} to 10^{-6} for compounds with sufficient evidence of animal carcinogenicity and a range of 10^{-4} to 10^{-5} for compounds with more limited evidence of animal carcinogenicity.

One commenter noted that strength of evidence should not be factored in the RMCLs and another commenter suggested setting non-zero RMCLs for all carcinogens at the same risk level, regardless of the amount of evidence of carcinogenicity.

One comment was received in which an alternate approach to setting RMCLs based on strength of evidence of carcinogenicity was proposed; this approach consisted of assigning letter scores to each chemical based upon the quantitative and qualitative evidence of carcinogenicity and assigning arbitrary concentration levels to each score. An AADI would be calculated for each chemical and the AADI would be compared to the arbitrary concentration level and the lower value would be used as the RMCL.

Response: EPA believes that all of the available scientific evidence should be used to determine whether a compound should be regulated and the basis for the regulation. A qualitative evaluation of the available data is carried out in order to determine the strength of evidence of carcinogenicity or other adverse health

effects. EPA then makes the decision on whether or not to regulate based upon a consideration of the potential for the compound to cause adverse health effects and the likelihood of the compound being found in drinking water.

The alternative approach provided by the commenter in which letter scores are assigned to each chemical is a valid method for ranking chemicals for further action considering priority to relative risk. However, such an approach does not appear to be the method of choice for setting RMCLs, as the concentration levels assigned to the number scores are purely arbitrary. The approach does not appear to satisfy the requirement that the RMCL be set at the no-effect level incorporating an adequate margin of safety.

EPA agrees with the commenters who stated that a conservative approach should be taken with regard to the regulation of chemicals with limited evidence of carcinogenicity or other adverse health effects. This approach is consistent with the intent of the SDWA that EPA should err on the side of safety in setting the regulations and that conclusive proof of human risk is not needed in order to regulate a substance. The legislative history states, "Because of the essentially preventive purpose of the legislation, the vast number of contaminants which may need to be regulated, and the limited amount of knowledge presently available on the health effects of various contaminants in drinking water, the Committee did not intend to require conclusive proof that any contaminant *will* cause adverse health effects as a condition for regulation of a as suspect contaminant. Rather, all that is required is that the Administrator make a reasoned and plausible judgment that a contaminant may have such an effect". The legislative history continues to say that, "the contaminant need not have the adverse effect directly in order for the Administrator to regulate it as a primary contaminant. If it is a precursor to a contaminant which may have such effect or if it may contribute to such effect, the contaminant should be controlled under primary regulations". H.R. 93–1185, 93rd Cong. 2d sess. at 10 (1974).

EPA agrees with the comments received stating that minimum criteria should be established for regulating substances as carcinogens. EPA has established criteria for regulating substances as carcinogens based upon the EPA Proposed Guidelines for Carcinogen Risk Assessment (49 FR 46294). These guidelines are directly derived from the IARC criteria. The EPA guidelines provide a classification system for dividing chemicals based on their strength of evidence of carcinogenicity. The classification scheme divides chemicals into five categories: Group A, human carcinogen; Group B, probable human carcinogen; Group C, possible human carcinogen; Group D, not classified; Group E, no evidence of carcinogenicity to humans. The IARC criteria divides chemicals into three categories: Group 1, chemical is carcinogenic to humans; Group 2, chemcial is probably carcinogenic to humans; Group 3, chemical cannot be classified as to its carcinogenicity to humans. The major difference between the two classification schemes is that IARC does not distinguish between those chemicals with inadequate evidence of carcinogenicity and those chemicals with no evidence of carcinogenicity, while the EPA scheme does.

EPA does not believe that it is appropriate to apply a strict rule in which chemicals are not regulated for carcinogenicity if IARC has classified them in Group 3. The IARC classifications are several years old and new data which was not available at the time of categorization may indicate possible carcinogenic effects for a compound. EPA believes that all available data should be considered in the analysis. Both positive and negative evidence is weighed together with the quality of the study, and the many case-specific factors which are present in evaluating each contaminant and study. Depending on the strength of evidence, negative evidence may outweigh positive evidence or vice versa. In addition, the IARC Group 3 includes those chemicals with inadequate evidence of carcinogenicity and those chemicals with no evidence of carcinogenicity. Thus, a chemical could be classified in Group 3 because it was never tested for carcinogenicity or because it has shown inconclusive results, and not necessarily because it has shown negative results in animal studies.

The EPA classification scheme distinguishes between chemicals with inadequate evidence and no evidence of carcinogenicity; Group D (inadequate evidence) is defined as follows: "because of major qualitative or quantitative limitations, the studies cannot be interpreted as showing either the presence or absence of a carcinogenic effect". Group E, (no evidence) indicates that "there is no increased incidence of neoplasms in at least two well-designed and well-conducted animal studies in different species". EPA believes that this scheme helps to differentitate between those chemicals which have been tested and those which have shown negative results.

The minimum level of evidence for a compound to be regulated as a probable human carcinogen (EPA's Group B2) consists of animal evidence which is considered to be sufficient, i.e., evidence which indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains or in multiple experiments, or to an unusual degree with regard to incidence, site of tumor, or age at onset. Therefore, EPA agrees with those commenters who would classify as carcinogens those contaminants with positive results in one or more animal studies. Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests or on chemical structure. This is consistent with the view held by the NAS and others that animal studies may be extrapolated to man.

For a compound to be considered an "equivocal" carcinogen (EPA's Group C), the evidence has been determined to be limited using EPA's proposed guidelines for carcinogenic risk assessment definition of "limited" evidence as follows: "the data suggest a carcinogenic effect but are limited because: (a) The studies involve a single species, strain, or experiment, or (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting, or (c) an increase in the incidence of benign tumors only."

EPA will promulgate RMCLs at zero for those substances classified in Groups A and B (vinyl chloride, benzene, carbon tetrachloride, 1,2-dichloroethane and trichloroethylene). This is based upon the same philosophy that was followed in the RMCL proposal; i.e., that RMCLs for chemicals with sufficient evidence of carcinogenicity should be set at zero. The basis was that the RMCLs are to be set at a level which would not result in adverse health effects with an adequate margin of safety. The legislative history of the SDWA states that if there is no safe threshold for a contaminant, the RMCL should be set at zero. EPA believes that for those chemicals in Group A or B (human carcinogen or probable human carcinogen), there is sufficient evidence of carcinogenicity to warrant setting the RMCLs at zero.

For the substance classified in Group C (1,1-dichloroethylene), the RMCL will be promulgated at a non-zero level, based upon chronic toxicity data (the ADI with an additional margin of safety). If chronic toxicity data were not available, the RMCL would be based upon cancer risk (the 10^{-5} or 10^{-6} risk level). The chemicals classified in Group C do not have sufficient evidence to be classified as carcinogens, yet there are some data to indicate possible concern. Thus, these substances should be treated more conservatively than non-carcinogens, yet less conservatively than those chemicals classified as probable human carcinogens. Even though insufficient data on potential carcinogenicity are available, the RMCL should still be set at a level which would represent and extremely low nominal risk. EPA believes that either the risk calculation approach or the ADI approach with an additional factor provide an RMCL which is very conservative to protect against potential adverse effects. In essence, setting a more conservative RMCL for these contaminants provides an appropriate additional margin of safety.

