REPÚBLICA DE CHILE
COMISIÓN NACIONAL DEL MEDIO AMBIENTE
RGR/HVA

DA INICIO A LA REVISIÓN DE LA NORMA DE CALIDAD PRIMARIA PARA MATERIAL PARTICULADO RESPIRABLE (MP 10) D.S. N° 59 DE 1998, DEL MINISTERIO SECRETARÍA GENERAL DE LA PRESIDENCIA.

SANTIAGO, 13 de Enero de 2010.

EXENTA N° 21

VISTOS:

Lo dispuesto en la Ley N°19.300, sobre Bases Generales del Medio Ambiente; en el Decreto Supremo N° 93 de 1995, del Ministerio Secretaría General de la Presidencia que aprueba el Reglamento para la Dictación de Normas de Calidad Ambiental y de Emisión; el D.S. N° 59 de 1998, del Ministerio Secretaría General de la Presidencia, que aprueba la norma de calidad primaria para Material Particulado Respirable (MP 10), modificado por el D.S. N° 45 de 2001, del mismo ministerio; y en la Resolución N° 1600 de 2008, de la Contraloría General de la Presidencia.

CONSIDERANDO:

Que la norma de calidad primaria para material particulado respirable (MP 10) fue establecida por el D.S. 59 de 1998 del Ministerio Secretaría General de la República, y modificada por el D.S. N° 45 de 2001 del mismo ministerio.

Que el artículo 36 del Reglamento para la Dictación de Normas de Calidad Ambiental y de Emisión, dispone que toda norma de calidad ambiental o de emisión debe ser revisada a lo menos cada 5 años.

Que de conformidad con lo preceptuado en el artículo 11° del D.S. N° 93 de 1995, del Ministerio Secretaría General de la Presidencia, corresponde a esta Dirección Ejecutiva dictar la resolución pertinente que permita dar inicio al proceso de revisión de la norma de calidad.

RESUELVO:

1° **Iníciese** el proceso de revisión de norma de calidad primaria para material particulado respirable MP 10 (D.S. 59 de 1998 del Ministerio Secretaría General de la República, modificado por el D.S. N° 45 de 2001 del mismo ministerio)

2° **Fórmese** un expediente para la tramitación del proceso de revisión de la referida norma.

3° **Fíjase** como fecha límite para la recepción de antecedentes sobre los contenidos a revisar respecto de la norma, el día número 70, contado desde la fecha de publicación de la presente resolución en el Diario Oficial y en un diario o

periódico de circulación nacional. Cualquier persona natural o jurídica podrá, dentro del plazo señalado precedentemente, aportar antecedentes técnicos, científicos y sociales sobre la materia.

4° **Publíquese** la presente Resolución en el Diario Oficial y en un diario o periódico de circulación nacional.

Anótese, comuníquese, publíquese y archívese.

COMISION NACIONAL DEL MEDIO AMBIENTE * DIRECTOR EJECUTIVO *

ÁLVARO SAPAG RAJEVIC
DIRECTOR EJECUTIVO
COMISIÓN NACIONAL DEL MEDIO AMBIENTE

CNF/IHC/MJG/DCF

Distribución:
- Departamento de Control de la Contaminación
- Departamento Jurídico
- Oficina de Partes
- Archivo

Lo que transcribo a Ud.
para su conocimiento
saluda atentamente a Ud.
NURY VALBUENA OVEJERO
Oficial de Partes
Comisión Nacional del
Medio Ambiente (CONAMA)

Ministerio Secretaría General de la Presidencia

Comisión Nacional del Medio Ambiente

DA INICIO A LA REVISIÓN DE LA NORMA DE CALIDAD PRIMARIA PARA MATERIAL PARTICULADO RESPIRABLE (MP 10) D.S. Nº 59, DE 1998

(Resolución)

Núm. 21 exento.- Santiago, 13 de enero de 2010.- Vistos: Lo dispuesto en la Ley Nº 19.300, sobre Bases Generales del Medio Ambiente; en el decreto supremo Nº 93 de 1995, del Ministerio Secretaría General de la Presidencia, que aprueba el Reglamento para la Dictación de Normas de Calidad Ambiental y de Emisión; el D.S. Nº 59 de 1998, del Ministerio Secretaría General de la Presidencia, que aprueba la norma de calidad primaria para Material Particulado Respirable (MP 10), modificado por el D.S. Nº 45 de 2001, del mismo Ministerio; y en la resolución Nº 1.600 de 2008, de la Contraloría General de la República.

Considerando:

Que la norma de calidad primaria para material particulado respirable (MP 10) fue establecida por el D.S. 59 de 1998 del Ministerio Secretaría General de la Presidencia, y modificada por el D.S. Nº 45 de 2001 del mismo Ministerio.

Que el artículo 36 del Reglamento para la Dictación de Normas de Calidad Ambiental y de Emisión dispone que toda norma de calidad ambiental o de emisión debe ser revisada a lo menos cada 5 años.

Que de conformidad con lo preceptuado en el artículo 11º del D.S. Nº 93 de 1995, del Ministerio Secretaría General de la Presidencia, corresponde a esta Dirección Ejecutiva dictar la resolución pertinente que permita dar inicio al proceso de revisión de la norma de calidad.

Resuelvo:

1º Iníciese el proceso de revisión de norma de calidad primaria para material particulado respirable MP 10 (D.S. 59 de 1998 del Ministerio Secretaría General de la Presidencia, modificado por el D.S. Nº 45 de 2001 del mismo Ministerio)

2º Fórmese un expediente para la tramitación del proceso de revisión de la referida norma

3º Fíjase como fecha límite para la recepción de antecedentes sobre los contenidos a revisar respecto de la norma, el día número 70, contado desde la fecha de publicación de la presente resolución en el Diario Oficial y en un diario o periódico de circulación nacional. Cualquier persona natural o jurídica podrá, dentro del plazo señalado precedentemente, aportar antecedentes técnicos, científicos y sociales sobre la materia.

4º Publíquese la presente resolución en el Diario Oficial y en un diario o periódico de circulación nacional.

Anótese, comuníquese, publíquese y archívese.- Álvaro Sapoznikow Rajevic, Director Ejecutivo Comisión Nacional del Medio Ambiente.

Lo que transcribo a Ud. para su conocimiento.- Saluda atentamente a Ud., Nury Valbuena Ovejero, Oficial de Partes Comisión Nacional de Medio Ambiente.

PODER JUDICIAL

CONCURSOS

Corte de Apelaciones de Arica.- Llámase a concurso, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Relator de la Corte de Apelaciones de Arica, perteneciente a la Tercera Categoría del Escalafón Primario del Poder Judicial, Grado V de la Escala de Sueldos del Personal Superior, vacante por promoción de don Luis Héctor Jorquera Pinto,

Rol Administrativo Nº 28-2010.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Leopoldo Parra Candia, Secretario(S).

Corte de Apelaciones de Arica, 2º Juzgado de Letras de Arica.- **Llámase** a concurso, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Oficial 4º, perteneciente a la Quinta Categoría del Escalafón de Empleados del Poder Judicial, Grado XIV de la Escala de Sueldos del Personal de Empleados, vacante por promoción de doña Cecilia del Carmen Díaz Reynaga.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Luz María Cortés Gutiérrez, Secretaria (S).

Corte de Apelaciones de Iquique, Juzgado de Letras del Trabajo de Iquique.- **Llámase** a concurso externo, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Auxiliar - Auxiliar Administrativo, pertenecientes a la Séptima Categoría del Escalafón de Empleados del Poder Judicial, Grado XVII de la Escala de Sueldos del Personal de Empleados, vacante por promoción de don Patricio Aquiles Cáceres Alegría.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl** - Administrador de Tribunal.

Corte de Apelaciones de Antofagasta, Juzgado de Garantía de Tocopilla.- Llámase a concurso interno, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Administrativo 1º - Administrativo de Atención de Público, perteneciente a la Cuarta Categoría del Escalafón de Empleados del Poder Judicial, Grado XIII de la Escala de Sueldos del Personal de Empleados, vacante por promoción de doña Noevia Verónica Ponce Paredes.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Administrador de Tribunal.

Corte de Apelaciones de Antofagasta, Juzgado de Familia de Calama.- Llámase a concurso externo, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Administrativo 2º, perteneciente a la Quinta Categoría del Escalafón de Empleados del Poder Judicial, Grado XIV de la Escala de Sueldos del Personal de Empleados, vacante por promoción de doña Mirza Soledad Ligues Fernández.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Administrador de Tribunal.

Corte de Apelaciones de Antofagasta, Juzgado de Letras del Trabajo de Antofagasta.- Llámase a concurso externo, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Auxiliar - Auxiliar Administrativo, perteneciente a la Séptima Categoría del Escalafón de Empleados del Poder Judicial, Grado XVII de la Escala de Sueldos del Personal de Empleados, vacante por promoción de don Víctor Hugo Droguett Villar.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Administrador de Tribunal.

Corte de Apelaciones de Copiapó.- Se recibe concurso, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Relator de la Corte de Apelaciones de Copiapó, perteneciente a la Tercera Categoría del Escalafón Primario del Poder Judicial, Grado V de la Escala de Sueldos del Personal Superior, vacante según Ley Nº 20.322.

Rol Administrativo Nº 141-2009.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Carlos Acevedo Eismann, Secretario.

