provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

X. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

EPA is committed to addressing environmental justice concerns and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income bears disproportionately high and adverse human health and environmental impacts as a result of EPA's policies, programs, and activities, and that all people live in clean and sustainable communities. In response to Executive Order 12898 and to concerns voiced by many groups outside the Agency, EPA's Office of Solid Waste and Emergency Response formed an Environmental Justice Task Force to analyze the array of environmental justice issues specific to waste programs and to develop an overall strategy to identify and address these issues (OSWER Directive No. 9200.3–17).

Today's rule delays the compliance date of new or more stringent requirements and will not result in any disproportionately negative impacts on minority or low-income communities relative to affluent or non-minority communities.

XI. Congressional Review

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability, applying only to a specific waste type at two facilities under particular (and, as noted, exceptional) circumstances.

A major rule cannot take effect until 60 days after it is published in the **Federal Register**. The direct final rule is not a ''major rule'' as defined by 5 U.S.C. 804 (2). This rule is effective on February 17, 2006.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 12, 2005.

Stephen L. Johnson,

Administrator.

■ For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 63—NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 63.1206 is amended by revising paragraphs (a)(1)(i)(A) and (a)(1)(i)(B)(*1*) to read as follows:

§ 63.1206 When and how must you comply with the standards and operating requirements?

(a) * * * (1) * * * (i) * * * (A) *Compliance dates for existing sources.* You must comply with the emission standards under §§ 6312.03, 63.1204, and 63.1205 and the other requirements of this subpart no later than the compliance date, September 30, 2003, unless the Administrator grants you an extension of time under § 63.6(i) or § 63.1213, except:

(*1*) Cement kilns are exempt from the bag leak detection system requirements under paragraph (c)(8) of this section;

(*2*) The bag leak detection system required under § 63.1206(c)(8) must be capable of continuously detecting and recording particulate matter emissions at concentrations of 1.0 milligram per actual cubic meter unless you demonstrate under § 63.1209(g)(1) that a higher detection limit would adequately detect bag leaks, in lieu of the requirement for the higher detection limit under paragraph (c)(8)(ii)(A) of this section; and

(*3*) The excessive exceedances notification requirements for bag leak detection systems under paragraph (c)(8)(iv) of this section are waived.

(B) * * * (*1*) If you commenced construction or reconstruction of your hazardous waste combustor after April 19, 1996, you must comply with the emission standards under §§ 63.1203, 63.1204, and 63.1205 and the other requirements of this subpart by the later of September 30, 1999 or the date the source starts operations, except as provided by paragraphs (a)(1)(i)(A)(*1*) through (*3*) and (a)(1)(i)(B)(*2*) of this section. The costs of retrofitting and replacement of equipment that is installed specifically to comply with this subpart, between April 19, 1996 and a source's compliance date, are not considered to be reconstruction costs.

* * * * *

[FR Doc. 05–24198 Filed 12–16–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[OAR–2003–0028, FRL–8009–5]

RIN: 2060–AI72

List of Hazardous Air Pollutants, Petition Process, Lesser Quantity Designations, Source Category List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the list of hazardous air pollutants (HAP) contained in section 112 of the Clean Air Act (CAA) by removing the compound methyl ethyl ketone (MEK) (2-Butanone) (CAS No. 78–93–3). This action is being taken in response to a petition submitted by the Ketones Panel of the American Chemistry Council (formerly the Chemical Manufacturers Association) on behalf of MEK producers and consumers to delete MEK from the HAP list. Petitions to remove a substance from the HAP list are permitted under section 112 of the CAA.

Based on the available information concerning the potential hazards of and projected exposures to MEK, EPA has made a determination pursuant to CAA section 112(b)(3)(C) that there are ''adequate data on the health and environmental effects [of MEK] to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.''

EFFECTIVE DATE: December 19, 2005.

ADDRESSES: EPA has established a docket for this action under Docket ID No. OAR–2003–0028 and A–99–03. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at EPA Docket Center (Air Docket), EPA/DC, EPA West, Room B–108, 1301 Constitution Avenue, NW., Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Morris, Office of Air Quality Planning and Standards, Emission Standards Division, C404–01, Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–5416; fax number: 919–541–0840; e-mail address: *morris.mark@epa.gov.*

SUPPLEMENTARY INFORMATION:

Regulated Entities. Entities potentially affected by this action are those industrial facilities that manufacture or use MEK. This action amends the HAP list contained in section 112(b)(1) of the CAA by removing the compound MEK. The decision to issue a final rule to delist MEK removes MEK from regulatory consideration under section 112(d) of the CAA.

Judicial Review. Under section 307(b)(1) of the CAA, judicial review is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by 60 days from publication in the **Federal Register**. Under section 307(d)(7)(B) of the CAA, only an objection to a rule or procedure raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by the final rule may not be challenged separately in any civil or criminal proceeding brought to enforce these requirements.

Outline. The information presented in this preamble is organized as follows:

I. Introduction
A. The Delisting Process
B. The Present Petition and Rulemaking
II. Completion of Final Inhalation Reference Concentration
III. Acute Effects From Exposure to MEK
IV. Voluntary Children's Chemical Evaluation Program Peer Review
V. Adverse Comments and EPA Responses
VI. Final Rule
A. Rationale for Action
B. Effective Date
VII. References
VIII. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Analysis
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act
J. Congressional Review Act

I. Introduction

A. The Delisting Process

Section 112 of the CAA contains a mandate for EPA to evaluate and control emissions of HAP. Section 112(b)(1) includes an initial HAP list that is composed of specific chemical compounds and compound classes to be used by EPA to identify source categories for which EPA will subsequently promulgate emissions standards.

CAA section 112(b)(2) requires EPA to make periodic revisions to the initial HAP list set forth in CAA section 112(b)(1) and outlines criteria to be applied in deciding whether to add or delete particular substances. Section 112(b)(2) identifies pollutants that should be listed as:

> * * * pollutants which present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise. * * *

To assist EPA in making judgments about whether a pollutant causes an adverse environmental effect, CAA section 112(a)(7) defines an ''adverse environmental effect'' as:

> * * * any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.

Section 112(b)(3) establishes general requirements for petitioning EPA to modify the HAP list by adding or deleting a substance. Although the Administrator may add or delete a substance on his own initiative, in the case where a party petitions the Agency to add or delete a substance, the burden has historically been on the petitioner to include sufficient information to support the requested addition or deletion under the substantive criteria set forth in CAA section 112(b)(3)(B) and (C). The Administrator must either grant or deny a petition within 18 months of receipt of a complete petition. If the Administrator decides to grant a petition, EPA publishes a written explanation of the Administrator's decision, along with a proposed rule to add or delete the substance. If the Administrator decides to deny the petition, EPA publishes a written explanation of the basis for denial. A decision to deny a petition is final Agency action subject to review in the DC Circuit Court of Appeals under CAA section 307(b).

To promulgate a final rule deleting a substance from the HAP list, CAA section 112(b)(3)(C) provides that the Administrator must determine that:

> * * * there is adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.

EPA will grant a petition to delete a substance and publish a proposed rule to delete that substance if it makes an initial determination that this criterion has been met. After affording an opportunity for comment and for a hearing, EPA will make a final determination whether the criterion has been met.