RMCLs will be promulgated based upon chronic toxicity (the ADI) for those substances classified in Groups D and E (1,1,1-trichloroethane and p-dichlorobenzene). Those chemicals classified in Groups D and E have inadequate evidence or no evidence of carcinogenicity to humans. EPA believes that the approach followed in the RMCL proposal for non-carcinogens (i.e., set the RMCL based upon chronic toxicity data) is the best method for establishing the "no effect" level with an adequate margin of safety for threshold toxicants. This method follows the state-of-the-art concepts in toxicology and is generally accepted by the scientific community at large.

In adopting this classification scheme and in categorizing contaminants, EPA must make science policy judgments which draw heavily on its expertise and experience. The Agency believes its scheme and the lines it draws between classes of carcinogens are based on scientific ground well-trod by IARC, NAS, and OSTP. As stated by a member of the SAB, "The decision of CAG to utilize the IARC classification system for carcinogenicity has been supported and encouraged by the SAB on several previous occasions, and when combined with the weight of evidence as described in Dr. Paynter's Standard Evaluation Procedure document, represents a logical and scientifically defendable course of action for the Agency. . . . It may be useful, for example, to consider the Safe Drinking Water Committee approach for Category 3 agents (ADI with safety factor) and to reserve the Weibull extrapolation method for Category I and II agents." The adoption of the scheme for regulatory purposes under the Safe Drinking Water Act provides a strong scientific basis for regulation and clear guidelines for Agency decisionmaking. Highly complex toxicological judgments must still be made in categorizing contaminants in the EPA scheme and in weighing the different types of evidence and their strength.

2. Mouse Liver Tumors

Comments: Four commenters suggested that an increased incidence of mouse liver tumors should not be used as a basis to regulate a substance as a human carcinogen. The rationale was that the induction of mouse liver tumors is not relevant to human hazard, as the mouse liver is known to develop spontaneous tumors with or without the application of the chemical. These commenters felt that the mouse is not a good model for effects in humans due to the development of spontaneous tumors which appear to be affected by sex, strain, diet and endocrine factors of the mice. In addition, several of these commenters stated that scientific consensus is that mouse liver tumors are not relevant to human hazard and cited the conclusions of the report of the Nutrition Foundation Expert Advisory Committee that, ". . . therefore, the relevance to human populations, at least in these regions, of such enhancement of spontaneous tumor incidences in the mouse is questionable".

Six commenters felt that the EPA should not dismiss an increased incidence of mouse liver tumors in assessing the potential carcinogenic risk. Two of the commenters stated that positive results in liver tumors in mice should be considered "limited" evidence of carcinogenicity or the weakest evidence of carcinogenicity in a continuum of strength of evidence. The other four comments suggested that EPA should take a conservative approach and consider mouse liver tumors as a predictor of human risk. Several of these commenters noted that studies have shown that most chemicals which induce liver tumors in mice also cause neoplasms in other rodents and in other tissues of mice. These commenters felt that mouse liver tumors should be considered as a strong indicator of carcinogenic potential, but other available evidence should also be factored in when making a determination. One of these commenters noted that mouse liver tumors fall under potential risks covered by the SDWA, as EPA should err on the side of caution.

One commenter noted that under certain conditions, a tumor response in the mouse liver should be given less weight and there would be little cause for restricting the chemical. These conditions are: (1) If the compound produces tumors only in the mouse liver, particularly if the tumors are benign neoplasms, (2) if the compound fails to covalently bind to cellular macromolecules, and (3) if the compound fails to show activity (negative results) in well-validated tests for DNA damage. Another commenter felt that questionable weight should be given to mouse liver tumors and other species of animals should provide supportive evidence as a basis for VOC regulation.

Response: EPA believes that all available evidence should be used in the evaluation of a chemical for a possible carcinogenic risk. Mouse liver tumors should be considered and evaluated along with all other available evidence. EPA feels that it is not appropriate to completely discount such data.

The U.S. Office of Science and Technology Policy's report on chemical carcinogens (50 FR 10417) examined the biological significance and human relevance of mouse liver tumors. They concluded,

> Some scientists are certain that the mouse liver is overly sensitive and will respond to almost any toxic insult by developing cancer. Other scientists are just as certain that the mouse liver is a reliable indicator of carcinogenicity and as good a predictor of potential human risk as any indicator available. In one review, 61 of 85 chemicals (73%) that increased the incidence of liver tumors in mice also induced tumors in other tissues of mice and/or in rats. Some toxicologists believe that part of the problem stems from work on C_3H strains of mice where the background liver tumor incidence is high and false positive errors are possible. Generally, there is consensus that the mouse liver model in principle does have significance in terms of human risk, but unambiguous diagnosis between "benign" or "hyperplastic" liver nodules and malignant neoplasia remains elusive and there is no apparent scientific consensus. A recent review of this issue has emphasized the need for judgment on a case-by-case basis and the possible relevance of other toxicological information.

EPA endorses the OSTP findings.

EPA's proposed guidelines for carcinogen risk assessment (49 FR 46294) state that mouse liver tumors, when other considerations for classification as "sufficient" evidence of animal carcinogenicity are met, should be considered to be sufficient evidence of carcinogenicity with the

understanding that this classification could be changed to "limited" when a number of factors are found to be present. These factors include occurrence of tumors only in the highest dose group, no substantial dose-related increase in the proportion of tumors that are malignant, predominately benign tumors showing no evidence of metasteses, no-dose-related shortening of the time to the appearance of tumors, negative or inconclusive results from short-term tests from mutagenic activity and the occurrence of excess tumors only in a single sex. The EPA proposed guidelines consider chemicals in Group A (human carcinogen) and Group B (probable human carcinogen) to have "sufficient" evidence of carcinogenicity. Chemicals classified in both of these groups are placed in Regulatory Category I; known or probable human carcinogens for the purpose of setting the RMCL. Chemicals classified in Group C are considered to have "limited" evidence of carcinogenicity and are placed in Regulatory Category II; equivocal evidence of carcinogenicity.

EPA believes that it is reasonable to follow a conservative approach with regard to mouse liver tumors. The report by the Office of Science and Technology Policy concluded that there is consensus that the mouse liver model does have significance in terms of human risk and the EPA guidelines also concluded that mouse liver tumors should be considered as evidence of animal carcinogenicity. The EPA guidelines examine additional factors which could result in the classification being changed to "limited", and thus allow for situations in which the mouse liver tumors should be given less weight depending on additional evidence. This approach is consistent with the legislative history of the SDWA which states that conclusive proof is not needed in order to regulate a substance; all that is required is that a judgment be made that a contaminant *may* have an adverse effect. The legislative history also notes that the SDWA is a preventive statute and EPA should err on the side of safety.

EPA agrees with the commenter who suggested that the presence of certain conditions, such as benign neoplasms, should result in giving less weight to a tumor response in the mouse liver. The EPA guidelines state that the presence of these sort of factors may result in changing the classification of the chemical from "sufficient" evidence of animal carcinogenicity to "limited" evidence. However, EPA does not agree with this commenter that there would thus be little cause for restricting the chemical. As discussed above, EPA believes that a preventive approach must be taken according to the SDWA.