Corte de Apelaciones de Valparaíso.- Prorróguese llamado a concurso, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Defensor Público de Putaendo, perteneciente a la Tercera Categoría, Primera Serie del Escalafón Secundario del Poder Judicial, vacante por renuncia de don Francisco Díaz Yubero.

Rol Administrativo Nº 667-2009.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Elena Ortega Aranda, Secretaria.

Corte de Apelaciones de Valparaíso.- **Llámase** a concurso, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Notario Público de Valparaíso con asiento en la comuna de Juan Fernández, perteneciente a la Primera Categoría, Segunda Serie, del Escalafón Secundario del Poder Judicial, vacante por promoción de don Francisco Javier Yávar Lozano.

Rol Administrativo Nº 80-2010.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Elena Ortega Aranda, Secretaria.

Corte de Apelaciones de Santiago.- Llámase a concurso, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer los cargos de Tres Jueces Titulares y Dos Jueces Suplentes para la confección del listado de abogados interesados en integrar el Tribunal de Contratación Pública, de conformidad a la ley Nº 19.886.

Los interesados deberán acreditar el cumplimiento de los requisitos exigidos por el artículo 22 de la ley Nº 19.886.

Rol Administrativo Nº 509-2010.

Mayor información disponible en **www.poderjudicial.cl**.- Sergio Mason Reyes, Secretario.

Corte de Apelaciones de Santiago, 1º Juzgado de Letras del Trabajo de Santiago.- Llámase a concurso interno, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Administrativo 1º, perteneciente a la Tercera Categoría del Escalafón de Empleados del Poder Judicial, Grado XII de la Escala de Sueldos del Personal de Empleados, vacante por promoción de doña Mabel Loreto del Carmen Moya Palominos.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

Mayor información disponible en **www.poderjudicial.cl**.- Administrador de Tribunal.

Corte de Apelaciones de Santiago, 3º Juzgado de Familia de Santiago.- Llámase a concurso externo, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Auxiliar - Auxiliar Administrativo, perteneciente a la Séptima Categoría del Escalafón de Empleados del Poder Judicial, Grado XVII de la Escala de Sueldos del Personal de Empleados, vacante por promoción de doña Syndy Andrea Astorga Candia.

Los interesados deben acreditar el cumplimiento de los requisitos legales.

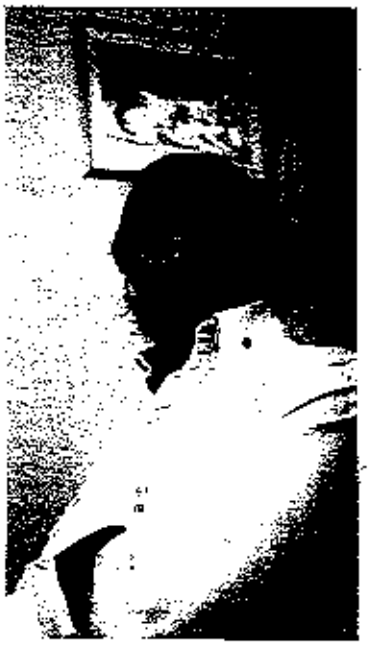
Mayor información disponible en **www.poderjudicial.cl**.- Administrador de Tribunal.

Corte de Apelaciones de San Miguel, 1º Juzgado de Garantía de Santiago.- Llámase a concurso interno, por el término de diez días contados desde la publicación de este aviso en el Diario Oficial, para proveer el cargo de Administrativo 1º - Administrativo de Actas, perteneciente a la Terce-

ASESOR DE IMAGEN

POR ÁNGEL CARCAMO LA

Vida y obra de la marca Zamorano Zamora



La idea de usar a Zamorano y María Alberó como rostros de la marca Zibel de La Polar me pareció extraordinaria. Antes, las estrellas locales del fútbol se vestían en Johnson, usaban zapatos Gino, iban a comer a las parrilladas de La Cuca y seguían casados con sus señoras regordetas de toda la vida. Zamorano rompió con esa práctica. Apenas tomó un avión y salió de Chile se convirtió en un fashionista internacional, una estrella del fútbol como no habíamos visto nunca antes, que impuso entre sus amigos futbolistas la onda del zapato italiano puntudo, los anteojos de marca, la chaquetina Armani y toda esa gama de artilugios por los que los pichangueros profesionales mueren. Sus historias de cama llenaron portadas y, para envidia de muchos, se tiró a las mejores minas del momento (incluso los picados le corrieron el rumor de que era gay). Para seducir a sus guachas, se las llevaba de viaje, les regalaba joyas, ropa, perros finos y hasta autos. Zamorano era un crack, la mismísima Madonna lo rankeó entre los hombres más guapos del planeta y hasta se dio el lujo de levantarse a una auténtica Larraín. Fue notable. Cuando la mujer lo plantó días antes de casarse porque según las lenguas rapaces no habían llegado a un acuerdo económico satisfactorio para ella, todo Chile solidarizó con él. Después del quiebre y la humillación del abandono, Zamorano se retiró del torbellino mediático, se casó con María Alberó, tuvo a Mía Pascale, luego a Ivancito Junior y se instaló comunicacionalmente como un hombre serio, de familia, lejos, muy lejos del huevón y la prensa de farándula. Su peor momento, cuando por hartas lucas se arrendó como rostro del Transantiago y sin quererlo se convirtió en la cara del peor fracaso social de los últimos años. Zamorano como producto perdió su valor, la gente le echó la culpa de todo y para sobrevivir tuvo que refugiarse en la intimidad de su casa en Los Domínicos hasta que ¡¡¡Milagro!!!: la empresa DirecTV, junto a Valderrama y Batistuta, lo relanzó al mercado. El resultado mucho mejor de lo que esperaba. Los chilenos ya le habían perdonado la estafa del Transantiago y nuevamente lo reconocían como una figura imitable. De ahí a rostro de Zibel junto a su mujer, abrazados, mirándose fogosos, vestidos con onda y ultraguapos, demostrándole a los chilenos que sólo les alcanza para La Polar, que el glamour y el éxito está al alcance de todos, que se puede sobrevivir al peor de los fracasos, y que la felicidad está a un Transantiago de distancia... grande Zamorano.

CINEDITAR

POR LIBICS VARAS

Sangre sobre el frágil hielo

Uno sabe que está frente a una buena película, no cuando colman tus expectativas -eso lo hacen las correctas-, si no cuando te arrastran más allá de los prejuicios iniciales y son capaces de dejarte con la boca cerrada. Hemos visto mucho vampiro dando vuelta, "Crepúsculo" y su fábula moralizante terminó por colmar la paciencia sobre las posibilidades del amor entre bestias y humanos. Pero "Criatura de la noche" ("Låt den rätte komma in"), del sueco Tomas Alfredson, viene a refundar ya no tanto el género sino la forma de entender el terror y la naturaleza de estos personajes.

En la cinta, Oskar (Kåre Hedebrant) es un niño retraído que vive en los suburbios de Estocolmo. Hijo de madre soltera, es continuamente molestado por sus compañeros y fantasea con la idea de cobrar venganza. Su ciudad es como cualquier ciudad de hoy: departamentos de vivienda social, sin gente en sus espacios públicos, con las cortinas cerradas y con vecinos que sólo se conocen para las catástrofes. Esa mirada de la convivencia es ya un punto a favor para el director: el terror es más simple y más cotidiano, lo que da miedo, de verdad, es la certeza que cualquier cosa vampiro no es un monstruo, es alguien que tiene otra forma de vida, como si sólo se tratase de un asunto de preferencias gastronómicas. Aparecen mucho más extraños los personajes del pueblo: la madre ausente, un hombre que vive con gatos, una pareja que se trata con indiferencia, compañeros de colegio que no dudan en usar la violencia.

Oskar y Eli son los hijos de ese ambiente, han tenido que buscar sus propios medios de defensa y protección. Por que el espectador se va liberando de esa forma de ver películas a la que estamos tan acostumbrados, y frente a la cual esperamos que todo se resuelva rápido, para bien o para mal.

"Criatura de la noche" es extremadamente consciente sobre el terreno en el que se mueve. Se sabe caminando sobre hielo a punto de romperse. El objetivo es el límite, entender que la naturaleza de las pasiones es de origen desconocido y ciertamente irrefrenable. Ver a Eli con

GOBIERNO DE CHILE

COMISION NACIONAL DEL MEDIO AMBIENTE

DA INICIO A LA REVISIÓN DE LA NORMA DE CALIDAD PRIMARIA PARA MATERIAL PARTICULADO RESPIRABLE (MP 10) D.S. N° 59 DE 1998, DEL MINISTERIO SECRETARÍA GENERAL DE LA PRESIDENCIA

SANTIAGO, 13 de Enero de 2010.

EXENTA N° 21

VISTOS:

Lo dispuesto en la Ley N°19.300, sobre Bases Generales del Medio Ambiente; en el Decreto Supremo N° 93 de 1995, del Ministerio Secretaría General de la Presidencia que aprueba el Reglamento para la Dictación de Normas de Calidad Ambiental y de Emisión; el D.S. N° 59 de 1998, del Ministerio Secretaría General de la Presidencia, que aprueba la norma de calidad primaria para Material Particulado Respirable (MP 10), modificado por el D.S. N° 45 de 2001, del mismo ministerio; y en la Resolución N° 1600 de 2008, de la Contraloría General de la Presidencia.

CONSIDERANDO:

Que la norma de calidad primaria para material particulado respirable (MP 10) fue establecida por el D.S. 59 de 1998 del Ministerio Secretaría General de la República, y modificada por el D.S. N° 45 de 2001 del mismo ministerio.