EPA does not interpret CAA section 112(b)(3)(C) to require absolute certainty that a pollutant will not cause adverse effects on human health or the environment before it may be deleted from the list. The use of the terms ''adequate'' and ''reasonably'' indicate that EPA must weigh the potential uncertainties and their likely significance. Uncertainties concerning the risk of adverse health or environmental effects may be mitigated if EPA can determine that projected exposures are sufficiently low to provide reasonable assurance that such adverse effects will not occur. Similarly, uncertainties concerning the magnitude

of projected exposure may be mitigated if EPA can determine that the levels that might cause adverse health or environmental effects are sufficiently high to provide reasonable assurance that exposures will not reach harmful levels. However, the burden remains on a petitioner to resolve any critical uncertainties associated with missing information. EPA will not grant a petition to delete a substance if there are major uncertainties that need to be addressed before EPA would have sufficient information to make the requisite determination.

B. The Petition and Rulemaking

On November 27, 1996, the American Chemistry Council's Ketones Panel submitted a petition to delete MEK (CAS No. 78–93–3) from the HAP list in CAA section 112(b)(1). Following the receipt of the petition, EPA conducted a preliminary evaluation to determine whether the petition was complete according to EPA criteria (58 FR 45081). To be deemed complete, a petition must consider all available health and environmental effects data. A petition must also provide comprehensive emissions data, including peak and annual average emissions for each source or for a representative selection of sources, and must estimate the resulting exposures of people living in the vicinity of the sources. In addition, a petition must address the environmental impacts associated with emissions to the ambient air and impacts associated with the subsequent cross-media transport of those emissions.

EPA published a notice of receipt of a complete petition to delist MEK in the **Federal Register** on June 23, 1999 (64 FR 33453), and requested information to assist us in technically reviewing the petition in addition to other comments. In response to the request for comment, EPA received ten submissions that included information to aid in the technical review of the petition.

Based on a comprehensive review of the data provided in the petition and from other sources, EPA made an initial determination that the statutory criterion for deletion of MEK from the HAP list had been met. EPA, therefore, granted the petition by the American Chemistry Council's Ketones Panel and issued a proposed rule to delist MEK on May 30, 2003 (68 FR 32608). EPA responded to substantive comments on the notice of receipt of a complete petition in the preamble to the proposed rule. The delay between receiving a complete petition and publishing the proposal to delist was due, in part, to the time it took to reevaluate and update the human health toxicity value for MEK.

EPA received a total of 57 comments on the proposed rule and responds to the substantive comments below. There was no request for a public hearing.

II. Completion of the 2003 Inhalation Reference Concentration

In the preamble to the proposed rule, EPA stated that it would not make the final decision whether to delist MEK until it considered the inhalation reference concentration (RfC) resulting from an updated Integrated Risk Information System (IRIS) review. This review was completed in 2003. The MEK RfC is a peer-reviewed value defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

The 2003 RfC was not yet finalized when EPA received the petition. However, to support statutory requirements and assist in the determination of the technical merits of the petition to delist MEK, EPA's Office of Research and Development derived an interim health effects threshold for MEK inhalation exposure that considered current data and current EPA science policy. That process resulted in the derivation of a prospective RfC of 9 milligrams per cubic meter (mg/m^3). The analysis underlying the development of the prospective RfC can be found in ''A Prospective Reference Concentration for MEK (78–93–3),'' which is in the docket. In the preamble to the proposed rule, EPA stated that while it would base its initial determination to delist MEK on the prospective RfC, it would rely on the RfC and other information resulting from the completed IRIS assessment in making its determination whether to delist MEK.

The 2003 RfC was published in IRIS on September 26, 2003. Where the prospective RfC was 9 mg/m^3, the 2003 RfC is slightly lower at 5 mg/m^3 because of a difference in dose-response methodology and interpretation of remaining uncertainties. To evaluate the potential impact of the 2003 RfC on the decision to delist, EPA recalculated the inhalation hazard quotient (HQ) using the 2003 RfC and the estimate of maximum exposure cited in the proposed rule. Whereas the HQ calculated in the proposed rule was 0.1, the new HQ is 0.2, or 20 percent of the RfC. EPA still finds the recalculated HQ to be below a level of concern. Thus, the 2003 RfC did not change the scientific basis of EPA's determination that emissions, ambient concentrations, bioaccumulation, or deposition of MEK may not reasonably be anticipated to cause adverse human health or environmental effects.

III. Acute Effects From Exposure to MEK

In the preamble to the proposed rule, EPA addressed acute exposure from MEK using the Dick *et al.* (1992) study (Dick study), which assessed neurotoxic effects. EPA concluded that the Dick study indicated that exposures to MEK of up to 200 parts per million (ppm) (590 mg/m^3) for up to 4 hours would be an appropriate no-adverse-effect concentration for the general population for both subjective effects (such as objectionable odor or irritancy) and for neurobehavioral effects.

EPA used the Dick study to examine the potential effects of short-term exposure to MEK because no short-term human health values have been finalized for MEK. The Dick study is the best study in the MEK database with which to assess short-term effects of MEK exposure.

During public comment, EPA did not receive any negative comment on our interpretation of the Dick study. EPA did, however, receive a request to address the potential for developmental effects as a result of short-term exposure because the RfC that EPA used to assess long-term exposure to MEK was based on a developmental endpoint.

EPA agrees that this is appropriate to do since the Agency, thus far, has not finalized an acute reference exposure methodology. EPA is in the process of developing this methodology and sought the Science Advisory Board's (SAB) review of the draft methodology in 1998 (The SAB report is available at: *http://www.epa.gov/sab/pdf/ehc9905.pdf*). Thus, EPA considered several types of analysis. One type of analysis EPA considered was a general approach consistent with that used for the chronic RfC and based on the developmental study that was the basis for the RfC.

The quantitative aspect of EPA's RfC methodology is a two-step approach that distinguishes analysis of the dose-response data from inferences made about lower doses. The first step is an analysis of dose and response in the range of observation of the experimental and/or epidemiologic studies. The modeling or statistical significance testing yields a point of departure (POD) from the range of observation. The second step is extrapolation to lower doses. Thus, the RfC is derived from the POD (in terms of human equivalent

exposure) for the critical effect by consistent application of uncertainty factors (UFs). The UFs are applied to account for recognized uncertainties in the extrapolations from the experimental data conditions to an estimate appropriate to the assumed human scenario (U.S. EPA, 1994).

The POD from the developmental study is a 24-hour human equivalent exposure concentration of 1,517 mg/m^3. In the derivation of the chronic RfC, this POD was divided by a cumulative UF of 300. The cumulative factor comprised three UFs, accounting for uncertainties in interspecies (3) and intraspecies (10) extrapolation, as well as uncertainty in the database with regard to chronic exposures (10). In calculating an acute reference value, the latter would not be relevant, resulting in a cumulative UF of 30. Thus, one analysis of the short-term exposure potential might result in a short-term (24 hour) reference value of 50 mg/m^3 by dividing 1,517 mg/m^3 by a cumulative UF of 30. The petitioner's maximum modeled 24-hour average MEK concentration in air of 10 mg/m3 is lower than this potential short-term reference value by a factor of 5.

An alternate approach is that routinely employed by EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS), which involves consideration of the margin of exposure (MOE) between the POD and the estimated exposure concentration of interest (67 FR 60886). For decision-making purposes, the OPPTS MOE level of concern is the value derived from multiplicative factors representing key outstanding areas of uncertainty with regard to the chemical's toxicity. Given the available data for MEK, which includes an animal study on developmental toxicity, the predominant outstanding areas of uncertainty with regard to short-term toxicity are the potential for interspecies and intraspecies differences in susceptibility. Assigning them each the traditional default value of 10 yields a MOE of 100.[1] Therefore, in evaluating the potential for adverse human health effects to occur from acute exposures to MEK from inhalation, EPA considers adverse effects to be unlikely if the MOE is at least 100.