Both trichloroethylene and tetrachloroethylene have shown an increase in mouse liver tumors and for both chemicals this evidence has been used to classify the chemicals in Group B2, according to the EPA classification system. For trichloroethylene, this was based upon the fact that an increase in mouse liver tumors was seen in two studies from exposure to trichloroethylene which was not associated with any of the factors discussed above. Thus, the mouse liver tumors are considered to be "sufficient" evidence of carcinogenicity. For tetrachloroethylene, mouse liver tumors were seen in two studies and mononuclear cell leukemias were noted in rats in one study. Thus, these results were considered "sufficient" evidence of carcinogenicity for tetrachloroethylene.

3. AADI Approach

Comments: Twenty-five comments were received which addressed the approach used for calculating the AADIs for non-carcinogens and/or the appropriateness of assuming a 20 percent contribution from drinking water. The majority of commenters (eighteen), basically agreed with the AADI approach. Several commenters agreed with the overall approach but suggested specific recommendations for changes. One commenter felt that there should be a requirement that both negative (no-observed-adverse-effect level (NOAEL)) response data and positive (low-observed-adverse-effect level (LOAEL)) response data be available within a narrow range while another commenter suggested that additional safety factors be employed for mutagens and teratogens. A comment was received which suggested that EPA should use the 10 kg child consuming 1 liter of water per day instead of the 70 kg adult consuming 2 liters of water per day as the basis for the calculations. A commenter stated that EPA's overall approach to calculating AADIs is basically sound but overly conservative in some of its assumptions, such as the assumption that the adult consumes 2 liters of water per day. This commenter felt that many ingested fluids either do not derive from drinking water or have been boiled so that much of the VOC content will have been driven off. One commenter agreed with the AADI approach, but felt several of the AADIs are too high. This commenter stated that it is inconsistent with EPA's definition of RMCLs to use the no-observed-adverse-effect level (NOAEL) instead of the no-observed-effect level (NOEL), and also inappropriate to use inhalation studies and studies of less than lifetime duration in calculating the AADIs. This commenter felt that when insufficient data are available, EPA may want to consider setting the RMCL at an arbitrary level.

Five commenters disagreed with the AADI approach. One commenter stated that the AADIs are too high when compared to the analytical detection limits and another commenter noted that AADIs could be used if people were exposed to only one contaminant at a time. A comment was received which said that EPA should base the AADIs upon the 10 kg child and EPA should also reevaluate the safety factors used. This commenter felt that safety factors of 10, 100 and 1000 are too arbitrary and a range of safety factors should be used depending on the quality and nature of the data. An additional commenter disagreed with the AADI approach because with animal tests divided by 10, 100 or 1000 and then reduced by 80 percent, a value lower than the calculated values could be used for RMCLs. A comment was received which stated that EPA has been overly conservative in computing certain of the AADIs and this commenter submitted a different approach to the calculation of AADIs.

On the question of EPA's use of a 20 percent drinking water contribution to the AADI, five commenters agreed with this approach while thirteen commenters disagreed. Of the comments received which agreed with a 20 percent contribution, four commenters felt that in the absence of experimental data 20 percent appears to be a reasonable approximation and one of these commenters suggested that if a substance accumulates to a high degree, a value as low as 1 percent contribution from drinking water should be used. One commenter stated that EPA should determine the precise contribution from food and air, and if drinking water is shown to be greater than 20 percent, the precise value should be used and if drinking water contributes less than 20 percent, 20 percent should be used.

Of the thirteen commenters who disagreed with the use of 20 percent, the majority noted that 20 percent is speculative and has not been justified. Two commenters stated that 20 percent is unduly conservative and one of these commenters suggested that RMCLs should be set at 100 percent of the AADI unless there are data to justify a lower level. An additional two comments were received which said that 20 percent

should be lowered in order to account for absorption through the skin and other intakes.

One commenter felt that the literature contains sufficient information for EPA to assess the actual contribution from inhalation and possibly oral exposure for some contaminants, and for pollutants lacking such information, an 80 percent to 90 percent correction may be justified. This was based upon a study which suggested that contaminated drinking water acting as a single source of contamination may contribute significantly to daily inhalation, oral and dermal burdens. A commenter suggested that the RMCL should be set based upon the AADI using a percentage of the total daily intake of 1 percent to 5 percent from drinking water if the toxicologic data meets some minimum criteria for completeness. Another commenter noted that if there are data which shows drinking water to be responsible for 20 percent of a person's VOC uptake, then 20 percent should be used. In the absence of such data, this commenter felt that it is more reasonable to attribute 50 percent of a person's intake to drinking water.

The National Drinking Water Advisory Council recommended that 20 percent contribution from drinking water is a reasonable value to use in setting the RMCLs for non-carcinogens in the absence of more definitive data. However, the Council stressed that EPA should work toward the improvement in the data base in these areas and should use actual data when available.

Response: EPA believes that the approach used for determining the AADIs follows state-of-the-art concepts in toxicology and is scientifically justified. The determination of the no-observed-adverse-effect level (NOAEL) from animal or human data and dividing this by an appropriate safety factor is well established and accepted in the scientific community. This approach is consistent with the SDWA which requires EPA to identify and regulate adverse effects and to prevent the occurrence of any known or anticipated adverse effect. Therefore, EPA rejects use of the no-observed-effect level in favor of the no-observed-adverse-effect level. EPA must also include an adequate margin of safety, unless there is no safe threshold for a contaminant.

The National Academy of Sciences (NAS) (*Drinking Water and Health,* Vol. I, 1977), used the ADI approach to determine health levels at which exposure to a chemical would not be anticipated to produce adverse health effects in humans. The NAS (*Drinking Water and Health,* Vol. I, 1977, pp. 803–804) recommended that the uncertainty factor should reflect the degree or amount of uncertainty when experimental data in animals are extrapolated to humans. They recommend that when the quality and quantity of data are high, the uncertainty should be low and that when data are inadequate or equivocal, the uncertainty factor should be larger. The NAS also suggested the following guidelines to be used in establishing uncertainty factors: uncertainty factor of 10 to be used with valid experimental results from studies on prolonged ingestion by man; uncertainty factor of 100 to be used with valid experimental results on long-term feeding studies on experimental animals, and uncertainty factor of 1000 to be used with scanty results on experimental animals (NAS, *Drinking Water and Health,* Vol. I, 1977). EPA has followed these guidelines in applying uncertainty factors in the derivation of the AADIs/DWELs.

EPA believes that the application of uncertainty factors following the NAS guidelines is a viable method for establishing a margin of safety which corresponds to the amount of data available. EPA agrees with the commenter who stated that a range of safety factors should be used depending on the quality and nature of the data, and EPA believes that the NAS guidelines establish such a range. EPA does not agree that safety factors of 10, 100 and 1,000 are too arbitrary; these safety factors have been established based on scientific precedent which has shown that order of magnitude safety factors have been protective. Regarding the suggestion that additional safety factors be employed for mutagens and teratogens, the NAS uncertainty factors relate to all types of non-carcinogenic data, including teratological effects. EPA considers all types of effects in the analysis of the available data to determine the uncertainty factor to be applied. Mutagenic effects are examined as a separate toxicological endpoint and also considered in the analysis of strength of evidence of carcinogenicity. In this regard, they play a role in determining the classification of the chemical according to the EPA guidelines.