Que el artículo 35 del Reglamento para la Dictación de Normas de Calidad Ambiental y de Emisión, dispone que toda norma de calidad ambiental o de emisión debe ser revisada a lo menos cada 5 años.

Que de conformidad con lo preceptuado en el artículo 1°.3 del D.S. N° 93 de 1995, del Ministerio Secretaría General de la Presidencia, corresponde a esta Dirección Ejecutiva dictar la resolución pertinente que permita dar inicio al proceso de revisión de la norma de calidad.

RESUELVO:

1° **Iníciese** el proceso de revisión de norma de calidad primaria para material particulado respirable MP 10 (D.S. 59 de 1998 del Ministerio Secretaría General de la República, modificado por el D.S. N° 45 de 2001 del mismo ministerio)

2° **Fórmese** un expediente para la tramitación del proceso de revisión de la referida norma.

3° **Fíjese** como fecha límite para la recepción de antecedentes sobre

000005

División de Política y Regulación Ambiental
Ministerio del Medio Ambiente

MEMORÁNDUM Nº 20 /2010.

De : Sra. Patricia Matus Correa
Jefa División de Política y Regulación Ambiental
Ministerio del Medio Ambiente

A : Sr. Rodrigo Benítez Ureta
Jefe División Jurídica
Ministerio del Medio Ambiente

Mat. : Solicita prórroga para formular anteproyecto de revisión de la Norma de Calidad Primaria para Material Particulado Respirable (MP10).

Fecha : 8 de octubre de 2010

Por medio del presente, solicito a Ud. considerar los siguientes antecedentes, con objeto de prorrogar el plazo de formulación del anteproyecto de la revisión del DS N°59/98 de MINSEGPRES, Norma de Calidad Primaria para Material Particulado Respirable (MP10).

- El proceso se inició formalmente el día 13 de enero de 2010, a través de Resolución Exenta N°21 la que fue publicada el día 26 y 28 de marzo de 2010, en el diario oficial y en el diario la Nación respectivamente.

- Según el art. 11° del DS N°93/95 de MINSEGPRES, Reglamento para la dictación de normas de calidad ambiental y de emisión, la elaboración del anteproyecto tendrá una duración de ciento cincuenta días, es decir hasta el día 29 de octubre del presente.

- Sin embargo, se ha planteado la necesidad de ampliar los plazos para la preparación del anteproyecto, fundado en la necesidad de contar con los resultados del proyecto definitivo de la Norma de Calidad Primaria para Material Particulado de MP2,5, proceso que se encuentra a la espera de ser aprobado por el Consejo de Ministros para la Sustentabilidad.

- Posterior al cumplimiento del punto anterior, se iniciarán las reuniones con el Comité Operativo de la revisión de la Norma de MP10, contando con un proyecto definitivo de Norma de MP2.5 aprobada y que permitirá definir de mejor forma los escenarios regulatorios que se plantearán en la revisión de la Norma de MP10, a partir del año 2012.

- Como parte de los antecedentes, se cuenta con los resultados del Estudio "Elementos para definir una estrategia nacional en la gestión y regulación de los contaminantes MP10 y MP 2.5", desarrollado por la empresa consultora DICTUC S.A año 2010 y los antecedentes técnicos generados en el proceso de elaboración de la Norma de MP2.5 los que debidamente analizados, servirán de sustento para la revisión de la presente normativa.

Por lo anteriormente expuesto, se ha evaluado que el plazo requerido para una prórroga comprende hasta el día **31 de junio de 2011**. Plazo que se estima suficiente para dar término al anteproyecto de la revisión de norma.

Sin otro particular, se despide atentamente,

Patricia Matus Correa
Jefa División de Política y Regulación Ambiental
Ministerio del Medio Ambiente

MPG/DOF/aat

C.c.:

- Archivo División de Política y Regulación Ambiental
- Archivo Departamento de Asuntos Atmosféricos

P. Matus
Res. Ex. Nº 18 000007
2763

GOBIERNO DE CHILE
MINISTERIO DEL MEDIO AMBIENTE

MINISTERIO DEL MEDIO AMBIENTE
DIVISIÓN JURÍDICA

MEMORANDUM DJ Nº 25/2010.-

DE : **RODRIGO BENÍTEZ URETA**
JEFE DEVISIÓN JURÍDICA

A : **PATRICIA MATUS CORREA**
JEFA DIVISIÓN DE POLÍTICA Y REGULACIÓN AMBIENTAL

ANT. : Su Memorándum 20, de 8 de octubre de 2010

MAT. : Pronunciamiento que indica

22 de octubre de 2010

Adjunto remito a Ud. propuesta de Resolución Exenta que AMPLIA PLAZO PARA PREPARACION DE ANTEPROYECTO PARA LA REVISIÓN DE NORMA DE CALIDAD PRIMARIA DE AIRE PARA MATERIAL PARTICULADO RESPIRABLE (MP10), DS Nº 59, DE 1998, MINSEGPRES, que tienen el visto bueno de esta División Jurídica.

Solicito a Ud. dar tramitación a dicho documento.

Sin otro particular, saluda atentamente a Usted,

MINISTERIO DEL MEDIO AMBIENTE
JEFE DIVISION JURIDICA

RODRIGO BENÍTEZ URETA
Jefe División Jurídica
Ministerio del Medio Ambiente

CRF/DAC
c.c.: Archivo División Jurídica

REPÚBLICA DE CHILE
Ministerio del Medio Ambiente
PMC/BEU

000008

AMPLIA PLAZO PARA PREPARACIÓN DE ANTEPROYECTO PARA LA REVISIÓN DE NORMA DE CALIDAD PRIMARIA DE AIRE PARA MATERIAL PARTICULADO RESPIRABLE (MP10), D.S. N° 59, DE 1998, MINSEGPRES.

Santiago, 22 de octubre de 2010

RESOLUCION EXENTA N° 18

VISTOS:

Lo dispuesto en la Ley N° 19.300, sobre Bases Generales del Medio Ambiente; el Decreto Supremo N° 93, de 1995, del Ministerio Secretaría General de la Presidencia, que establece el Reglamento para la Dictación de Normas de Calidad Ambiental y de Emisión; la Resolución Exenta N° 21, de 13 de enero de 2010, de la Dirección Ejecutiva de la Comisión Nacional del Medio Ambiente, publicada en el Diario Oficial el dia 26 de marzo de 2010 y en el diario La Nación el 28 del mismo mes, que dio inicio al proceso de revisión de la norma primaria de calidad de aire para Material Particulado respirable (MP10) (D.S. N° 59, de 1998, del Ministerio Secretaría General de la Presidencia de la República); lo dispuesto en los articulos 40 y 70 letras a) y n), de la Ley 19.300, sobre Bases Generales del Medio Ambiente; la Resolución N° 1.600, de 2008, de la Contraloría General de la República, y

CONSIDERANDO:

Que el día 29 de octubre de 2010, vence el plazo para el proceso de elaboración del anteproyecto de revisión de la norma de calidad señalada en los vistos.

Que mediante el memorándum N° 20, de 8 de octubre de 2010, la jefa de la División de Política y Regulación Ambiental solicitó ampliar el plazo para la preparación del anteproyecto de revisión de la norma de calidad aludida, dado que se estima razonable esperar a la dictación de la norma de calidad ambiental primaria de MP 2,5, debido a que ambas normativas se encuentran íntimamente relacionadas debido a que se trata del mismo contaminante. Se señala además, que posteriormente se iniciarán las reuniones con el Comité Operativo de la revisión de la Norma de MP10, ya que contando con una de Norma de MP2.5 aprobada permitirá definir de mejor forma los escenarios regulatorios que se plantearán en la revisión de la Norma de MP10, a partir del año 2012. Asimismo, menciona que los antecedentes técnicos generados en el proceso de elaboración de la Norma de MP2.5, servirán de sustento para la revisión de la presente normativa.

Que conforme lo dispone el inciso segundo del artículo 40 de la ley 19.300, sobre Bases Generales del Medio Ambiente, modificado por la letra b) del N° 47, del artículo primero de la ley N° 20.417, corresponderá al Ministerio del Medio Ambiente proponer, facilitar y coordinar la dictación de normas de emisión, para lo

cual deberá sujetarse a las etapas señaladas en el artículo 32, inciso tercero, y en el respectivo reglamento, en lo que fueren procedentes.

Que el Reglamento que fija el procedimiento para la dictación de normas de calidad ambiental y de emisión, D.S. Nº93 de 1995, del Ministerio Secretaría General de la Presidencia, dispone en su artículo 16 que dentro del plazo de ciento cincuenta días, el Director, por resolución fundada, podrá prorrogar o disminuir los plazos establecidos para la preparación de los informes o del anteproyecto de norma,

Que la mención hecha al Director Ejecutivo de CONAMA debe entenderse hecha al Ministro del Medio Ambiente, conforme lo dispone el mencionado artículo 40 de la Ley N° 19.300,

RESUELVO:

Amplíase hasta el día 30 de junio de 2011, el plazo para la preparación del anteproyecto de revisión de la norma primaria de calidad de aire para Material Particulado respirable (MP10), D.S. N° 59, de 1998, MINSEGPRES.

Anótese, comuníquese, y archívese.