Using the petition's maximum modeled 24-hour average MEK concentration in air of 10 mg/m^3, and the 24-hour human equivalent exposure concentration at the POD from the study used to develop the RfC of 1,517 mg/m^3, EPA calculates a margin of exposure of 152. Therefore, based on either of the two approaches outlined above, the predicted 24-hour exposures to MEK may not reasonably be anticipated to pose appreciable risk of adverse developmental health effects. This conclusion, when added to the previous conclusions described in the preamble to the proposed rule, further supports our determination that emissions of MEK may not reasonably be anticipated to cause adverse health or environmental effects.

Since proposal, EPA's OPPTS has proposed several Acute Exposure Guideline Levels (AEGLs) for MEK. The AEGLs represent threshold exposure limits for the general public for various degrees of severity of toxic effects, and are applicable to emergency exposure periods ranging from 10 minutes to 8 hours. It is believed that the recommended exposure levels are applicable to the general population including infants and children, and other individuals who may be susceptible.

The AEGL value for the lowest severity level, the AEGL–1, is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure. With increasing airborne concentrations above each AEGL, there is a progressive increase in the likelihood of occurrence and the severity of effects described for each corresponding AEGL. Although the AEGL values represent threshold levels for the general public, including susceptible subpopulations, such as infants, children, the elderly, persons with asthma, and those with other illnesses, it is recognized that individuals, subject to unique or idiosyncratic responses, could experience the effects described at concentrations below the corresponding AEGL.

The interim AEGL–1 value for MEK is 200 ppm (for all exposure periods up to 8 hours). This is the same concentration as the no-adverse-effect concentration for the general population derived from the Dick Study, which provides further support for the use of the Dick study for assessing short-term exposures.

IV. Voluntary Children's Chemical Evaluation Program Peer Review

In the preamble to the proposed rule, EPA stated that it would not make the final decision whether to delist MEK until it considered the results of the peer consultation of the industry's tier 1 submission for MEK under the Voluntary Children's Chemical Evaluation Program (VCCEP). The VCCEP is intended to provide information to enable the public to understand the potential health risks to children associated with exposures to certain chemicals. Under the VCCEP, EPA has asked industries that manufacture or import certain chemicals to sponsor these chemicals to develop assessments regarding the potential health effects, exposures, and risks of those chemicals to children (see *http://www.epa.gov/chemrtk/vccep/index.htm*).

EPA received the industry's submission under the VCCEP on December 1, 2003. The peer consultation meeting for MEK was held on February 19, 2004. On April 19, 2004, EPA received the report of the peer consultation. Peer consultation panel members concluded that the MEK database and submission were adequate, and the key areas of hazard, exposure, and risk were sufficient to characterize risks to children for the purposes of the VCCEP. None of the panelists thought that further data or analyses were needed to characterize MEK's risks to children for the purposes of the VCCEP. Subsequent to completion of the final meeting report, EPA requested additional MEK exposure information from the industry sponsors. This information was provided to EPA on January 12, 2005 (see *http://www.tera.org/peer/vccep/MEK/MEKwelcome.html*).

The only substantive issue raised by the peer consultation that is relevant to the final rule pertains to acute exposures to MEK. To characterize potential impacts from short-term exposures to MEK, the VCCEP submission took much the same approach that EPA took in the proposed rule. That is, they estimated maximum short-term exposures and compared them to a short-term health value that was based on irritation. Like the public commenter, the VCCEP peer consultation panel requested that the sponsor compare the short-term exposures to a developmental endpoint because the RfC was based on a developmental endpoint.

The sponsors proposed one of the approaches EPA considered above, the approach based on the RfC. The sponsors proposed to begin with the 2003 RfC of 5 mg/m^3, then remove the 10-fold database uncertainty factor. This results in a 24-hour value of 50 mg/m^3. The reason given for the removal of the

[1] Note that the value of 10 that EPA assigned here for interspecies variability is greater than the value of 3 that EPA assigned in developing the RfC for MEK. This adds another layer of conservatism to our evaluation of the potential for MEK to cause acute effects.

uncertainty factor is that it was applied to the RfC to account for the lack of chronic studies. Since considering chronic studies is not relevant to the development of a short-term health value, there is no need for the 10-fold database uncertainty factor. EPA agrees with the approach submitted to the VCCEP and, as described above, EPA considered this approach as well as other methods.

V. Adverse Comments and EPA Responses

Of the 57 written comments EPA received pertaining to the proposed delisting of MEK, 42 supported the proposal to delist, 13 opposed the proposal to delist and 2 comments neither supported nor opposed the proposal. EPA received comments on the development of the RfC used in the decision and on the exposure assessment.

EPA has considered carefully all the comments, focusing in particular on comments which suggested potential deficiencies in the substantive rationale upon which EPA based its initial determination that the criterion in CAA section 112(b)(3)(C) had been met. A summary of the comments and EPA responses has been included in the docket. In this preamble, EPA will discuss adverse comments received and our responses to them.

The proposed rule invited comment from interested parties on the proposal to delist MEK. In addition, EPA specifically requested comments on our prospective RfC for MEK (the interim health value EPA developed for the proposal). EPA also solicited comment on the portion of our human health risk characterization based on this prospective RfC. In addition, EPA requested comment on whether it would be appropriate to delist MEK if the RfC resulting from an updated IRIS review differed from the prospective RfC; for example, EPA requested comment on the appropriateness of delisting if the RfC were 3 mg/m^3, the level suggested by industry in its petition, or if it remained unchanged from the 1992 RfC of 1 mg/m^3.

Comment: One commenter asserted that the 1992 RfC of 1 mg/m^3 was set to protect against birth defects and it should not be changed. Another commenter stated that the 2003 RfC (external review draft), which was based on the same study from 1991, does not adequately provide an estimate ''likely to be without an appreciable risk of deleterious effects during a lifetime.''

Response: The RfC is designed to consider all adverse noncancer effects associated with lifetime exposure to a chemical. The 2003 RfC is also based on developmental effects, and is based on the methodologies that were in place at the time of derivation, including (1) the methods for the use of inhalation dosimetry to extrapolate from animal to human exposures (U.S. EPA, 1994) and (2) benchmark dose methods (U.S. EPA, 2000, external review draft). Those methods have been subject to peer review.

Comment: One commenter asserted that the toxicological database is not complete regarding developmental effects, and stated that there is inadequate evidence to assess the carcinogenic potential of MEK (i.e., there are no 2-year animal cancer bioassays).

Response: There are adequate data on developmental effects and on cancer effects to support a decision to delist MEK. The principal study (Schwetz *et al.*, 1991), a developmental toxicity study in the mouse, is well-designed and tests several exposure concentrations over a reasonable range that include maximum tolerated doses for dams and fetuses. Also, animal studies in a second species (rats) corroborate the effect level for developmental toxicity (Deacon *et al.*, 1981; Schwetz *et al.*, 1974).

Regarding carcinogenicity, the current IRIS file (completed in September of 2003) states that the data for MEK are characterized as ''inadequate for an assessment of human carcinogenic potential.'' The ''Toxicological Review of Methyl Ethyl Ketone'' (U.S. EPA, 2003) (Toxicological Review of MEK), upon which the IRIS file is based states, ''Under EPA's draft revised cancer guidelines (U.S. EPA, 1999), data are inadequate for an assessment of human carcinogenic potential for MEK because studies of humans chronically exposed to MEK are inconclusive, and MEK has not been tested for carcinogenicity in animals by the oral or inhalation routes.'' Recent revision of these guidelines does not materially affect this conclusion.