In regard to the comment concerning negative (NOAEL) and positive (LOAEL) data, EPA uses all of the available dose-response data to determine the best study upon which to base the ADI. Ideally, EPA will use the NOAEL to determine the ADI, since the purpose of the ADI is to determine the level at which adverse health effects would *not* be observed. However, EPA believes that it is appropriate to use the LOAEL, when a NOAEL is not available, with the application of an additional uncertainty factor to account for the observed effects. It is not necessary that data show they are within a narrow range to protect against adverse effects. First, in many cases, fully complete data will not be available and the SDWA clearly contemplates regulation where there is sufficient evidence to identify an adverse effect through a NOAEL or a LOAEL. Second, even where complete data are available, some contaminants will have a LOAEL that is not within a narrow range of the LOAEL. Certainly, regulation of these contaminants posing an adverse effect is justified under the Act. For these reasons, EPA is justified using either a NOAEL or LOAEL and applying additional uncertainty factors for the LOAEL.

As stated above, EPA believes that all of the available data should be examined and a determination made of the most appropriate study upon which to base the ADI. Ideally, that study will be a lifetime study via ingestion. However, the ideal data base is rarely available and EPA uses the best available valid study, even if the study has limitations such as the route of exposure or the number of animals. EPA believes that the use of an additional uncertainty factor will account for the study's limitations and is the best method available for deriving the ADI. So, for example, while a drinking water study is preferred, an inhalation study may be useful for assessing drinking water effects and may be the basis for an RMCL if an additional uncertainty factor is employed. EPA feels that basing the ADI upon the best available scientific data is appropriate and rejects setting the RMCL at an arbitrary level, which has no basis in science.

EPA believes that it is reasonable to assume two liters per day for drinking water consumption. This value was used by the NAS in *Drinking Water and Health,* Vol. I, 1977 and has been used in subsequent volumes. According to the NAS (p. 11), "The average per capita water (liquid) consumption per day as calculated from a variety of nine different literature sources was 1.63 liters. . . . However, the larger volume of 2 liters/day was adopted as representing the intake of the majority of water consumers." The National Interim Primary Drinking Water Regulations also used a value of 2 liters of water per day, based upon the data which indicated that a tremendous variation in individual consumption exists, but that 2 liters per day constituted a high but reasonable average intake for an adult male.

In reference to the comment which stated that the AADIs are too high when compared to the analytical detection limits; the AADIs are numbers based upon the scientific data which indicate that level at which adverse health effects would not be anticipated over a lifetime exposure. The analytical detection limits are not health based numbers; they simply represent the current state-of-the art in analytical capabilities. Thus, EPA believes that it is not appropriate to compare these two values as they represent two different end-points.

EPA agrees with the commenter who noted that people are exposed to more than one contaminant and thus a conservative approach should be taken. However, EPA does not agree that AADIs should not be used, as the AADIs are calculated with a significant margin of safety built in.

The use of the 70 kg adult rather than the 10 kg child as the basis for the AADIs is considered appropriate, except in those instances where the child has been shown to be the more sensitive subpopulation for a given effect. In these cases, the 10 kg child will be the basis. The basis for the 70 kg adult is that the RMCLs are intended to be protective for a lifetime exposure and a 10 kg child is not exposed over a 70 year lifetime. Calculating AADIs on the basis of a child's body weight would not provide a meaningful measure of the effects over a lifetime exposure. EPA agrees with the commenter who stated, "while we agree that RMCLs should be targeted to protect sensitive members of the population, we believe it inappropriate to presume *a priori* that children are the sensitive subpopulation. Increased dose per unit of body weight should not be confused with truly increased sensitivity to a chemical. We support the use of *actual* sensitivity data to determine no observed adverse effect levels and to calculate ADIs." Commenters provided related reasons for rejecting ADI's based on children. EPA agrees with those commenters. EPA believes that by applying uncertainty factors in the calculations, the health effects numbers are sufficiently protective for all segments of the population.

EPA has discussed the comments' suggestions concerning specific AADIs and the alternative approach suggested for the calculation of AADIs in the background "Summary of Comments" document.

With respect to an assumed 20 percent contribution from drinking water, EPA is following the recommendations of the National Drinking Water Advisory Council and is applying a 20 percent relative source contribution factor in the absence of data indicating the actual contribution of the chemical from air, food and water. If there are data showing the precise contribution from food and air, EPA will use this data and factor it into the RMCL determination. EPA agrees with the recommendations of the National Drinking Water Advisory Council that further work is needed in this area and will continue to support efforts to better define the contributions from various media to overall exposure.

A 20 percent drinking water contribution was used in the National Interim Primary Drinking Water Regulations and by the NAS who used projections of 1 percent and 20 percent as illustrations of drinking water contribution. The NAS did not recommend a specific value for drinking water contribution. EPA has used a 20 percent drinking water contribution factor as a reasonable approximation of the actual exposure and recognizes that this value may somewhat either overestimate or underestimate the actual drinking water contribution. EPA does not believe that it is appropriate to set the RMCL at 100 percent of the ADI, as drinking water is not the sole contributor to total exposure, and using 100 percent of the ADI would underestimate the other sources of exposure. Because VOCs are high volume industrial chemicals, some of which are commonly used by consumers (e.g., benzene in gasoline) or appear in consumer products (e.g., 1,1,1-trichloroethane) is very likely that there will be exposure from other sources than drinking water. EPA also recognizes that dermal absorption may contribute to the overall exposure. However, EPA does not feel that the methodology is well enough developed to factor this specific exposure into the RMCL calculations. In addition, the application of the uncertainty factor and 20 percent drinking water contribution helps to take into account possible additive or synergistic effects and the possible high exposure portion of the population.

4. RMCLs for Carcinogens at Zero

Comments: Seventy-three commenters addressed the issue of whether RMCLs for carcinogens should be set at zero. Twenty-seven commenters said that the RMCLs for carcinogens should be set at zero, primarily based upon the House Report which stated that the RMCL for contaminants for which there is no safe threshold should be set at zero. In addition, many of these commenters stated that carcinogens should not be present in drinking water and the RMCLs as health based goals would demonstrate EPA's commitment to this philosophy. Two of these commenters presented strategies in which RMCLs were set at zero for known human carcinogens and at risk levels for compounds with more limited evidence of carcinogenicity. A commenter stated that those compounds with sufficient evidence of human or animal carcinogenicity should be set at zero, while those with substantial doubt as to carcinogenicity should be set at the ADI with an added safety factor. One commenter felt that RMCLs of zero should be set for all chemicals, non-carcinogens as well as carcinogens and another commenter noted that guidance on levels actually attainable is more appropriately provided in the context of the MCLs.

Forty-seven commenters stated that RMCLs for carcinogens should not be set at zero for any contaminant. The major reasons were that zero is not measurable or attainable and is scientifically undefinable. If was noted by several commenters that setting RMCLs at zero is counterproductive as it will project an unscientific image to the public, i.e., that zero concentration is achievable. In addition, several commenters suggested that RMCLs at zero will confuse and alarm the public and will be generally interpreted as being standards. These commenters generally felt that RMCLs should be workable levels which would provide actual guidance on levels attainable in public water systems.