MARÍA IGNACIA BENÍTEZ PEREIRA
MINISTRA DEL MEDIO AMBIENTE
MINISTERIO DEL MEDIO AMBIENTE

MFG/CRF/IPC

Cc:
División Jurídica
División de Políticas y Regulaciones Ambientales
Comité Operativo de la revisión de norma
Expediente de la revisión de norma
Archivo

LO QUE TRANSCRIBO A UD., PARA SU CONOCIMIENTO.
SALUDA ATTE. A UD.,

300010

Daniela Caimanque Fredes

De:	Hassett-Sipple.Beth@epamail.epa.gov
Enviado el:	Miércoles, 12 de Enero de 2011 13:53
Para:	Daniela Caimanque Fredes
CC:	Stallworth.Holly@epamail.epa.gov; Jenkins.Scott@epamail.epa.gov; Martin.Karen@epamail.epa.gov
Asunto:	Re: Fw: Question about Review PM10 annual

Daniela, the background materials for the PM NAAQS review completed in 2006 are available at:

http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr.html

You may want to begin by looking at the 2005 Staff Paper and 2004 Criteria Document. Please note, that in the US, the PM10 standard provides protection for effects associated with thoracic coarse particles (PM10-2.5) exposures. EPA has also established annual and 24-hour PM2.5 standards to provide protection for effects associated with fine particle exposures

If you have additional questions on the PM10 standard, please contact Dr. Scott Jenkins (919 541 4605; jenkins.scott@epa.gov). If you have any questions on the PM2.5 standards or the current review of the suite of PM standards, you may contact me. Information related to our current review of the PM NAAQS is available at:

http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html

Best regards,
Beth

Beth M. Hassett-Sipple
Environmental Health Scientist
Ambient Standards Group (C504-06)
Health and Environmental Impacts Division
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency
109 TW Alexander Drive
RTP, NC 27711

(919) 541-4605
Hassett-Sipple.Beth@epa.gov
(919) 541-0237 (FAX)

-----Holly Stallworth/DC/USEPA/US wrote: -----

To: Beth Hassett-Sipple/RTP/USEPA/US@EPA
From: Holly Stallworth/DC/USEPA/US
Date: 01/12/2011 11:06AM
Subject: Fw: Question about Review PM10 annual

Beth -- would you like to reply to this? Hope so. H

----- Forwarded by Holly Stallworth/DC/USEPA/US on 01/12/2011 11:06 AM -----

From: "Daniela Caimanque Fredes" <dcaimanque@mma.gob.cl>

To: Holly Stallworth/DC/USEPA/US@EPA

Federal Register

Tuesday,
October 17, 2006

Part II

Environmental Protection Agency

40 CFR Part 50
National Ambient Air Quality Standards for Particulate Matter; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2001–0017; FRL–8225–3]

RIN 2060–AI44

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for particulate matter (PM), EPA is making revisions to the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively. With regard to primary standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), EPA is revising the level of the 24-hour $PM_{2.5}$ standard to 35 micrograms per cubic meter ($\mu g/m^3$) and retaining the level of the annual $PM_{2.5}$ standard at $15 \mu g/m^3$. With regard to primary standards for particles generally less than or equal to 10μm in diameter (PM_{10}), EPA is retaining the 24-hour PM_{10} and revoking the annual PM_{10} standard. With regard to secondary PM standards, EPA is making them identical in all respects to the primary PM standards, as revised.

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

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2001–0017. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.* 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 through *www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 202–566–1741. The telephone number for the Public Reading Room is 202–566–1744.

The EPA Docket Center suffered damage due to flooding during the last week of June 2006. The Docket Center is continuing to operate. However, during the cleanup, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to visit the Public Reading Room to view documents. Consult EPA's **Federal Register** notice at 71 FR 38147 (July 5, 2006) or the EPA Web site at *www.epa.gov/epahome/dockets.htm* for current information on docket status, locations and telephone numbers.

FOR FURTHER INFORMATION CONTACT: Ms. Beth M. Hassett-Sipple, Mail Code C504–06, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone: (919) 541–4605, e-mail: *hassett-sipple.beth@epa.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

The following topics are discussed in today's preamble:

I. Background

A. Summary of Revisions to the PM NAAQS

Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for particulate matter (PM), EPA is making revisions to the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively.

With regard to primary standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), EPA is revising the level of the 24-hour $PM_{2.5}$ standard to 35 micrograms per cubic meter μg/m³), providing increased protection against health effects associated with short-term exposure (including premature mortality and increased hospital admissions and emergency room visits), and retaining the level of the annual $PM_{2.5}$ standard at 15 μg/m³, continuing protection against health effects associated with long-term exposure (including premature mortality and development of chronic respiratory disease). The EPA is revising the form of the annual $PM_{2.5}$ standard with regard to the criteria for spatial averaging, such that averaging across monitoring sites is allowed if the annual mean concentration at each monitoring site is within 10 percent of the spatially averaged annual mean, and the daily values for each monitoring site pair yield a correlation coefficient of at least 0.9 for each calendar quarter.

With regard to primary standards for particles generally less than or equal to 10μm in diameter (PM_{10}), EPA is retaining the 24-hour PM_{10} standard to protect against the health effects associated with short-term exposure to coarse particles (including hospital admissions for cardiopulmonary diseases, increased respiratory symptoms and possibly premature mortality). Given that the available evidence does not suggest an association between long-term exposure to coarse particles at current ambient levels and health effects, EPA is revoking the annual PM_{10} standard.

With regard to secondary PM standards, EPA is revising the current 24-hour $PM_{2.5}$ secondary standard by making it identical to the revised 24-hour $PM_{2.5}$ primary standard, retaining the annual $PM_{2.5}$ and 24-hour PM_{10} secondary standards, and revoking the annual PM_{10} secondary standard. This suite of secondary PM standards is intended to provide protection against PM-related public welfare effects, including visibility impairment, effects on vegetation and ecosystems, and materials damage and soiling.

B. Legislative Requirements

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list "air pollutants" that "in his judgment, may reasonably be anticipated to endanger public health and welfare" and whose "presence * * * in the ambient air results from numerous or diverse mobile or stationary sources" and to issue air quality criteria for those that are listed. Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air * * *."

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants listed under section 108. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." [1] A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air." [2]

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association* v. *EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied*, 449 U.S. 1042 (1980); *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at a background concentration level (see *Lead Industries Association* v. *EPA*, *supra*, 647 F.2d at 1156 n. 51), but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead*

[1] The legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group" [S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970)].

[2] Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

Industries Association v. *EPA*, *supra*, 647 F.2d at 1161–62.

In setting standards that are "requisite" to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In establishing primary and secondary standards, EPA may not consider the costs of implementing the standards. See generally *Whitman* v. *American Trucking Associations*, 531 U.S. 457, 465–472, 475–76 (2001).

Section 109(d)(1) of the CAA requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards * * * and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with [the provisions in section 109(b) on primary and secondary standards]." This includes the authority to modify or revoke a standard or standards, as appropriate under these provisions. Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria * * * and the national primary and secondary ambient air quality standards * * * and shall recommend to the Administrator any new * * * standards and revisions of existing criteria and standards as may be appropriate * * *." This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

C. Overview of Air Quality Criteria and Standards Review for PM

Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. Particles originate from a variety of anthropogenic stationary and mobile sources as well as from natural sources. Particles may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides (SO_X), nitrogen oxides (NO_X), and volatile organic compounds (VOC). The chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, thus complicating the assessment of health and welfare effects.

More specifically, the PM that is the subject of the air quality criteria and standards reviews includes both fine particles and thoracic coarse particles, which are considered as separate subclasses of PM pollution based in part on long-established information on differences in sources, properties, and atmospheric behavior between fine and coarse particles (EPA, 2005, section 2.2). Fine particles are produced chiefly by combustion processes and by atmospheric reactions of various gaseous pollutants, whereas thoracic coarse particles are generally emitted directly as particles as a result of mechanical processes that crush or grind larger particles or the resuspension of dusts. Sources of fine particles include, for example, motor vehicles, power generation, combustion sources at industrial facilities, and residential fuel burning. Sources of thoracic coarse particles include, for example, traffic-related emissions such as tire and brake lining materials, direct emissions from industrial operations, construction and demolition activities, and agricultural and mining operations. Fine particles can remain suspended in the atmosphere for days to weeks and can be transported thousands of kilometers, whereas thoracic coarse particles generally deposit rapidly on the ground or other surfaces and are not readily transported across urban or broader areas.

The last review of PM air quality criteria and standards was completed in July 1997 with notice of a final decision to revise the existing standards (62 FR 38652, July 18, 1997). In that decision, EPA revised the PM NAAQS in several respects. While EPA determined that the PM NAAQS should continue to focus on particles less than or equal to 10 μm in diameter (PM_{10}), EPA also determined that the fine and coarse fractions of PM_{10} should be considered separately. The EPA added new standards, using $PM_{2.5}$ as the indicator for fine particles (with $PM_{2.5}$ referring to particles with a nominal aerodynamic diameter less than or equal to 2.5 μm), and using PM_{10} as the indicator for purposes of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or coarse-fraction particles; generally including particles with a nominal aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm, or $PM_{10-2.5}$). The EPA established two new $PM_{2.5}$ standards: An annual standard of 15 μg/m³, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors; and a 24-hour standard of 65 μg/m³, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area. Also, EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and adopted rules for determining attainment of the new standards. To continue to address thoracic coarse particles, EPA retained the annual PM_{10} standard, while revising the form, but not the level, of the 24-hour PM_{10} standard to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by making them identical in all respects to the primary standards.