The traditional 2-year animal cancer study has not been conducted for MEK, nor is EPA aware of any organization planning to conduct one. EPA believes one reason no cancer assay has been done is that the results from the majority of the genotoxicity tests (which are often used as an indicator of the need to pursue a 2-year cancer study) are negative, indicating that MEK is a low priority for further study. In 1997, the Organization for Economic Cooperation and Development (OECD) reached this conclusion. OECD's report states that ''MEK is not genotoxic and is not likely to be carcinogenic.'' (OECD, 1997). The report also states that MEK is ''* * * currently of low priority for further work.'' (OECD, 1997).

The general descriptors recommended by EPA's ''Guidelines for Carcinogen Risk Assessment'' (U.S. EPA, 1999) for characterizing the weight of evidence with regard to a chemical's potential for human carcinogenicity did not explicitly recognize this situation. The descriptor applied to MEK in the 2003 IRIS assessment (i.e., ''data are inadequate for an assessment of human carcinogenic potential'') pertains to cases where ''* * * there is a lack of pertinent or useful data.'' (U.S. EPA, 1999). While lacking data or studies that would clearly support their placement in other categories (e.g., the traditional 2-year rodent study), chemicals included within this broad category may, however, have pertinent or useful data which do not indicate any potential for carcinogenicity, consequently providing no support for the performance of the traditional, resource-intensive studies.

Accordingly, EPA's Toxicological Review of MEK also states, ''the majority of short-term genotoxicity testing of MEK has demonstrated no activity, and the Structure Activity Relationship (SAR) analysis suggests that MEK is unlikely to be carcinogenic.'' (U.S. EPA, 2003). One study (Woo *et al.*, 2002) has given MEK and other unsubstituted mono-ketones (a compound class to which MEK belongs) a low concern rating (unlikely to be of cancer concern) because these chemicals lack electrophilic activity (*i.e.,* a structural alert of carcinogenicity) and are generally not associated with carcinogenicity.

There is an absence of positive results in the majority of mutagenicity and genotoxicity tests which are designed to indicate the potential for carcinogenicity. Methyl ethyl ketone has been tested for activity in an extensive spectrum of *in vitro* and *in vivo* genotoxicity assays and has shown no evidence of genotoxicity in most conventional assays (National Toxicology Program, no date; World Health Organization 1992; Zeiger *et al.*, 1992). Methyl ethyl ketone tested negative in bacterial assays (both the *S. typhimurium* (Ames) assay, with and without metabolic activation, and *E. coli*), the unscheduled deoxyribonucleic acid (DNA) synthesis assay, the assay for sister chromatid exchange (SCE) in Chinese hamster ovary (CHO) cells, the mouse lymphoma assay, the assay for chromosome aberrations in CHO cells, and the micronucleus assay in the mouse and hamster. The only evidence of mutagenicity was mitotic

chromosome loss at high concentrations in a study of aneuploidy in yeast *S. cerevisiae* (Zimmerman *et al.*, 1985), but the relevance of this finding to humans is questionable. Overall, studies of MEK yield little or no evidence of genotoxicity.

However, the finding of low potential for genotoxicity alone is not the sole criterion for an assessment of carcinogenic potential, as non-genotoxic mechanisms can also result in carcinogenesis. While developing the final rule, EPA learned that preliminary results of a recent cancer bioassay by the National Toxicology Program suggested that methyl isobutyl ketone (MIBK) appears to be a weak or marginally active carcinogen in rats and mice, possibly by a nongenotoxic mode of action. Both MEK and MIBK are small molecular weight alkyl ketones, and this similarity raised some questions regarding the possible relevance of the preliminary MIBK results to MEK. To investigate this further, EPA undertook SAR analysis of MIBK and MEK. These two ketones have a key difference in their chemical structure: MIBK is branched, while MEK is linear. EPA's SAR analysis indicates that MIBK's toxicity and possible carcinogenicity are likely due to its branched alkyl structure. Methyl ethyl ketone, like acetone, is linear and lacks this structure. Thus, the analysis concluded that in analogy to acetone and its metabolite isopropanol (which has shown no evidence of carcinogenicity), MEK and its metabolite (2-butanol) are linear and, therefore, have low concern for carcinogenicity potential. A short document describing the analysis, ''Acetone, MEK, and MIBK—SAR Analysis on Carcinogenicity/Toxicity,'' is included in the docket. Subsequently, EPA conducted an external peer review of this document. All three reviewers found the reasoning to be sound and supported the conclusions of the analysis. These reviews are also included in the docket. Thus, EPA concludes that the available scientific evidence shows a low potential for carcinogenicity in MEK.

Comment: One commenter suggested that the UFs for the prospective RfC were not adequate. The commenter disagreed with the reduction of the interspecies UF and stated that it should have remained at 10 because there are no developmental and reproductive studies available for humans and animals. Another commenter suggested that the human equivalent concentration (HEC) resulted in low confidence because it was based on the same mouse study (1991) as the 1992 RfC, and the prospective RfC was not robust enough to warrant decreasing the interspecies UF from 10 to 3. This commenter also asserted that the chronic and reproductive studies are still missing and, therefore, EPA's proposal of reducing the database UF is not valid. The commenter contended that the lack of current information results in continued low confidence in the database because the data used are from the original studies used to develop the 1992 RfC. The commenter believes that the Dick study did not provide adequate statistical power. Consequently, the commenter believes that the lack of toxicity was not demonstrated, and that the modifying factor should be maintained at 3. The commenter concluded that the ''absence of data should not conclude an absence of toxicity.''

Response: An interspecies UF of 3 was applied in deriving both the prospective RfC and the 2003 RfC, consistent with EPA guidance for deriving RfCs in effect at the time (U.S. EPA, 1994). The UF for interspecies extrapolation is not intended to address database deficiencies. A database UF of 10 was used in developing the 2003 RfC to account for the lack of a chronic inhalation toxicity study and multigeneration reproductive toxicity study.

Modifying factors have been used in the past in RfC derivations, where the magnitude of the factor reflected the scientific uncertainties of the study and database that were not explicitly treated with standard uncertainty factors. For the 2003 RfC, the default modifying factor of one was used because EPA concluded that the modifying factor was sufficiently subsumed in the general database UF.

Comment: The petitioner stated that EPA did not present adequate scientific justification for applying a duration adjustment to the inhalation developmental toxicity study and, at the very least, the additional conservatism added by the application of this factor should be explicitly recognized. The commenter pointed to the draft Toxicological Review that indicated that MEK was rapidly absorbed, distributed, and metabolized, suggesting that the duration adjustment may be inappropriate.

Response: Duration adjustment of the exposure concentrations in the developmental study of MEK (Schwetz *et al.*, 1991) was performed consistent with the EPA Risk Assessment Forum RfD/RfC Technical Panel report, ''A Review of the Reference Dose and Reference Concentration Processes'' (U.S. EPA, 2002). The report recommends that procedures for adjusting to continuous exposure based on the product of concentration and time be used as a default for inhalation developmental toxicity studies as it is for other health effects from inhalation exposure. While the recommendation is based on evidence that shows that some agents cause developmental toxicity more as a function of peak concentration, the effects of other agents are related to area-under-the-curve (AUC). The latter is true even of some developmental toxicants with a short half-life. In the absence of data that support peak concentration or AUC as more closely correlated with developmental toxicity, EPA's 2002 review document recommends duration adjustment as the more health-protective default procedure. As noted in the Toxicological Review of MEK, because the data are insufficient to argue convincingly for either peak exposure level or AUC as the most appropriate metric, the more health-protective procedure (duration adjustment) was applied as a policy matter.