The National Drinking Water Advisory Council recommended that RMCLs not be set at zero, as zero was not considered to provide a realistic/practical health goal for public water systems, because zero is undefinable in the analytical sense and unachievable. A minority of the members of Council felt that RMCLs for some, if not all, carcinogens should be set at zero since RMCLs are health goals, not practical, achievable levels, and as such should be set at zero to be consistent with the scientific community on the safety of exposure to carcinogens.

Responses: EPA has concluded that the RMCLs for probable human carcinogens (EPA's Group A or Group B) should be set at zero. This approach is consistent with the guidance provided in the House Report which stated that if there is no safe threshold for a contaminant, the RMCL should be set at zero. EPA believes that the zero level is necessary to prevent known or anticipated effects from human or probable human carcinogens including a margin of safety. No other margin of safety would be adequate since EPA

does not believe a threshold for carcinogens exists. Thus, there is likely to be some known or anticipated adverse effects at levels above zero.

EPA does not believe a zero RMCL is appropriate for chemicals with equivocal evidence of carcinogenicity. In setting the RMCL, EPA would be oversimplifying to treat contaminants with equivocal evidence of carcinogenicity the same as contaminants with sufficient evidence of carcinogenicity and that have not been shown to exhibit a threshold. To treat these contaminants as carcinogens is to ignore the equivocal evidence. Probability of an adverse effect is not a prerequisite for setting an RMCL which takes account the equivocal evidence. Legislative history provides that EPA is to regulate even where faced with uncertainty.

EPA does not agree with the comment that RMCLs of zero should be set for all chemicals. For those chemicals which have not demonstrated carcinogenic effects, the ADI approach is a well established method for determining the level at which adverse health effects would not be anticipated. This approach considers threshold evidence and is an appropriate technique for determining non-zero levels for non-carcinogens. Of course, a margin of safety is incorporated, which provides an additional measure of protection.

In response to the commenters who stated that RMCLs should be set at practical levels, rather than at zero, EPA believes that the MCLs reflect technological and economic feasibility, and the RMCLs purely reflect health considerations. The RMCLs are goals which may or may not be practically achievable and the practicality of these levels should be factored into the MCLs, not the RMCLs.

With regard to the concern that setting RMCLs at zero will alarm the general public and project an unscientific image, EPA believes that the public will be able to distinguish between RMCLs as goals and MCLs as enforceable standards and will not be alarmed at setting a goal of zero. RMCLs are only health goals to be used by EPA in setting the MCLs. Public water systems are not required to meet the RMCLs. EPA has emphasized in the rulemaking that zero is not a measurable level in scientific terms and will continue to emphasize this point to the public. That zero is not measurable or attainable is irrelevant to the purpose of setting RMCLs which is to set a health goal to prevent adverse effects with a margin of safety. Even if the public were to be alarmed or concerned at RMCLs set at zero, EPA would still choose RMCLs set at zero as most consistent with its statutory mandate, as explained above.

5. RMCLs for Carcinogens at the Analytical Detection Limit

Comment: One comment was received which suggested that RMCLs for carcinogens be set at the analytical detection limit. This commenter stated that he recommended that RMCLs represent the ideal; potable water free from harmful constituents. Because attainment of this level (zero) is impossible to validate, the RMCLs would be effectively established at the existing detection limit. One commenter stated that as a last resort an RMCL equal to or double the detection limit might be considered, while twenty-four commenters thought that RMCLs set at the analytical detection limit were not appropriate. The reasons given were that the detection limit has no relationship to health risk, is dependent on the technology of the time and is constantly changing. In addition, problems with interlaboratory variation were cited.

Response: EPA agrees with the majority of commenters that RMCLs for carcinogens should not be set at the analytical detection limit. The analytical detection limit is not based upon health risk. It is usually an extremely low number representing the lowest measurement above zero. However, the analytical detection limit is a moving target as the state-of-the-art in chemistry progresses and is very much dependent on the technology of the time.

RMCLs are not meant to be standards for public water systems to achieve; they are to be set by EPA based on health considerations alone. RMCLs are only promulgated by the Agency as health targets for the MCL rulemaking. In addition, RMCLs are to be set to prevent known and anticipated adverse effects to include a margin of safety; they are not to be set at analytical detection limits under the statute.

6. RMCLs for Carcinogens Based on Risk Calculations

Comments: Thirty-four comments were received which suggested that RMCLs for carcinogens should be established at a non-zero level based upon negligible risk determinations. The primary basis was that risk models provide a scientific means for assessing the risk to the human population from chemicals in drinking water and are sufficiently conservative to provide an ample margin of safety. The general risk range most often mentioned as a target level was one in a hundred thousand (10^{-5}) to one in a million (10^{-6}). Five commenters said that a (10^{-5}) level was appropriate while five commenters felt that a level of (10^{-6}) should be used. One commenter stated that if the potential human exposure is less than the best estimates of risk, the RMCL should be set a (10^{-6}) risk level, while if the potential human exposure exceeds this level of risk all data should be reviewed and an appropriate RMCL adapted. One commenter suggested that a one in a million *yearly* risk should be used with the upper 98th percentile of the probability distribution of the risk coefficient and another commenter stated that an annual risk of (10^{-5}) to (10^{-6}) is appropriate. Three comments were received which said that the upper and lower confidence limits as well as the best estimates should be provided for each risk estimate. Several commenters stated that the linearized multi-stage model overestimates the actual risk while one commenter noted that the multi-stage model is relatively conservative and protective. Another commenter suggested that linearized models be abandoned until more data are gathered on synergistic effects.

The National Drinking Water Advisory Council recommended that RMCLs for carcinogens be set at the (10^{-6}) risk level using a conservative risk model. This was based upon the premise that a one in a million excess risk rate presents a virtually negligible risk which should be socially acceptable. A minority of the members of the Council felt that RMCLs for carcinogens should not be set based upon a risk calculation approach, but set at zero, as discussed in Issue 4.

Responses: EPA has concluded that the RMCLs for known and probable carcinogens should be set at zero rather than based upon calculations of risk and a subjective judgment as to what is a negligible or acceptable risk. For known and probable carcinogens, zero best meets the direction of Congress that EPA set RMCLs to prevent known or anticipated effects with a margin of safety. For contaminants with equivocal evidence of carcinogenicity, a zero RMCL is not considered appropriate, as explained above. A risk estimate may be used to set a more conservative RMCL for these contaminants than would otherwise be established considering non-carcinogenic endpoints. EPA is using risk estimates for these contaminants to provide an additional margin of safety.

In regard to the comments concerning specific mathematical models, as the shape of the dose-response curve is not known, it is not possible to state whether a particular model such as the

linearized multi-stage model underestimates or overestimates the actual risk for a particular chemical. The presentation of upper and lower confidence limits as well as best estimates is a valid means of presenting the results; however such a range of numbers would not help determine the no-effect-level for purposes of determining the RMCL.