Following promulgation of the revised PM NAAQS, petitions for review were filed by a large number of parties, addressing a broad range of issues. In May 1999, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit issued an initial decision that upheld EPA's decision to establish fine particle standards, holding that "the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards." *American Trucking Associations* v. *EPA*, 175 F.3d 1027, 1055–56 (D.C. Cir. 1999) ("ATA I") rehearing granted in part and denied in part, 195 F.3d 4 (D.C. Cir. 1999) ("ATA II"), affirmed in part and reversed in part, *Whitman* v. *American Trucking Associations*, 531 U.S. 457 (2001). The Panel also found "ample support" for EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that EPA's justification for the use of PM_{10} as an indicator for coarse particles was arbitrary. 175 F.3d at 1054–55. Pursuant to the court's decision, EPA removed the vacated 1997 PM_{10} standards from the regulations (CFR) (69 FR 45592, July 30, 2004) and deleted the regulatory provision (at 40 CFR 50.6(d)) that controlled the transition from the pre-existing 1987 PM_{10} standards to the 1997 PM_{10} standards (65 FR 80776, December 22, 2000). The pre-existing 1987 PM_{10} standards remained in place. *Id.* at 80777.

More generally, the panel held (over one judge's dissent) that EPA's approach to establishing the level of the standards in 1997, both for PM and for ozone NAAQS promulgated on the same day, effected "an unconstitutional delegation of legislative authority." *Id.* at 1034–40. Although the panel stated that "the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable," it remanded the rule to EPA, stating that when EPA considers these factors for potential non-threshold pollutants "what EPA lacks is any determinate criterion for

drawing lines" to determine where the standards should be set. Consistent with EPA's long-standing interpretation and D.C. Circuit precedent, the panel also reaffirmed prior rulings holding that in setting NAAQS EPA is "not permitted to consider the cost of implementing those standards." *Id.* at 1040–41.

Both sides filed cross appeals on these issues to the United States Supreme Court, and the Court granted *certiorari*. In February 2001, the Supreme Court issued a unanimous decision upholding EPA's position on both the constitutional and cost issues. *Whitman* v. *American Trucking Associations*, 531 U.S. 457, 464, 475–76 (2001). On the constitutional issue, the Court held that the statutory requirement that NAAQS be "requisite" to protect public health with an adequate margin of safety sufficiently guided EPA's discretion, affirming EPA's approach of setting standards that are neither more nor less stringent than necessary. The Supreme Court remanded the case to the Court of Appeals for resolution of any remaining issues that had not been addressed in that court's earlier rulings. *Id.* at 475–76. In March 2002, the Court of Appeals rejected all remaining challenges to the standards, holding under the traditional standard of judicial review that EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not "arbitrary and capricious." *American Trucking Associations* v. *EPA*, 283 F. 3d 355, 369–72 (D.C. Cir. 2002) ("*ATA III*").

In October 1997, EPA published its plans for the current periodic review of the PM criteria and NAAQS (62 FR 55201, October 23, 1997), including the 1997 $PM_{2.5}$ standards and the 1987 PM_{10} standards. The approach in this review continues to address fine and thoracic coarse particles separately. This approach has been reinforced by new information that has advanced our understanding of differences in human exposure relationships and dosimetric patterns characteristic of these two subclasses of PM pollution, as well as the apparent independence of health effects that have been associated with them in epidemiologic studies (EPA, 2004a, section 3.2.3). See also *ATA I*, 175 F. 3d at 1053–54, 1055–56 (EPA justified in establishing separate standards for fine and thoracic coarse particles).

As part of the process of preparing an updated Air Quality Criteria Document for Particulate Matter (henceforth, the "Criteria Document"), EPA's National Center for Environmental Assessment (NCEA) hosted a peer review workshop in April 1999 on drafts of key Criteria Document chapters. The first external review draft Criteria Document was reviewed by CASAC and the public at a meeting held in December 1999. Based on CASAC and public comment, NCEA revised the draft Criteria Document and released a second draft in March 2001 for review by CASAC and the public at a meeting held in July 2001. A preliminary draft of a staff paper, Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information (henceforth, the "Staff Paper") prepared by EPA's Office of Air Quality Planning and Standards (OAQPS) was released in June 2001 for public comment and for consultation with CASAC at the same public meeting. Taking into account CASAC and public comments, a third draft Criteria Document was released in May 2002 for review at a meeting held in July 2002.

Shortly after the release of the third draft Criteria Document, the Health Effects Institute (HEI)[3] announced that researchers at Johns Hopkins University had discovered problems with applications of statistical software used in a number of important epidemiological studies that had been discussed in that draft Criteria Document. In response to this significant issue, EPA took steps in consultation with CASAC and the broader scientific community to encourage researchers to reanalyze affected studies and to submit them expeditiously for peer review by a special expert panel convened at EPA's request by HEI. The results of this reanalysis and peer-review process were subsequently incorporated into a fourth draft Criteria Document, which was released in June 2003 and reviewed by CASAC and the public at a meeting held in August 2003.

The first draft Staff Paper, based on the fourth draft Criteria Document, was released at the end of August 2003, and was reviewed by CASAC and the public at a meeting held in November 2003. During that meeting, EPA also consulted with CASAC on a new framework for the final chapter (integrative synthesis) of the Criteria Document and on ongoing revisions to other Criteria Document chapters to address previous CASAC comments. The EPA held additional consultations with CASAC at public meetings held in February, July, and September 2004, leading to publication of the final Criteria Document in October 2004 (EPA, 2004a). The second draft Staff Paper, based on the final Criteria Document, was released at the end of January 2005, and was reviewed by CASAC and the public at a meeting held in April 2005. The CASAC's advice and recommendations to the Administrator, based on its review of the second draft Staff Paper, were further discussed during a public teleconference held in May 2005 and are provided in a June 6, 2005 letter to the Administrator (Henderson, 2005a). The final Staff Paper takes into account the advice and recommendations of CASAC and public comments received on the earlier drafts of this document. The Administrator subsequently received additional advice and recommendations from the CASAC, specifically on potential standards for thoracic coarse particles, in a teleconference on August 11, 2005, and in a letter to the Administrator dated September 15, 2005 (Henderson, 2005b). The final Staff Paper was reissued in December 2005 to add CASAC's final letter as an attachment (EPA, 2005).

The schedule for completion of this review is governed by a consent decree resolving a lawsuit filed in March 2003 by a group of plaintiffs representing national environmental organizations. The lawsuit alleged that EPA had failed to perform its mandatory duty, under section 109(d)(1), of completing the current review within the period provided by statute. *American Lung Association* v. *Whitman* (No. 1:03CV00778, D.D.C. 2003). An initial consent decree was entered by the court in July 2003 after an opportunity for public comment. The consent decree, as modified by the court, provides that EPA will sign for publication notices of proposed and final rulemaking concerning its review of the PM NAAQS no later than December 20, 2005 and September 27, 2006, respectively.

On December 20, 2005, EPA issued its proposed decision to revise the NAAQS for PM (71 FR 2620, January 17, 2006) (henceforth "proposal"). In the proposal, EPA identified proposed revisions to the standards, based on the air quality criteria for PM, and to related data handling conventions and federal reference methods for monitoring PM. The proposal solicited public comments on alternative primary and secondary standards and related matters.

The EPA held several public hearings across the country to provide direct opportunities for public comment on the proposed revisions to the PM NAAQS. On March 8, 2006, EPA held three concurrent 12-hour public hearings in Philadelphia, PA; Chicago, IL; and San Francisco, CA. At these public hearings, EPA heard testimony

[3] The HEI is a non-profit, independent research institute jointly and equally funded by EPA and multiple industries that conducts research on the health effects of air pollution.

from 280 individuals representing themselves or specific interested organizations.

More than 120,000 comments were received from members of the public and various interested groups on the proposed revisions to the PM NAAQS by the close of the public comment period on April 17, 2006. CASAC provided additional advice to EPA in a letter to the Administrator requesting reconsideration of CASAC's recommendations for both the primary and secondary $PM_{2.5}$ standards as well as standards for thoracic coarse particles (Henderson, 2006). Major issues raised in the public comments are discussed throughout the preamble of this final action. A comprehensive summary of all significant comments, along with EPA's responses (henceforth "Response to Comments"), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2001–0017).

In the proposal, EPA recognized that there were a number of new scientific studies on the health effects of PM that had been published recently and therefore were not included in the Criteria Document.[4] The EPA committed to conduct a review and assessment of any significant "new" studies, including studies submitted during the public comment period. The purpose of this review was to ensure that the Administrator was fully aware of the "new" science before making a final decision on whether to revise the current PM NAAQS. The EPA screened and surveyed the recent literature, including studies submitted during the public comment period, and conducted a provisional assessment (EPA, 2006a) that places the results of those studies of potentially greatest policy relevance in the context of the findings of the Criteria Document.

The provisional assessment found that the "new" studies expand the scientific information and provide important insights on the relationship between PM exposure and health effects of PM. The provisional assessment also found that "new" studies generally strengthen the evidence that acute and chronic exposure to fine particles and acute exposure to thoracic coarse particles are associated with health effects; some of the "new" epidemiologic studies report effects in areas with lower concentrations of $PM_{2.5}$ or $PM_{10-2.5}$ than those in earlier reports; "new" toxicology and epidemiologic studies link various health effects with a range of fine particle sources and components; and "new" toxicology studies report effects of thoracic coarse particles but do not provide evidence to support distinguishing effects from exposure to urban and rural particles. Further, the provisional assessment found that the results reported in the studies do not dramatically diverge from previous findings, and, taken in context with the findings of the Criteria Document, the new information and findings do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Criteria Document.