Comment: The petitioner commented on our interpretation of the Cavender *et al.* (1983) study. They stated that EPA regarded 5,000 ppm in a 90-day inhalation study as the Lowest Observed Adverse Effect Level (LOAEL) based on reduced weight gain, increased liver weight, and decreased brain weight. The commenter stated that this was inconsistent with the 1992 IRIS database where EPA indicated that a change in liver weight may not be conclusively caused by MEK inhalation. The petitioner recommended that 5,000 ppm be the No Observed Adverse Effect Level (NOAEL).

Response: In the 2003 IRIS assessment, EPA gave further consideration to the biological significance of the findings in the 5,000 ppm animals in the Cavender *et al.* (1983) study, specifically the organ weight findings. Although the decrease in brain weight in female high-dose animals is of some concern, EPA agrees that this effect, in the absence of corresponding histopathology and functional abnormalities, cannot be clearly characterized as being of toxicological relevance. In light of these uncertainties, characterization of the effects associated with the 5,000 ppm exposure level as adverse, use of that level as a LOAEL, and the use of mid-dose group (2,518 ppm) as a NOAEL were dropped.

Comment: Three commenters suggested that the actual emissions of MEK may result in environmental concentrations below the RfC, but allowable emissions would not. This

means that should the emissions reach allowable limits, then the concentrations of MEK will be above the RfC. One commenter provided an example of a facility that emits 500 tons per year (tpy) of MEK but is permitted to emit up to 2,200 tpy. The commenter states that a simple screening model run (most likely similar to the tier 1 or tier 2 analysis submitted by the petitioner) of this facility at the allowable emission rate predicts 24-hour peak concentrations to be about 75 mg/m^3, which is above the maximum predicted 24-hour average concentration of 10 mg/m3 that EPA cited in the preamble.

Response: The maximum offsite 24-hr MEK concentration for the worst-case facility in the petition as predicted by the Industrial Source Complex Short Term 3 (ISCST3) model was 10 mg/m^3. The maximum annual concentration was 1.2 mg/m^3. This facility emits about 500 tpy MEK. The maximum offsite concentration occurs within a few hundred meters of the facility.

The commenters provided limited information on the facility that has the potential to emit 2,200 tpy. EPA contacted the commenter in order to understand how they estimated the value of 75 mg/m^3. EPA was told that the SCREEN3 model was used to estimate this concentration. However, EPA was unable to obtain the modeling runs which would contain important model input data (e.g., stack heights and distances from stacks to fence lines). From the comment, EPA does know that the maximum offsite concentration for this facility as predicted by the SCREEN3 model was 75 mg/m^3 for a 24-hr average and 1.1 mg/m^3 for an annual average. If this facility were modeled with a more refined dispersion model, such as the ISCST3 model, EPA would expect impacts that are considerably lower than those predicted with the more conservative SCREEN3 model. Most likely, the maximum offsite concentration for the facility would be much closer to 10 mg/m^3 for a 24-hr average near the facility, and well below 1 mg/m^3 for the annual average. EPA would suspect that the facility to which the commenter refers has much better dispersion characteristics than the petitioner's worst-case facility, which had a very low stack and nearby fenceline.

Comment: Three commenters stated that EPA failed to meet the CAA deadline (18 months) for adding or deleting a substance from the HAP list, instead taking 78 months total. Therefore, the commenters believed the 1994 Toxic Release Inventory (TRI) data used in the assessment were not appropriate and that current TRI data should have been used. These commenters also contended that the calculations in the petition did not consider potential increases in MEK use once MEK is delisted, and that EPA should base its decision to delist MEK on emission levels and locations expected after delisting.

Response: EPA interprets the CAA to require consideration of current emissions. It is not appropriate to make a decision on what can only be speculative emissions. EPA states in the final rule to delist caprolactam (61 FR 30816, June 18, 1996) that ''EPA does not interpret section 112(b)(3)(C) to require consideration of hypothetical emissions from facilities that might be constructed in the future. The logical consequence of such an expansive construction would be that no substance could ever be delisted, due to the hypothetical possibility of some future facility that has uncontrolled emissions large enough to cause adverse effects. In the event some future facility has uncontrolled caprolactam emissions great enough to change the conclusion of the current EPA risk assessment, EPA can revisit its decision to delist caprolactam at that time.'' It is not the case, however, that EPA can never take potential increases in emissions into account. For example, such consideration is appropriate where EPA has information regarding specific facilities, such as the information it considered in denying the methanol delisting petition (66 FR 21929, May 2, 2001).

Using similar logic in this case, EPA does not interpret CAA section 112 (b)(3)(C) to require consideration of hypothetical emissions from facilities that might be constructed in the future, nor projections of increases in emissions from existing facilities.

There are several reasons why EPA does not expect that increases in emissions of MEK will cause health or environmental concerns. With regard to increased emissions themselves, EPA believes that such increases will be limited by good housekeeping practices which are designed to save product. Methyl ethyl ketone is an effective solvent, but one that evaporates readily. Employing techniques to prevent wasting the product also results in decreased emissions.

Due to the health-protective nature of the analysis upon which the decision to delist is based, EPA concludes that the potential risks from outdoor exposures to MEK are overestimated. It is unlikely that future emissions increases will result in unacceptable risk. For example, the petitioner based the risk assessment on 1994 TRI total air emissions of MEK, which were 628 tpy for the worst-case facility. This facility's modeled annual average concentration is only 20 percent of the RfC. This facility could increase emissions significantly before the concentration would be above a level of concern. The highest-emitting facility in the 2003 TRI emits 638 tpy of MEK, only slightly higher than the 1994 TRI emissions for the worst-case facility.

In addition, the national trend in MEK emissions is distinctly downward. Comparing the 1994 and 2003 TRI MEK air emissions data for the 100 highest-emitting facilities indicates that emissions have decreased by approximately 20 percent during that nine year period.

The risk assessment was based on a maximum off-site concentration. The assessment did not consider the amount of time people would be at that location, or other factors that address the amount of exposure faced by actual individuals. Further, this maximum concentration was located at the entrance to a facility in an industrial park. The probability that an individual would live at this location in the future is extremely low.

Given the low hazard presented by the worst-case facility, the health-protective nature of the analysis, and the overall downward trend of MEK emissions over the last several years, EPA believes that emissions of MEK may not reasonably be anticipated to cause adverse human health effects.

The preamble to the proposed rule discussed the March 30, 1998, **Federal Register** notice (63 FR 15195) in which EPA issued a Denial of Petition entitled ''Methyl Ethyl Ketone; Toxic Chemical Release Reporting; Community Right-to-Know.'' The denial was in response to a petition from the Ketones Panel of the Chemical Manufacturers Association (CMA) that requested the deletion of MEK from the list of chemicals reportable under section 313 of the Emergency Planning and Community Right-To-Know Act of 1986 (EPCRA) and section 6607 of the Pollution Prevention Act.

The American Chemistry Council (formerly the Chemical Manufacturers Association) filed suit challenging EPA's decision in the United States District Court for the District of Columbia. Subsequently, the court granted summary judgment in favor of EPA (*American Chemistry Council* v. *Whitman,* 309 F.Supp. 2d 111 (D.D.C. 2004)). On appeal, the Court of Appeals for the District of Columbia Circuit reversed the lower court's decision, vacating the lower court's decision, and directed the district court to issue an order to ''direct EPA to delete MEK from

the TRI'' (406 F.3d 738, 742 (DC Cir. 2005)). The circuit court issued its mandate on June 13, 2005 and, accordingly, on June 30, 2005, EPA issued a final rule (70 FR 37698) revising the EPCRA section 313 list of reportable chemicals in 40 CFR 372.65 to delete MEK.