7. RMCLs for Carcinogens at a Range of Risk Levels

Comments: Several commenters suggested that RMCLs be set at varying risk levels depending on the strength of evidence of carcinogenicity (see Question 1), however no comments were received which suggested that a range of risk levels instead of a single value be used as the RMCL.

Response: EPA agrees that the RMCL should be a single value, rather than a range of risk levels. A range of risk levels would not serve the purpose of providing a health-based goal with a margin of safety and would be confusing to the public. In addition, RMCLs set at a range of risk levels would not provide a clear target level for setting the MCLs.

8. RMCL and MCL for Total VOCs

Comments: Twenty-six commenters addressed the issue of setting an RMCL and an MCL for total VOCs. Thirteen commenters were in favor of establishing an RMCL for total VOCs while thirteen commenters were against such an RMCL. The major reasons why an RMCL was favored was the need to be protective of public health and consider possible synergistic effects, the suggestion that such an RMCL would make enforcement easier and that an RMCL for total VOCs is supported by the technology (most treatment techniques remove more than one chemical at a time). Many of these commenters also noted that in the absence of more scientific data, EPA should consider the potential health risks of multiple contaminants to be additive. One commenter suggested that a default level of 100 μg/l for total VOCs is reasonable.

The basis for the majority of the comments which did not favor setting an RMCL for total VOCs was that scientific information does not exist to support such a level as it is not possible to state whether compounds will act in an additive, synergistic or antagonistic fashion. One commenter proposed that EPA establish an approach based upon pragmatic considerations, rather than purely scientific considerations. This approach consisted of setting MCLs for individual compounds and then setting a standard in which the total concentration of the mixture should not exceed the MCL of the individual component with the highest MCL. Another commenter felt that an RMCL for total VOCs is not needed because the application of step-by-step safety factors for the individual chemicals tends to build in a bottom line safety factor.

The National Drinking Water Advisory Council recommended that an RMCL for total VOCs not be established at this time due to the lack of scientific data on synergistic, antagonistic or additive effects of exposure to more than one substance at a time. A minority of members of the Council supported establishment of an RMCL for total VOCs in order to protect against the potential additive effects of unregulated VOCs or regulated VOCs present at levels just below their MCLs.

Responses: EPA agrees with the many commenters who believed that an RMCL for total VOCs would not be scientifically valid. EPA is following the recommendations of the National Drinking Water Advisory Council and has concluded that sufficient data are not available upon to which to base an RMCL for total VOCs. There are not adequate data available to indicate that chemicals in mixtures act in an additive fashion; synergistic or antagonistic effects may be seen. EPA agrees with the commenter who stated that, "In summary, VOCs vary greatly in their toxicity and chemical properties. It would not be possible realistically to establish a single RMCL that would represent a no-effect level for the different VOCs that might be found in drinking water".

EPA has provided general guidelines for the assessment of chemical mixtures (50 FR 1170). However, as a matter of priority, EPA is attempting to regulate as many VOCs as possible which meet its criteria for regulation. EPA may reassess additive and synergistic effects at a later date.

In addition, an RMCL for total VOCs would be impossible because both carcinogens and non-carcinogens are regulated. An RMCL of zero adjusted with a higher number would produce a number greater than zero. EPA would not be setting a level that prevented known or anticipated adverse effects for known or probable carcinogens if a non-zero number were chosen. On the other hand, zero as an RMCL for total VOCs would be overly stringent as EPA is today establishing non-zero RMCLs for several VOCs.

B. Additional Issues

1. Analytical Methods

Comments: Two commenters discussed the available analytical methods for monitoring for VOCs in drinkings water. Both of these commenters stated that the EPA methods (550.1, 502.1, 503.1 and 450.1) are not precise, accurate and simple and are more expensive than EPA assumes. The commenters noted that the methods have not been subjected to peer reveiw or evaluated in a scientific manner and interferences are manifold in the analyses.

Responses: For purposes of determining whether a drinking water regulation is appropriate, and therefore in determining whether to set an RMCL, EPA must determine whether contaminants can be detected in drinking water. If there is no way to determine if a contaminant may be in drinking water, EPA is unlikely to establish a drinking water regulation. Therefore, in its RMCL proposal, EPA noted that methods appeared to be available to detect the presence of VOCs in drinking water. Comments relating to the precision, accuracy, cost, and peer review of methods will be addressed in the MCL rulemaking. However, EPA will make a preliminary response to these comments here.

EPA has recently revised two of the methods (502.1 and 503.1) to provide additional information on the precision and accuracy of these methods from an interlaboratory validation study. These methods were tested by 20 laboratories using drinking water spiked with VOCs at various levels. Single operator precision, overall precision and method accuracy were found to be related to the concentration of the analyte.

EPA agrees that interference problems are significant and recommends that precautionary measures to avoid contamination of samples be followed as well as other good laboratory practices in quality control. In reference to costs of analysis, EPA does not believe that EPA's analytical costs are an underestimate of the actual costs per sample. EPA conducted a survey of analytical costs associated with the analysis of VOCs which included 28 commerical laboratories across the United States. The range of prices quoted was from $50 to $300 for Method 502.1 and $75 to $500 for Method 503.1. These prices are presently being charged by these laboratories and appear to be representative of laboratories across the country.

2. Occurrence

Comments: Seven comments were received which addressed the occurrence of VOCs in drinking water. Four commenters noted problems with the EPA surveys used to estimate the occurrence of the VOCs in drinking water. Two of these commenters stated that the surveys have not been made available for outside review and comment and that there were problems with the precision and reproducibility of the data in the surveys. One commenter noted that of the five surveys employed quantitatively to make projections of national occurrence for trichloroethylene, only one was acceptable from both a qualitative and quantitative standpoint. Data from the other four surveys was judged to be only qualitatively acceptable. In addition, this commenter suggested that a major deficiency of several of the surveys was the long unrefrigerated holding period of the samples prior to analysis.

Several commenters provided specific comments on the Occurrence Documents for individual chemicals. The major points discussed dealt with the minimum quantification levels assumed, the additional sources of total exposure (air and food) and the sampling techniques used to estimate national occurrence.

Responses: All of the EPA surveys have been available for outside review and comment before the proposed rule and were included in the rulemaking record available to the public. In addition, the data from these surveys have been summarized and tabulated in the individual occurrence documents on each chemical.

In reference to the occurrence surveys, these surveys are used as general information to support EPA's finding that such contaminants have occurred in drinking water or are likely to occur in drinking water. Their quantitative evidence is not particularly significant in this rulemaking. Therefore, the fact that a contaminant level may have been overestimated or underestimated does not render the studies useless. Projections of national occurrence are provided as background data for determining priorities and for public information and are not used to determine whether or not a compound should be regulated.

In regard to the long holding period of the samples prior to analysis, this holding time can lead to a reduction in the measured contaminant level which is recognized as a potential factor in underestimating the actual occurrence levels. Thus, EPA believes that this holding time does not affect the decision on whether or not to regulate a compound based on occurrence, since the holding period would underestimate the actual occurrence.

EPA has addressed the specific comments on the Occurrence Documents in the background document, "Summary of Comments" and EPA Responses on **Federal Register** Notices on Volatile Synthetic Organic Chemicals in Drinking Water".