The EPA believes it was important to conduct a provisional assessment in this case, so that the Administrator would be aware of the science that developed too recently for inclusion in the Criteria Document. However it is also important to note that EPA's review of that science to date has been limited to screening, surveying, and preparing a provisional assessment of these studies. Having performed this limited provisional assessment, EPA must decide whether to consider the newer studies in this review and take such steps as may be necessary to include them in the basis for the final decision, or to reserve such action for the next review of the PM NAAQS.

As in prior NAAQS reviews, EPA is basing its decision in this review on studies and related information included in the Criteria Document and Staff Paper, which have undergone CASAC and public review. The studies assessed in the Criteria Document, and the integration of the scientific evidence presented in that document, have undergone extensive critical review by EPA, CASAC, and the public during the development of the Criteria Document. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process. As described above, the provisional assessment did not and could not provide that kind of in-depth critical review.

This decision is consistent with EPA's practice in prior NAAQS reviews. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria. See *e.g.*, 36 FR 8186 (April 30, 1971) (EPA based original NAAQS for six pollutants on scientific studies discussed in air quality criteria documents and limited consideration of comments to those concerning validity of scientific basis); 38 FR 25678, 25679–25680 (September 14, 1973) (EPA revised air quality criteria for sulfur oxides to provide basis for reevaluation of secondary NAAQS). This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. EPA has consistently followed this approach. 52 FR 24634, 24637 (July 1, 1987) (after review by CASAC, EPA issued a post-proposal addendum to the PM Criteria Document, to address certain new scientific studies not included in the 1982 Criteria Document); 61 FR 25566, 25568 (May 22, 1996) (after review by CASAC, EPA issued a post-proposal supplement to the 1982 Criteria Document to address certain new health studies not included in the 1982 Criteria Document or 1986 Addendum). The EPA recently reaffirmed this approach in its decision not to revise the ozone NAAQS in 1993, as well as in its final decision on the PM NAAQS in the 1997 review. 58 FR 13008, 13013–13014 (March 9, 1993) (ozone review); 62 FR 38652, 38662 (July 18, 1997) (The EPA conducted a provisional assessment but based the final PM decision on studies and related information included in the air quality criteria that had been reviewed by CASAC).

As discussed in EPA's 1993 decision not to revise the NAAQS for ozone, new studies may sometimes be of such significance that it is appropriate to delay a decision on revision of NAAQS and to supplement the pertinent air quality criteria so the new studies can be taken into account (58 FR at 13013–13014, March 9, 1993). In the present case, the provisional assessment of recent studies concludes that, taken in context, the new information and findings do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Criteria

[4] For ease of reference, these studies will be referred to as "new" studies or "new" science, using quotation marks around the word *new*. Referring to studies that were published too recently to have been included in the 2004 Criteria Document as "new" studies is intended to clearly differentiate such studies from those that have been published since the last review and are included in the 2004 Criteria Document [these studies are sometimes referred to as new (without quotation marks) or more recent studies, to indicate that they were not included in the 1996 Criteria Document and thus are newly available in this review].

Document. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking. Accordingly, EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review. The EPA will consider the newly published studies for purposes of decision making in the next periodic review of the PM NAAQS, which will provide the opportunity to fully assess them through a more rigorous review process involving EPA, CASAC, and the public.

In order to facilitate a comprehensive and timely review of the newly available science, the Administrator has directed EPA staff to begin the next review of the PM NAAQS immediately.[5]

D. Related Control Programs To Implement PM Standards

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the CAA (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration (PSD) program under sections 160–169 of the CAA (42 U.S.C. 7470–7479) for these pollutants. In addition, the Act provides for nationwide reductions in emissions of these and other air pollutants through related programs, such as the Federal Mobile Source Control Program under Title II of the CAA (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, nonroad and off-highway engines and aircraft emissions; the new source performance standards under section 111 (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 (42 U.S.C. 7412).

As described in a recent EPA report, *The Particle Pollution Report: Current Understanding of Air Quality and Emissions through 2003* (EPA, 2004b), State and Federal programs have made substantial progress in reducing ambient concentrations of PM_{10} and $PM_{2.5}$. For example, PM_{10} concentrations have decreased 31 percent nationally since 1988. Regionally, PM_{10} concentrations decreased most in areas with historically higher concentrations—the Northwest (39 percent decline), the Southwest (33 percent decline), and southern California (35 percent decline). Direct emissions of PM_{10} have decreased approximately 25 percent nationally since 1988.

Programs aimed at reducing direct emissions of particles have played an important role in reducing PM_{10} concentrations, particularly in western areas. Some examples of PM_{10} controls include paving unpaved roads and using best management practices for agricultural sources of resuspended soil. Of the 87 areas that were designated nonattainment for PM_{10} in the early 1990s, 64 now meet those standards. In cities that have not attained the PM_{10} standards, the number of days above the standards is down significantly.

Nationally, $PM_{2.5}$ concentrations have declined by 10 percent from 1999 to 2003. Generally, $PM_{2.5}$ concentrations have also declined the most in regions with the highest concentrations—the Southeast (20 percent decline), southern California (16 percent decline), and the Industrial Midwest (9 percent decline). With the exception of the Northeast, the remaining regions posted modest declines in $PM_{2.5}$ concentrations from 1999 to 2003. Direct emissions of $PM_{2.5}$ have decreased by 5 percent nationally over the past 5 years.

National programs that affect regional emissions have also contributed to lower sulfate concentrations and, consequently, to lower $PM_{2.5}$ concentrations, particularly in the Industrial Midwest and Southeast. National ozone-reduction programs designed to reduce emissions of volatile organic compounds (VOCs) and nitrogen oxides (NO_X) have also helped reduce carbon and nitrates, both of which are components of $PM_{2.5}$. Additionally, EPA's Acid Rain Program has substantially reduced sulfur dioxide (SO_2) emissions from power plants since 1995 in the eastern United States, contributing to lower PM concentrations. Nationally, SO_2 emissions have declined 9 percent, NO_X emissions have declined 9 percent, and VOC emissions have declined by 12 percent from 1999 to 2003. In eastern States affected by the Acid Rain Program, sulfates decreased 7 percent over the same period.

Over the next 10 to 20 years, national and regional regulations will make major reductions in ambient $PM_{2.5}$ levels. The Clean Air Interstate Rule (CAIR) and the NO_X SIP Call will further reduce SO_2 and NO_X emissions from electric generating units and industrial boilers across the eastern half of the U.S.; regulations to implement the 1997 ambient air quality standards for $PM_{2.5}$ will require direct $PM_{2.5}$ and $PM_{2.5}$ precursor controls in nonattainment areas; and new national mobile source regulations affecting heavy-duty diesel engines, highway vehicles, and other mobile sources will reduce emissions of NO_X, direct $PM_{2.5}$, SO_2, and VOCs. The EPA estimates that these regulations for stationary and mobile sources will cut SO_2 emissions by 6 million tons annually in 2015 from 2001 levels. Emissions of NO_X will be cut by 9 million tons annually in 2015 from 2001 levels. Emissions of VOCs will drop by 3 million tons, and direct $PM_{2.5}$ emissions will be cut by 200,000 tons in 2015, compared to 2001 levels.

In 2005, 39 nonattainment areas were designated as not attaining the $PM_{2.5}$ standards established in 1997. SIPs for these areas are due in April 2008. Nonattainment areas are required to attain the standards as "expeditiously as practicable" based on implementation of federal measures already in place and the adoption of other reasonable control strategies for sources located in the nonattainment area and state. The presumptive timeframe for attainment is within five years of designation, although EPA may approve extended attainment dates of an additional one to five years for areas with more serious problems.

Modeling done by EPA indicates that by 2010, 18 of the 39 currently designated nonattainment areas are projected to come into attainment with those standards just based on regulatory programs already in place, including CAIR, the Clean Diesel Rules, and other Federal measures. Between 2010 and 2015, further reductions in PM concentrations in the eastern U.S. are projected due to existing federal programs alone, on the order of 0.5 to 1.5 $\mu g/m^3$. All areas in the eastern U.S. will have lower $PM_{2.5}$ concentrations in 2015 relative to present-day conditions. In most cases, the predicted improvement in $PM_{2.5}$ ranges from 10 percent to 20 percent.

E. Summary of Proposed Revisions to the PM NAAQS

For reasons discussed in the proposal, the Administrator proposed to revise the current primary and secondary $PM_{2.5}$ and PM_{10} standards. With regard to the primary $PM_{2.5}$ standards, the Administrator proposed to revise the level of the 24-hour $PM_{2.5}$ standard to 35

[5] The EPA has recently conducted a review of the process by which the Agency performs periodic NAAQS reviews to identify ways in which the process could be strengthened and streamlined (EPA, 2006b). The EPA intends to incorporate recommendations from the NAAQS process review into the next PM NAAQS review.

$\mu g/m^3$, and to revise the form of the annual $PM_{2.5}$ standard by changing the constraints on the optional use of spatial averaging to include the criterion that the minimum correlation coefficient between monitor pairs to be averaged be 0.9 or greater, determined on a seasonal basis, and the criterion that differences between monitor values not exceed 10 percent. Related revisions for $PM_{2.5}$ data handling conventions and for the reference method for monitoring PM as $PM_{2.5}$ were also proposed.