The deletion of MEK from the EPCRA section 313 list eliminates the main source of data EPA uses to track MEK emissions. However, there are other data sources available to estimate MEK emissions, including market research data on MEK production, import, export, and consumption. Consumption of MEK should provide an adequate surrogate for emissions to determine whether significant increases in emissions are occurring. If data indicate that MEK emissions are increasing significantly, EPA has the option to add MEK back on the HAP list.

Comment: One commenter suggested that the risk was not adequately identified because the industry was not studied comprehensively enough to determine chronic exposure.

Response: In order to determine the risks from emissions of MEK, the petitioner used the 1994 TRI as the basis of an emissions inventory intended to quantify annual emissions of MEK, to identify and locate emissions sources, and to acquire some facility-specific emissions information. The 1994 TRI shows that there are over 2,000 sources with reported emissions of MEK. The petition states that over 85 percent of these facilities (approximately 1,700) emit 25 tpy or less. The petition also states that approximately 800 facilities emit between 10 and 200 tpy, and 27 facilities emit 200 tpy or more. In addition to using the 1994 TRI, the petitioner queried a subset of individual sources to obtain site-specific source, release, and facility information for the purpose of conducting more detailed risk assessments. EPA has determined that this approach to establishing reasonable worst-case exposures to MEK emissions is an adequate basis upon which to base a decision to delist MEK. EPA states in the preamble to the proposed rule that it does not interpret CAA section 112(b)(3)(C) to require absolute certainty that a pollutant will not cause adverse effects on human health or the environment before it may be deleted from the list. The use of the terms ''adequate and ''reasonably'' indicate that EPA must weigh the potential uncertainties and likely significance. In this case, the uncertainty in the predicted exposure levels is biased toward protecting public health. Therefore, EPA concludes that delisting MEK is appropriate.

Comment: Several commenters contended that chronic effects of MEK had not been adequately studied or evaluated, and that the delisting was not supported by new or compelling scientific evidence. One commenter requested that EPA conduct long-term health effects studies. Additionally, the commenters stated that there were no lifetime-chronic studies included, no studies evaluating developmental effects, nor studies concerning reproductive toxicity. Moreover, these commenters asserted, there were no multigenerational studies included, and the evaluation of the carcinogenic potential was not adequate.

Response: EPA's RfC methodology (U.S. EPA, 1994) does not always require a complete database in order to develop an RfC; however, the database must at least meet minimum data requirements. For MEK, ''* * * confidence in the database is medium * * *.'' (U.S. EPA, 2003). ''The subchronic study by Cavender *et al.* (1983) satisfies the minimum inhalation database requirements for derivation of an RfC.'' (U.S. EPA, 2003).

In the case where there are enough quality data with which to set an RfC, but where the database is less than complete, EPA adds a database uncertainty factor to account for the lack of data. For MEK, that factor is 10. EPA acknowledges the lack of a chronic toxicity bioassay and an inhalation multigeneration reproductive toxicity study (an oral multigeneration is available), but notes that contrary to the commenters' statements, the developmental toxicity of MEK has been well studied.

As stated above, the RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Because maximum expected ambient air concentrations are well below the RfC, EPA does not expect adverse noncancer effects to result.

In addition, the health-protective nature of the assessment described above adds to our confidence that no adverse health effects will occur from ambient exposures to MEK.

Comment: One commenter asserted that the appropriate averaging time for assessing the potential for adverse developmental effects to occur is the 24-hour average, not an annual average. The commenter held that evaluating developmental toxicity on a 24-hour basis is supported by EPA guidelines for evaluating developmental risk. This issue was also raised by the VCCEP review panel as they considered the information industry submitted on MEK and children's health.

Response: EPA agrees with the commenter that potential concern for developmental effects from short-term exposures should be addressed, and EPA did so elsewhere in this preamble. With regard to the use of endpoint-specific reference values, EPA's review of the RfD/RfC processes recommended against the use of endpoint-specific reference values, and instead recommended that duration-specific reference values be derived in consideration of the full range of adverse effects.

Comment: A commenter remarked that EPA did not take into account all routes of exposure to MEK and, therefore, did not adequately identify the risk.

Response: MEK is neither bioaccumulative nor persistent. It has a half-life of approximately 9 days. The releases of MEK to air are unlikely to result in elevated concentrations in surface water, ground water, or the food supply. Therefore, the route of exposure EPA is concerned with is direct inhalation of MEK released to the ambient air. For this reason, inhalation was the focus of the analysis. The petitioner also assessed the potential for risks due to ingestion of water contaminated with MEK. In both cases, the risks were below a level of concern.

Comment: One commenter asserted that the risk assessment did not fully address: (1) Other solvents released from stationary and area sources of MEK, (2) actual ambient concentrations near stationary and area sources (only modeled concentrations were used), and (3) the human health effects within the facilities as opposed to fenceline ambient concentrations.

Response: The maximum annual average air concentration resulting from emissions of MEK is not expected to exceed an HQ of 0.2. This value, which is 20 percent of the RfC, is quite low. EPA believes that there is a large enough margin of exposure to preclude a need to address any other emitted HAP that may affect the same target organ as MEK.

The petitioner did not monitor ambient air around actual MEK-emitting facilities. Such an effort would not add to the analysis, or change EPA's conclusion with regard to delisting. This is because the maximum monitored concentration EPA found in the U.S. was over two orders of magnitude below the maximum modeled concentration, and because the modeling conducted was designed to over-estimate ambient concentrations. For example, the model

assumed that individuals are continuously exposed to the maximum modeled concentrations of MEK in air for 70 years, and EPA used the maximum annual average concentration as a surrogate for long-term exposure. Also, the model used 1994 emission rates which are significantly higher than current emissions for the facility with the highest estimated HQ of 0.2. EPA believes that the health-protective air dispersion modeling performed as part of the petition and described in detail in the proposed rule resulted in higher concentrations than would monitoring around facilities.

EPA cannot consider the health effects of emissions within facility boundaries. That is the purview of the Occupational Safety and Health Administration.

Comment: One commenter recommended that a comparative analysis with the 1998 Office of Pollution Prevention and Toxics (OPPT) assessment (located in the docket) be done to fully assess the risks of MEK.

Response: EPA agrees with the comment, and EPA conducted a comparison of the 1998 OPPT assessment and the assessment in the proposal to delist MEK.

The assessment presented in the petition to delist MEK estimated a maximum annual average MEK concentration of 1.2 mg/m^3. It used the ISCST3 model, which is a refined air dispersion model that predicts an annual average by averaging 8,760 hours of real time meteorological data. The ISCST3 model predicted a maximum 24-hour average MEK concentration of 10 mg/m^3.

The 1998 OPPT study estimated maximum 24-hour average concentrations of 100–200 mg/m^3. It used a screening model similar to the SCREEN3 model and predicted 1-hour average concentrations under defined meteorological conditions with the assumption that the receptor is always directly downwind from the source. Such screening model runs typically result in high air concentrations as compared to the ISCST3 model. EPA would expect the difference in concentrations to be as high as a factor of 10. In addition, the OPPT study applied a multiplicative factor to predict typical (5), stagnant (10), and maximum (60) acute impacts. Thus, the difference between the two model results can be attributed to the multiplicative factors and differences between a refined and screening model.

Comment: One commenter recommended that EPA not wait for the formal IRIS review of MEK or the VCCEP results to make a final decision regarding delisting of MEK, as there was enough evidence to delist MEK without the additional information. Another commenter asserted that if the RfC resulting from the completed IRIS assessment is different from the prospective RfC, then the petition should be reconsidered and an additional public comment period should be allowed giving the public an opportunity to comment on EPA's decision. This commenter also stated that the results of the VCCEP should be concluded before the comments on the delisting are due.