3. Risk Assessment

Comments: Seven commenters discussed varying issues involving the risk assessment process. One commenter stated that EPA has been unable to separate risk assessment from risk management. This commenter felt that EPA regulates a compound because the risk assessment is there, regardless of whether the hazard is real or not. Risk assessment was defined as the summation of all known data on the substance and not merely a statistical exercise.

Another commenter noted that EPA's regulatory objective should be on setting a goal for risk reduction, i.e., maximizing health protection by providing the greatest risk reduction for the population at risk. This commenter felt that this should be accomplished through a process of hazard evaluation in which the data are first examined to determine if they are of sufficient quality to warrant quantitative hazard evaluation. If the data are of sufficient quality, the geometric mean of all the risk estimates should be used. All this information is then made available to the decisionmaker and then the strength of evidence is taken into consideration. The stronger and more reliable the evidence, the less risk one would take, and the weaker the evidence, the higher the estimated risk one may find acceptable.

A commenter stated that EPA should formalize its methodology for risk assessment, seek public comments on the process and ensure that risk assessments are consistent among all Agency programs. One comment was received which suggested that EPA propose alternate approaches for predicting cancer risks for compounds with sufficient and limited evidence of carcinogenicity. This commenter noted that distinctions have not been made between these two classifications with regard to quantitative risk assessment and that the risk assessment process should try to deal in a quantitative manner with differences in the quality of evidence.

One commenter stated that linearized risk assessment models should be abandoned until synergistic data are gathered and another commenter felt that VOC regulations must incorporate a provision allowing the use of water having the lower cancer risk where differing risk estimates exist. An additional comment was received which noted that with federally provided health effects information, the local governments can develop the necessary information to inform the consumers as to the cost in meeting risk. This commenter suggested that the public should be able to vote as to the cost/benefit of meeting the RMCL.

Responses: The process of risk assessment is carried out in several general steps which are dependent upon experienced scientific judgment. Each substance must be evaluated on a case-by-case basis using all of the information at hand, however imperfect it may be. First, the available data is evaluated in order to establish *qualitatively* the potential for adverse health consequences. The general relationship between level of exposure and the nature and severity of effects is evaluated. Next, risk characterization is carried out which involves the quantitation of the risk from an acceptable data base. In the case of the development of drinking water regulations, this step would conclude with the derivation of an RMCL.

The type of data which is used to qualitatively evaluate the potential for adverse health effects include a wide variety of information on toxicity and toxicokinetics obtained in a number of species, even the human, as well as certain types of structure activity relationship investigations. For quantitation of the risk, a more vigorous measure is applied to the acceptability of data. In this case, only studies which are conducted in an appropriate manner (e.g., with sufficient numbers and quality control, etc.) can be included. These studies should identify the presence or absence of a dose-response relationship for at least one if not several parameters in a system which can be extrapolated/interpolated to the human. In addition, at least one of those studies should have adequate duration of exposure (no less than subchronic), preferably but not necessarily by the oral route, and meet the other criteria stated above so that it can be used as the basis for the development of an estimated exposure level on the health of persons with an adequate margin of safety.

EPA agrees that the process of risk assessment should be separated from risk management. EPA first carries out the risk assessment process, as discussed above, and for those chemicals with equivocal evidence of

carcinogenicity and for non-carcinogens, the quantitation of risk is used as the basis for the RMCLs. The risk management process is then carried out which consists of management decisions on how the risk assessment is to be applied. In this case, EPA has adopted the three-category regulatory scheme for contaminants as the risk management decision-making criteria.

EPA does not believe that the RMCLs should be set on the basis of risk reduction, as suggested by one commenter. According to the SDWA, the RMCLs are to be set at levels at which "no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety". Basing the RMCLs upon risk reduction would not allow for an adequate margin of safety and would not be set at the no-effect level, as mandated by the SDWA.

EPA agrees with the comment that the methodology for risk assessment should be formalized. EPA has published Proposed Guidelines for Carcinogen Risk Assessment (49 FR 26294) which is a methodology for assessing carcinogens in a formalized process, including public comment and review. These proposed guidelines discuss a categorization scheme for chemicals based upon strength of evidence of carcinogenicity.

In response to the suggestion that linearized risk models be abandoned, risk extrapolation models which include the linear models are the only methods currently available to estimate cancer risk and EPA believes that they provide a useful function in evaluating relative risks from chemical contaminants. Sufficient scientific data are not available upon which to choose which model is more likely to more reasonably reflect true risks. Of course, these models are not used in establishing RMCLs for carcinogens. They are nevertheless useful in providing a means of incorporating an additional margin of safety for contaminants with equivocal evidence of carcinogenicity.

In response to the suggestion that the local governments develop the necessary information to inform the consumers as to the cost in meeting the risk, EPA feels that the local water utilities should decide with their customers the best means of reducing risk. However, EPA is required under the SDWA to set National Primary Drinking Water Regulations for contaminants that public water supplies must meet.

4. Criteria for Setting RMCLs/MCLs

Comments: Fifteen commenters addressed the criteria to be used to determine the need for regulation of compounds in drinking water. Four commenters suggested that compounds be regulated if they are present in drinking water with some frequency or have widespread occurrence and present a risk to human health. Two commenters noted that data presented by EPA do not reflect a need to regulate many of these compounds, given their minimal incidence of detection in drinking water supplies and the low concentrations at which they are found. One of these commenters felt that controlling these substances will not result in a measurable decrease in cancer incidence.

Six commenters felt that a preventive approach should be used to determine which chemicals should be regulated. These commenters noted that regulation should be considered for contaminants which pose a potential threat to human health if they were to contaminate a public water supply, and that government must err on the side of protection in deciding whether to impose control limits. One of these commenters suggested an approach to regulating compounds for which there are inadequate health data consisting of regulating compounds as a group and setting MCLs for specific chemicals within each group as data become available.

An additional comment was received which stated that EPA should set priorities for the chemicals to be regulated based upon the relative risk levels. A commenter suggested that if substantial doubt exists as to whether a substance causes serious health effects, EPA should provide a regulatory decision which reflects this lack of evidence. Another commenter stated that there is a clear need for national standard setting for VOCs as most States lack the resources to develop standards on their own. This commenter further stated that EPA is the best, and sometimes only, information source in this regard.

The National Drinking Water Advisory Council recommended that the basis for selection of contaminants for regulation should be: (a) Sufficient health effects data, and (b) the occurrence or potential occurrence of contaminants in drinking water. A further condition was recommended that suggested that regulations be set for known human carcinogens, even if they do not occur widely in drinking water. It was recommended that RMCLs be set for all the VOCs in the proposal except for 1,1-dichloroethylene and p-dichlorobenzene, due to the limited occurrence and health effects data on these two compounds. A minority of the members of the Council felt that RMCLs should be set for 1,1-dichloroethylene and p-dichlorobenzene due to health effects information and the potential for widespread occurrence of these compounds in drinking water.