With regard to the primary PM_{10} standards, the Administrator proposed to revise the current standards to provide more targeted protection from thoracic coarse particles that are of concern to public health. In part, the Administrator proposed to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, the definition of which included qualifications that identified both the mix of such particles that were provisionally determined to be of concern to public health, and were thus included in the indicator, and those for which currently available information was provisionally determined to be insufficient as a basis from which to infer a public health concern, and were thus excluded. More specifically, the proposed $PM_{10-2.5}$ indicator was qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and to exclude any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. The Administrator also proposed that agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting the proposed standard. The Administrator proposed to replace the current primary 24-hour PM_{10} standard with a 24-hour standard defined in terms of this new $PM_{10-2.5}$ indicator. The proposed new standard would be met at an ambient air quality monitoring site when the 3-year average of the annual 98th percentile 24-hour average $PM_{10-2.5}$ concentration is less than or equal to 70 $\mu g/m^3$, which would generally maintain the degree of public health protection afforded by the current PM_{10} standards from short-term exposure to thoracic coarse particles of concern. Requirements for monitoring sites that would be appropriate for determining compliance with this proposed $PM_{10-2.5}$ standard were included as part of proposed revisions to EPA's ambient air monitoring regulations (see 71 FR 2710, 2736–2728 and 71 FR 2706–2707 (proposing to incorporate these requirements as part of the standard)). These proposed requirements included a five-part test for determining whether a potential monitoring site is suitable for comparison to the standard, all five parts of which had to be met. In summary, the suitability test included the following general provisions: a monitoring site must be within an urbanized area that has a population of at least 100,000 persons; the site must be within a block group with a population density greater than 500 people per square mile; the site must be a "population-oriented" site; the site may not be adjacent to a large emissions source or otherwise within the micro-scale environment affected by a large source; and, if the first four provisions are met, a site-specific assessment must show that the ambient mix of $PM_{10-2.5}$ sampled at the site would be dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and would not be dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. Related new $PM_{10-2.5}$ data handling conventions and a new reference method for monitoring PM as $PM_{10-2.5}$ were also proposed. The Administrator also proposed to revoke and not replace the annual PM_{10} standard.

With regard to the secondary $PM_{2.5}$ and PM_{10} standards, the Administrator proposed to revise the current standards by making them identical in all respects to the proposed primary $PM_{2.5}$ and $PM_{10-2.5}$ standards to address PM-related welfare effects including visibility impairment, effects on vegetation and ecosystems, materials damage and soiling, and effects on climate change.

F. Organization and Approach to Final PM NAAQS Decisions

This action presents the Administrator's final decisions on the review of the current primary and secondary $PM_{2.5}$ and PM_{10} standards. Primary standards for fine particles and for thoracic coarse particles are addressed below in sections II and III, respectively. Consistent with the decisions made by EPA in the last review and with the conclusions in the Criteria Document and Staff Paper, fine and thoracic coarse particles continue to be considered as separate subclasses of PM pollution. Secondary standards for fine and thoracic coarse particles are addressed below in section IV. Related data handling conventions and federal reference methods for monitoring PM are addressed below in sections V and VI, respectively.

Today's final decisions separately addressing fine and thoracic coarse particles are based on a thorough review in the Criteria Document of scientific information on known and potential human health and welfare effects associated with exposure to these subclasses of PM at levels typically found in the ambient air. These final decisions also take into account: (1) Staff assessments in the Staff Paper of the most policy-relevant information in the Criteria Document as well as a quantitative risk assessment based on that information; (2) CASAC advice and recommendations, as reflected in its letters to the Administrator, its discussions of drafts of the Criteria Document and Staff Paper at public meetings, and separate written comments prepared by individual members of the CASAC PM Review Panel [6] (henceforth, "CASAC Panel"); (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately; and (4) extensive public comments received on the proposed rulemaking.

II. Rationale for Final Decisions on Primary $PM_{2.5}$ Standards

A. Introduction

1. Overview

This section presents the Administrator's final decisions regarding the need to revise the current primary $PM_{2.5}$ NAAQS, and, more specifically, regarding revisions to the level of the 24-hour standard and to the form of the annual standard. As discussed more fully below, the rationale for the final decision on appropriate revisions to the primary $PM_{2.5}$ NAAQS includes consideration of: (1) Evidence of health effects related to short- and long-term exposures to fine particles; (2) insights gained from a quantitative risk assessment; and (3) specific conclusions regarding the need for revisions to the current standards and the elements of $PM_{2.5}$ standards (i.e., indicator, averaging time, form, and level) that, taken together, are requisite to protect public health with an adequate margin of safety.

In developing this rationale, EPA has drawn upon an integrative synthesis of the entire body of evidence on associations between exposure to

[6] The CASAC PM Review Panel is comprised of the seven members of the chartered CASAC, supplemented by fifteen subject-matter experts appointed by the Administrator to provide additional scientific expertise relevant to this review of the PM NAAQS.

ambient fine particles and a broad range of health endpoints (EPA, 2004a, Chapter 9), focusing on those health endpoints for which the Criteria Document concluded that the associations are likely to be causal. This body of evidence includes hundreds of studies conducted in many countries around the world, using various indicators of fine particles. In its assessment of the evidence judged to be most relevant to decisions on elements of the primary $PM_{2.5}$ standards, EPA has placed greater weight on U.S. and Canadian studies using $PM_{2.5}$ measurements, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

As with virtually any policy-relevant scientific research, there is uncertainty in the characterization of health effects attributable to exposure to ambient fine particles, most generally with regard to whether observed associations are likely causal in nature and, if so, whether there are exposure levels below which such associations are no longer likely. As discussed below, an unprecedented amount of new research has been conducted since the last review, with important new information coming from epidemiologic, toxicologic, controlled human exposure, and dosimetric studies. Moreover, the newly available research studies evaluated in the Criteria Document have undergone intensive scrutiny through multiple layers of peer review, with extended opportunities for review and comment by CASAC and the public. While important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence provides an adequate basis for regulatory decision making at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient fine particles and health effects.

The health effects information and quantitative risk assessment were summarized in sections II.A and II.B of the proposal (71 FR 2626–2641) and are only briefly outlined below in sections II.A.2 and II.A.3. Subsequent sections of this preamble provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that it is appropriate to revise the current primary $PM_{2.5}$ standards (section II.B), as well as a more complete discussion of the Administrator's rationale for retaining or revising the specific elements of the primary $PM_{2.5}$ standards, namely the indicator (section II.C); averaging time (section II.D); form (section II.E); and level (section II.F). A summary of the final decisions on revisions to the primary $PM_{2.5}$ standards is presented in section II.G.

2. Overview of Heath Effects Evidence

This section briefly outlines the information presented in Section II.A of the proposal on the health effects associated with exposure to fine particles. As was true in the last review, evidence from epidemiologic studies plays a key role in the Criteria Document's evaluation of the scientific evidence. Some highlights of the new epidemiologic evidence available since the last review include:

(1) New multi-city studies that use uniform methodologies to investigate the effects of various indicators of PM on health with data from multiple locations with varying climate and air pollution mixes, contributing to increased understanding of the role of various potential confounders, including gaseous co-pollutants, on observed associations with fine particles. These studies provide more precise estimates of the magnitude of an effect of exposure to PM, including fine particles, than most smaller-scale individual city studies.

(2) More studies of various health endpoints evaluating associations between effects and exposures to fine particles and thoracic coarse particles (discussed below in section III), as well as ultrafine particles or specific components (e.g., sulfates, nitrates, metals, organic compounds, and elemental carbon) of fine particles.

(3) Numerous studies of cardiovascular endpoints, with particular emphasis on assessment of cardiovascular risk factors or physiological changes.

(4) Studies relating population exposure to fine particles and other pollutants measured at centrally located monitors to estimates of exposure to ambient pollutants at the individual level. Such studies have led to a better understanding of the relationship between ambient fine particle levels and personal exposures to fine particles of ambient origin.

(5) New statistical approaches to addressing issues related to potential confounding by gaseous co-pollutants, possible thresholds for effects, and measurement error and exposure misclassification.[7]

(6) Efforts to evaluate the effects of fine particles from different sources (e.g., motor vehicles, coal combustion, vegetative burning, crustal [8]), using factor analysis or source apportionment methods with fine particle speciation data.

(7) New "intervention studies" providing evidence for improvements in respiratory or cardiovascular health with reductions in ambient concentrations of particles and gaseous co-pollutants.

In addition, the body of evidence on PM-related effects has greatly expanded since the last review with findings from studies of potential mechanisms or pathways by which particles may result in the effects identified in the epidemiologic studies. These studies include important new dosimetry, toxicologic and controlled human exposure studies, as highlighted below.

(8) Animal and controlled human exposure studies using concentrated ambient particles (CAPs), new indicators of response (e.g., C-reactive protein and cytokine levels, heart rate variability), and animal models simulating sensitive human subpopulations. The results of these studies are relevant to evaluation of plausibility of the epidemiologic evidence and provide insights into potential mechanisms for PM-related effects.

(9) Dosimetry studies using new modeling methods that provide increased understanding of the dosimetry of different particle size classes and in members of potentially sensitive subpopulations, such as people with chronic respiratory disease.