Response: Regarding the first comment, EPA waited to make a final decision to delist MEK until the 2003 IRIS RfC was determined and until the information submitted by industry under the VCCEP was reviewed in case the results of each of these processes altered our decision to remove MEK from the HAP list.

Regarding the second comment, EPA considers an additional comment period unnecessary for a number of reasons. First, EPA explicitly solicited comment on the effect of a difference between the prospective RfC and the RfC resulting from the completed IRIS assessment. EPA specifically requested comments on the decision in light of potential values for the RfC of 9 mg/m^3, 3 mg/m^3 and 1 mg/m^3. The 2003 RfC of 5 mg/m^3 is in the middle of the range upon which EPA solicited comment. Second, while the 2003 RfC is lower than the prospective RfC, the result of this change was only to increase the HQ for the maximum annual average ambient exposure from 0.1 to 0.2 (20 percent of the RfC). This HQ is well below a level of concern.

In addition, EPA judges that the exposures to MEK of actual persons living in the immediate vicinity of an MEK emission source would more typically be at least a factor of 2 to 10 less than the predicted maximum ambient concentration presented in the petition of 1 mg/m^3. This is because the concentration of MEK declines very rapidly as the plume disperses, and the analysis showed that people do not live at the point of maximum concentration. Therefore, actual exposed individuals would be subject to MEK concentrations less than 1 mg/m^3. If EPA were to replace the maximum ambient concentration with a more realistic exposure scenario, it would yield an HQ less than 0.2. Based on the current information, and given the conservative nature of the parameters used to estimate the maximum exposure, and because the petition and subsequent analyses characterize the vast majority of MEK exposures from stationary sources, EPA concludes that by applying the RfC of 5 mg/m^3, potential ambient exposures to MEK may not reasonably be anticipated to cause adverse human health effects.

With respect to the results of the VCCEP, EPA found it unnecessary to extend the public comment period until after the review of the industry-submitted information was complete. This is because the industry provided no new information to EPA that was not already available. Therefore, there was no new information upon which to solicit comments.

Comment: Many commenters noted that the interactions with n-hexane and other ketones have not been sufficiently investigated should the MEK emissions increase. These commenters stated that MEK interactions with n-hexane have been shown to increase neurotoxicity of n-hexane.

Response: EPA stated in the preamble to the proposed rule that MEK has been shown to potentiate the neurotoxicity of other solvents in experiments with laboratory animals when both MEK and the other solvent are present in high concentrations. EPA also stated that studies of occupationally-exposed populations (as reviewed by Noraberg and Alien-Soborg, 2000) provide some evidence of possible interactions in humans. EPA reviewed the occupational epidemiology literature in more depth during the development of the 2003 RfC for MEK. These findings are summarized in the Toxicological Review for MEK (*http://www.epa.gov/iris/toxreviews/0071-tr.pdf,* section 4.4.4). Available occupational studies involving multiple chemical exposures do not provide information adequate to clearly establish an interaction between MEK and other neurotoxic solvents in humans. In studies suggesting a potential interaction, neurotoxicity has been observed only in workplace populations exposed to solvent mixtures where reported MEK air concentrations reached levels at or above the Threshold Limit Value (TLV) (200 ppm or 590 mg/m^3). EPA concluded that the concerns for chemical interactions are especially diminished at the low levels seen in this assessment: Less than 1 mg/m^3 for chronic exposures, 10 mg/m^3 for 24-hour exposures and 25 mg/m^3 for a 1-hour exposure. These exposures are all well below the reversible effects level of 590 mg/m^3. Therefore, EPA does not expect possible potentiation of n-hexane by MEK at the low environmental concentrations that would be associated with industrial releases.

Comment: One commenter was concerned that MEK was detected by

the National Health and Nutrition Examination Survey in biomonitoring programs.

Response: EPA acknowledged in the preamble to the proposed rule that MEK has been reported to be found in blood. EPA also stated that the data indicated the source of the MEK is likely a by-product of normal human metabolism, and it is reasonable to expect it did not result from an air exposure to MEK at the concentrations seen in the ambient air.

Comment: One commenter requested that EPA consider the role of MEK as an ozone precursor in deciding the petition.

Response: EPA stated in the preamble to the proposed rule that it was inappropriate to consider the role of MEK as an ozone precursor because the ''dual structure (differentiating between HAP and criteria pollutants/precursors) would lose its significance if EPA were to include substances on the HAP list solely as a result of their contribution to concentrations of criteria air pollutants.'' Specifically, the structure of the CAA is best protected by including compounds on the HAP list only where such inclusion is warranted based upon the HAP noncriteria pollutant related effects. This interpretation is supported by the following prohibition related to listing of new HAP contained in CAA section 112(b)(2): ''No air pollutant which is listed under section 7408(a) of this title [the criteria pollutant list] may be added to the list under this section, except that the prohibition of this sentence shall not apply to any pollutant which independently meets the listing criteria of this paragraph and is a precursor to a pollutant which is listed under section 7408(a) * * *.''

Comment: One commenter stated that decisions to list or delist are governed by the precautionary principle. The commenter stated that, ''in considering whether a petitioner has met the heavy burden of demonstrating that a substance should be removed from the hazardous air pollutant list, the precautionary principle requires that EPA resolve uncertainty in favor of more protection, not less. The recognition of uncertainty in the listing and delisting process does not give EPA discretion to delist a chemical based on incomplete and outdated information as it has proposed to do with MEK.''

Response: EPA does not believe it is appropriate to require that all uncertainty be resolved in favor of not delisting. Such a requirement of absolute certainty is inconsistent with our interpretation of the requirement that to delist a HAP, EPA must determine that there are ''adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation or deposition of the substance may not reasonably be anticipated to cause any adverse effect to human health or adverse environmental effects.'' As explained in denying the petition to delist methanol, EPA does ''not interpret CAA section 112(b)(3)(C) to require absolute certainty that the pollutant will not cause adverse effects on human health * * * before it may be deleted from the list. The use of the terms 'adequate' and 'reasonably' indicate that EPA must weigh the potential uncertainties and their likely significance.'' (See 66 FR 21929–21930, May 2, 2001.) For the reasons explained above, EPA determined that this burden has been met here. Responses with respect to the contention that the database was outdated and/or incomplete are also addressed elsewhere is this preamble.

Comment: One commenter asserted that EPA has not adequately considered the odor problems associated with MEK. The commenter stated that odors can cause neurological problems such as fatigue, dizziness, headache, and nausea resulting in a diminished quality of life. The commenter also stated that odor thresholds for MEK have been reported in the range of 6–250 mg/m^3, and the estimates presented in the proposed rule for a 1-hour maximum concentration near MEK sources is 25 mg/m^3, which is within the range of the reported odor thresholds. The commenter also suggested that EPA recognize that the risk to sensitive individuals could increase after delisting.

Response: While EPA does not expressly consider odor as a health endpoint, EPA considers the physiological effects of chemical exposures, including the neurological effects that the commenter described. In the proposed rule, EPA stated the following, ''The IRIS assessment of MEK states that at present, there is no convincing experimental evidence that MEK is neurotoxic * * * other than possibly inducing CNS (central nervous system) depression at high exposure levels.'' The IRIS documentation shows that no peripheral neurohistopathological changes were reported in rats exposed continuously to 3,320 mg/m^3 of MEK for up to 5 months (Saida *et al.*, 1976). No treatment-related central or peripheral neurohistopathology was observed in rats exposed for 90 days (6 hours/day, 5 days/week) at concentrations of MEK as high as 14,865 mg/m^3, even among animals in animal tissues specifically prepared and examined for neurohistopathology (Cavender *et al.*, 1983). Also, ten of ten rats exposed to MEK at 17,700 mg/m^3 and higher for 8 hours/day, 7 days/week, died in the seventh week of exposure without neurological symptoms or histopathology (Altenkirch *et al.*, 1978).