Responses: EPA has used three primary criteria for selection of contaminants for possible regulation: (1) The analytical ability to detect a contaminant in drinking water, (2) the potential health risk and, (3) the occurrence or potential for occurrence in drinking water. These factors are examined for each of the chemicals that EPA is considering regulating, following the "logic train" discussed in section IV. EPA feels that it is appropriate to base the selection of contaminants upon the potential risk and the occurrence or potential for occurrence in drinking water, rather than using widespread occurrence and a significant health risk as the criteria.

Requiring widespread occurrence and a significant risk of harm to the public before regulating would not be consistent with the preventive purpose of the statute. Congress expected EPA to protect public health before adverse effects occurred. The legislative history of the SDWA states, "Because of the essentially preventive purpose of the legislation, the vast number of contaminants which may need to be regulated, and the limited amount of knowledge presently available on the health effects of various contaminants in drinking water, the Committee did not intend to require conclusive proof that any contaminant *will* cause adverse health effects as a condition for regulation of a suspect contaminant. Rather, all that is required is that the Administrator make such a reasoned and plausible judgment that a contaminant *may* have such an effect". Controlling these contaminants when there is some evidence of drinking water contaminantion even if not widespread or at high levels, is clearly consistent with EPA's mandate to protect public health.

In addition, EPA need not determine that there will be a measurable decrease in cancer incidence before it is justified in regulating these drinking water contaminants. First, epidemiological studies on VOCs in drinking water are not available. Second, as noted above, EPA need not wait until a significant harm or risk of harm occurs before regulating drinking water. However, as noted in the draft Regulatory Impact Analysis, EPA believes that the incidence of cancer will be reduced if the proposed MCLs are adopted.

In response to the comment concerning regulation of compounds as

a group, EPA does not agree that compounds should be regulated where there are inadequate health data. The RMCLs are based upon the best available health data and if the data are insufficient as a basis for the derivation of the RMCL, an RMCL will not be set. However, EPA considers it appropriate to regulate compounds as a group as appropriate, as was done in the case of the trihalomethanes.

EPA agrees that priorities of chemicals to be regulated should be set based upon a variety of factors, including relative risk levels. EPA regulates compounds where there is a possibility of an adverse health effect. The RMCLs reflect the degree of evidence of carcinogenicity through the three-category approach, and the lack of evidence is reflected in the chemicals categorized as having "equivocal" evidence of carcinogenicity.

EPA realizes that many States lack resources to develop RMCLs independently. Congress also recognized this fact when it enacted the SDWA giving EPA broad authority to establish standards for drinking water contaminants.

EPA agrees with the minority opinion of the National Drinking Water Advisory Council that there are sufficient health effects information and potential for occurrence in drinking water to set RMCLs for 1,1-dichloroethylene and p-dichlorobenzene. (See the background Summary of Comments document for further discussion of the specific chemicals.)

5. Simultaneous Proposal of RMCLs and MCLs

Comments: Six commenters suggested that the two-step regulatory process be collapsed so that RMCLs and MCLs are proposed simultaneously. Two of these commenters felt that RMCLs and MCLs should be combined into a single set of numbers. The basis was that simultaneous proposal would reduce the potential for confusion by the public and the media, and would reduce the lengthy regulatory process. Two additional comments were received which stated that the current practice of proposing RMCLs prior to MCLs is very confusing. One of these commenters suggested that EPA take special pains to educate the public on the RMCL/MCL process.

Response: EPA agrees that by simultaneously proposing RMCLs and MCLs the regulatory procedure would be shortened and would tend to minimize potential confusion among the public. However, the SDWA currently specifies that RMCLs and MCLs are to be proposed in sequence and EPA will follow this statutory direction.

6. RMCLs as Standards

Comments: Twelve commenters stated that even though RMCLs are intended to be used as non-enforceable guidelines, they will be adapted by States and local agencies as enforceable standards. In addition, it was noted that RMCLs will be applied in areas other than public water systems, such as for hazardous waste clean-up standards and ground water monitoring levels. One of these commenters stated that there is no difference to the populace between a goal and a standard if it is promulgated by EPA.

Responses: RMCLs are only targets for EPA's MCL rulemaking. States may adopt MCLs that are more stringent; however, EPA does not require or encourage States or localities to adopt the RMCLs as enforceable drinking water standards. Any use of RMCLs by EPA or States or localities would have to be accomplished through legislation or rulemaking. The public would have an opportunity to address this or any other use of RMCLs.

7. Control of Contaminants

Comments: Four comments were received that urged EPA to control contaminants at the source and to prevent their discharge into drinking water supplies. One commenter stated that water operators should not be penalized for treating VOCs not naturally found in water.

Responses: EPA agrees that contaminants should be controlled at the source and is working through the National Pollution Discharge Elimination System, the Hazardous Waste and Superfund programs and other EPA programs to control source discharges. The majority of cases of VOC contamination do not involve point discharges to surface water. Most VOC problems are in ground water, where source clean-up is very difficult.

8. Monitoring

Comments: Five commenters addressed monitoring for contaminants in drinking water. Three commenters stated that increased monitoring of drinking water to better define the public's exposure to VOCs is warranted. One comment was received which presented a monitoring scenario in which all public water systems would carry out one round of monitoring for VOCs. If no contamination was detected, the water system would then monitor at three-year intervals. If contamination was detected below the MCLs, monitoring would take place yearly while contamination above the MCL would dictate quarterly samples. This commenter also noted that it is preferable to do preventive monitoring for VOCs than to try afterwards to provide treatment for VOCs removal which is more expensive. An additional commenter was concerned with the reliability of the available monitoring methods and stated that standards should be set in such a manner that recognizes the range of uncertainties that may be inherent in the data generated by the techniques.

Responses: EPA agrees that monitoring is a key element in regulatory compliance as well as in identifying the possible need for additional controls and public information. The uncertainties in the data generated by analytical methods is discussed in the MCL proposal. EPA recognizes that a great deal of variability surrounds the results of the monitoring methods and has factored this uncertainty into the determination of the MCLs. Monitoring is addressed in detail in the MCL proposal.

For the reasons set out in the preamble, Part 141 of Title 40, Code of Federal Regulations is amended as set forth below.

1. The authority citation for Part 141 is revised to read as follows:

Authority: 42 U.S.C. 300g–1, 300g–3, 300j–4, and 300j–9.

2. The title of Part 141 is revised to read as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

3. A new paragraph (u) is added to read as follows:

§ 141.2 Definitions.

* * * * *

(u) "Recommended maximum contaminant level" or "RMCL" means the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which includes an adequate margin of safety. Recommended maximum contaminant levels are nonenforceable health goals.

4. A new Subpart F, consisting of §§ 141.50 and 141.51, is added to read as follows:

Subpart F—Recommended Maximum Contaminant Levels

Sec.

Subpart F—Recommended Maximum Contaminant Levels

§ 141.50 Recommended maximum contaminant levels for organic contaminants.

(a) RMCLs are zero for the following contaminants:

(1) Benzene
(2) Vinyl chloride
(3) Carbon tetrachloride
(4) 1,2-dichloroethane
(5) Trichloroethylene

(b) RMCLs for the following contaminants are as indicated:

Contaminant	RMCL in mg/l
(1) 1,1-dichloroethylene	0.007
(2) 1,1,1-trichloroethane	0.20
(3) p-dichlorobenzene	0.75

§141.51 [Reserved]

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