Regarding sensitive individuals, EPA could not identify any specific data that address the potential differences in susceptibility to adverse effects from MEK exposure. In the MEK Toxicological Review in support of the IRIS assessment, EPA did note that ''The potential exists for increased susceptibility to neurotoxicity, hepatotoxicity, and renal toxicity following exposure to MEK in combination with certain other solvents * * *.'' The potentiating effects of MEK on the toxicity of other solvents have only been demonstrated at relatively high exposure concentrations (200–1,000 ppm or 590–2950 mg/m^3).

Comment: One commenter recommended changing the hazardous waste regulations that apply to MEK as follows: Remove MEK as a listed toxicity characteristic in 40 CFR 261.64; remove MEK as a toxic constituent in part 261, appendix VIII; and remove MEK from the F005 listing, but it may be appropriate to add it to F2003 listing.

Response: EPA was petitioned under CAA section 112(b)(3) to remove MEK from the CAA section 112 HAP list. This is the only action under consideration as part of the final rule.

VI. Final Rule

A. Rationale for Action

The detailed factual rationale for supporting EPA's initial determination that the criterion in CAA section 112(b)(3)(C) had been met is set forth in the proposed rule published in the **Federal Register** on May 30, 2003 (68 FR 32606). Although, as described above, EPA has done some additional analysis pursuant to public comments received on the subsequent action, none of those comments nor EPA analyses have caused EPA to revise the scientific basis upon which that initial determination was predicated. Except as modified or clarified above, EPA hereby incorporates into its rationale for the final rule the substantive assessment of potential hazards, projected exposures, human risk, and environmental effects set forth in the proposed rule to delist MEK. Based on that assessment, EPA's evaluation of the comments and additional information submitted during the rulemaking process (as summarized above), and on other materials, EPA has made a determination that there are

adequate data on the health and environmental effects of MEK to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the compound may not reasonably be anticipated to cause adverse human health or environmental effects.

B. Effective Date

The final rule will be effective on December 19, 2005. Although section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), provides that substantive rules must be published at least 30 days prior to their effective date, this requirement does not apply to this action. First, the final rule was promulgated pursuant to CAA section 307(d), and that provision expressly states that the provisions of section 553 of the Administrative Procedure Act do not apply to this action. Second, even under section 553, the requirement that a rule be published 30 days prior to its effective date does not apply to a rule, ''which grants or recognizes an exemption or relieves a restriction.''

VII. References

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VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is ''significant'' and, therefore, subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adverse affect in a material way the economy, a sector to the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligation of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is, therefore, not subject to OMB review.

B. Paperwork Reduction Act

Today's final action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The final action will remove MEK from the CAA section 112(b)(1) HAP list and, therefore, eliminate the need for information collection under the CAA. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

C. Regulatory Flexibility Act (RFA)

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administrations' regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant *adverse* economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities.'' 5 U.S.C. sections 603 and 604. Thus, an agency may conclude that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

The final rule will eliminate the burden of additional controls necessary to reduce MEK emissions and the associated operating, monitoring and reporting requirements. EPA has, therefore, concluded that today's final rule will relieve regulatory burden for all small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 1044, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for final and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule contains no Federal mandates for State, local, or tribal governments or the private sector. The final rule imposes no enforceable duty on any State, local or tribal governments or the private sector. In any event, EPA has determined that the final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. Because the final rule removes a compound previously labeled in the CAA as a HAP, it actually reduces the burden established under the CAA. Thus, today's final rule is not subject to the requirements of sections 202 and 205 of the UMRA. Since the final rule contains no Federal mandates and imposes no enforceable duties on any entity, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

The final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's final rule removes the substance MEK from the list of HAP contained under section 112(b)(1) of the CAA. It does not impose any additional requirements on the States and does not affect the balance of power between the States and the Federal government. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' The final rule does not have tribal implications, as specified in Executive Order 13175.

A review of the available emission inventory does not indicate tribal MEK emissions sources subject to control under the CAA and, therefore, the final rule is not anticipated to have tribal implications. In addition, the final rule will eliminate control requirements for MEK and, therefore, reduce control costs and reporting requirements for any tribal entity operating a MEK source subject to control under the CAA which EPA might have missed. Thus, Executive Order 13175 does not apply to the final rule.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. The final rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This determination is based on the fact that the RfC is determined to be protective of sensitive sub-populations, including

children. Also, the single study cited during public comment to indicate a potential effect on children has been reviewed during this petition process and found to be limited in design and execution. Consequently, EPA determined that the study was of insufficient quality to provide information regarding health risks (leukemia) of MEK to children. Also, EPA evaluated industry's submission to the first tier of the VCCEP program and has determined that there are no data which specifically indicate that the RfC will not be protective of children.

H. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

The final rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 112(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) 915 U.S.C. 272 note), directs all Federal agencies to use voluntary consensus standards instead of government-unique standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., material specifications, test method, sampling and analytical procedures, business practices, etc.) that are developed or adopted by one or more voluntary consensus standards bodies. Examples of organizations generally regarded as voluntary consensus standards bodies include the American society for Testing and Materials (ASTM), the National Fire Protection Association (NFPA), and the Society of Automotive Engineers (SAE). The NTTAA requires Federal agencies like EPA to provide Congress, through OMB, with explanations when an agency decides not to use available and applicable voluntary consensus standards. The final rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing today's final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). The final rule will be effective on December 19, 2005.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 13, 2005.

Stephen L. Johnson,

Administrator.

■ For the reasons set out in the preamble, part 63, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart C—[Amended]

■ 2. Subpart C is amended by adding § 63.61 to read as follows:

§ 63.61 Deletion of methyl ethyl ketone from the list of hazardous air pollutants.

The substance methyl ethyl ketone (MEK, 2-Butanone) (CAS Number 78–93–3) is deleted from the list of hazardous air pollutants established by 42 U.S.C. 7412(b)(1).

[FR Doc. 05–24200 Filed 12–16–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA–HQ–OPPT–2004–0106; FRL–7743–9]

RIN 2070–AC61

TSCA Inventory Update Reporting Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the Toxic Substances Control Act (TSCA) section 8(a) Inventory Update Reporting (IUR) regulations. The IUR currently requires manufacturers (including importers) of certain chemical substances listed on the TSCA Chemical Substances Inventory to report data on chemical manufacturing, processing, and use every 4 years. In this amendment, EPA is extending the reporting cycle, modifying the timing of the submission period, further clarifying the new partial exemption for specific chemicals for which certain IUR data are of low current interest, amending the petroleum refinery process streams partial exemption, amending the list of consumer and commercial product categories, revising the manner in which production volume would be reported, restricting reporting of processing and use information to domestic processing and use activities only, clarifying the polymer exemption definition, and removing a provision regarding the confidentiality of production volume within specified ranges.

DATES: This final rule is effective on January 18, 2006.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2004–0106. All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will not be placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the OPPT Docket, EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744, and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566–0280.

FOR FURTHER INFORMATION CONTACT: *For general information contact:*

Colby Lintner, Regulatory Coordinator, Environmental Assistance