Section II.A of the proposal provides a detailed summary of key information contained in the Criteria Document (EPA, 2004a, Chapters 8–9), and in the Staff Paper (EPA, 2005, Chapter 3), on the known and potential effects associated with exposure to fine particles including information on specific constituents and information on the effects of fine particles in combination with other pollutants that are routinely present in the ambient air

[7] "Confounding" occurs when a health effect that is caused by one risk factor is attributed to another variable that is correlated with the causal risk factor; epidemiologic analyses attempt to adjust or control for potential confounders (EPA, 2004a, section 8.1.3.2; EPA, 2005, section 3.6.4). A "threshold" is a concentration below which it is expected that effects are not observed (EPA, 2004a, section 8.4.7; EPA, 2005, section 3.6.8). "Gaseous co-pollutants" generally refer to other commonly-occurring air pollutants, specifically O_3, CO, SO_2 and NO_2. "Measurement error" refers to uncertainty in the air quality measurements, while "exposure misclassification" includes uncertainty in the use of ambient pollutant measurements in characterizing population exposures to PM (EPA, 2004a, section 8.4.5; EPA, 2005, section 3.6.2).

[8] "Crustal" is used here to describe particles of geologic origin, which can be found in both fine- and coarse-fraction PM.

(71 FR 2626–2637). The information highlighted there summarizes:

(1) Multiple biologic mechanisms that may be responsible for morbidity/mortality effects associated with exposure to ambient fine particles, including potential mechanisms or pathways related to direct effects on the respiratory system, systemic effects that are secondary to effects in the respiratory system including cardiovascular effects, or direct cardiovascular effects.

(2) The nature of the effects that have been reported to be associated with fine particle exposures including premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency department visits), changes in lung function and increased respiratory symptoms, as well as new evidence for more subtle indicators of cardiovascular health.

(3) An integrated evaluation of the health effects evidence, with emphasis on key issues raised in interpreting epidemiological studies, along with supporting evidence from experimental (e.g., dosimetric and toxicologic) studies.

(4) Sensitive or vulnerable subpopulations that appear to be at greater risk to such effects, including individuals with pre-existing heart and lung diseases, older adults, and children.

(5) Conclusions, based on the magnitude of these subpopulations and risks identified in health studies, that exposure to ambient fine particles can have substantial public health impacts.

3. Overview of Quantitative Risk Assessment

In addition to a comprehensive evaluation of the health effects evidence available in this review, EPA conducted a quantitative health risk assessment for selected health effects to provide additional information and insights that can help inform decision making on the NAAQS, while recognizing the limitations of such an assessment.[9] As discussed in section II.B of the proposal, the approach used to develop quantitative risk estimates associated with exposures to $PM_{2.5}$ was built upon the more limited risk assessment conducted during the last review (61 FR 65650). The expanded and updated assessment conducted in this review included estimates of risks of mortality (total non-accidental, cardiovascular, and respiratory), morbidity (hospital admissions for cardiovascular and respiratory causes), and respiratory symptoms (not requiring hospitalization) associated with recent short-term (daily) ambient $PM_{2.5}$ levels and risks of total, cardiopulmonary, and lung cancer mortality associated with long-term exposure to $PM_{2.5}$ in a number of example urban areas.[10]

The EPA recognized that there were many sources of uncertainty and variability inherent in the inputs to this assessment and that there was a high degree of uncertainty in the resulting $PM_{2.5}$ risk estimates. Such uncertainties generally relate to a lack of clear understanding of a number of important factors, including, for example, the shape of concentration-response functions, particularly when, as here, effect thresholds can neither be discerned nor determined not to exist; issues related to selection of appropriate statistical models for the analysis of the epidemiologic data; the role of potentially confounding and modifying factors in the concentration-response relationships; issues related to simulating how $PM_{2.5}$ air quality distributions will likely change in any given area upon attaining a particular standard, since strategies to reduce emissions are not yet defined; and whether there would be differential reductions in the many components within $PM_{2.5}$ and, if so, whether this would result in differential reductions in risk. While some of these uncertainties were addressed quantitatively in the form of estimated confidence ranges around central risk estimates, other uncertainties and the variability in key inputs were not reflected in these confidence ranges, but rather were addressed through separate sensitivity analyses or characterized qualitatively.

The concentration-response relationships used in the assessment were based on findings from human epidemiological studies that relied on fixed-site, population-oriented, ambient monitors as a surrogate for actual ambient $PM_{2.5}$ exposures. The risk assessment included a series of base case estimates that, for example, included various cutpoints intended as surrogates for alternative assumed population thresholds. In its review of the Staff Paper and risk assessment, the CASAC Panel commented that for the purpose of estimating public health impacts, it "favored the primary use of an assumed threshold of 10 $\mu g/m^3$" and that "a major research need is for more work to determine the existence and level of any thresholds that may exist or the shape of nonlinear concentration-response curves at low levels of exposure that may exist" (Henderson, 2005a). Other uncertainties were addressed in various sensitivity analyses (e.g., the use of single-versus multi-pollutant models, use of single-versus multi-city models, use of a distributed lag model) and had a more moderate and often variable impact on the risk estimates in some or all of the cities.

Key observations and insights from the $PM_{2.5}$ risk assessment, together with important caveats and limitations, were discussed in section II.B of the proposal. In general, estimated risk reductions associated with going from just meeting the current suite of $PM_{2.5}$ standards to just meeting alternative suites of annual and 24-hour standards for all the various assumed cutpoints show patterns of increasing estimated risk reductions as either the annual or 24-hour standard, or both, were reduced over the range considered in this assessment, and the estimated percentage reductions in risk were strongly influenced by the assumed cutpoint level (see EPA, 2005, Figures 5–1, 5–2, 5A–1, and 5A–2). In comparing the risk estimates for the only two specific locations that were included in both the prior and current assessments, the magnitude of the estimates associated with just meeting the current annual standard, in terms of percentage of total incidence, were very similar for mortality associated with long-term exposures. Current risk estimates for just meeting the current suite of $PM_{2.5}$ standards were similar in one of the locations (Philadelphia) and somewhat lower in the other location (Los Angeles) for mortality associated with short-term exposures.

B. Need for Revision of the Current Primary $PM_{2.5}$ Standards

1. Introduction

The initial issue to be addressed in the current review of the primary $PM_{2.5}$ standards is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standards should be revised. As discussed in section II.A of the proposal (71 FR 2625–2637), the Staff Paper concluded, based on the information and

[9] The EPA continues to support the development and application of risk assessment methods with the goal of improving the characterization of risks and the communication of uncertainties in such risk estimates.

[10] The risk assessment was discussed in the Staff Paper (EPA, 2005, chapter 4) and presented more fully in a technical support document, Particulate Matter Health Risk Assessment for Selected Urban Areas (Abt Associates, 2005). The assessment scope and methodology were developed with considerable input from the CASAC Panel and the public, with CASAC concluding that the general assessment methodology and framework were appropriate (Hopke, 2002).

conclusions presented in the Criteria Document, that while important uncertainties and research questions remain, much progress has been made since the last review in reducing some key uncertainties related to our understanding of the scientific evidence. The newly available information generally reinforces and provides increased confidence in the likely causal nature of the associations between short- and long-term exposure to $PM_{2.5}$ and mortality and morbidity effects observed in the last review, and provides additional information to inform judgments as to the extent to which such associations likely remain at lower exposure levels within the range of ambient air quality.

The examination of short- and long-term exposures to specific components, properties, and sources of fine particles and mixtures of fine particles with gaseous co-pollutants that are linked with health effects, and the biological mechanisms underlying the observed linkages, remain important research needs. Other important research needs include better characterizing the shape of concentration-response functions, including identification of potential threshold levels, and methodological issues such as those associated with selecting appropriate statistical models in time-series studies to address time-varying factors (such as weather) and other factors (such as other pollution variables), and better characterizing population exposures.

Nonetheless, important progress has been made in advancing our understanding of potential mechanisms by which ambient $PM_{2.5}$, alone and in combination with other pollutants, is causally linked with cardiovascular, respiratory, and lung cancer associations observed in epidemiologic studies. Due to reanalyses and extensions of key long-term exposure studies, there is now greater confidence in the causal nature of associations with long-term exposures to fine particles than in the last review. There is also an increased understanding of the populations that are the most susceptible to $PM_{2.5}$-related effects. In addition, health effect associations reported in epidemiologic studies have been found to be generally robust to confounding by co-pollutants, especially for the more numerous short-term exposure studies. Further, while groups of commenters had differing views on the extent to which, if at all, newly available evidence increases confidence in associations between $PM_{2.5}$ and mortality and morbidity effects, and on the extent of progress that has been made in reducing uncertainties since the last review, virtually no commenters argued for any relaxation of the current $PM_{2.5}$ standards. Based on these considerations, EPA finds that overall the available evidence has increased the scientific basis supporting the health impacts of exposure to $PM_{2.5}$, and not lessened it, providing clear support for fine particle standards that are at least as protective as the current $PM_{2.5}$ standards.

Having reached this initial conclusion, EPA addresses the question whether the available evidence supports consideration of standards that are more protective than the current $PM_{2.5}$ standards. In considering this question, EPA first notes that the current standards were set as a suite that together would most effectively and efficiently protect the public against health effects related to both short- and long-term exposures to fine particles (62 FR at 38669). In so doing, the Agency set the annual standard to be the "generally controlling" standard for lowering both short- and long-term $PM_{2.5}$ concentrations. In conjunction with such an annual standard, the current 24-hour standard was set to provide only supplemental protection against days with high peak $PM_{2.5}$ concentrations, localized "hotspots," or risks arising from seasonal emissions that might not be well controlled by a national annual standard. As discussed below in section II.F, in considering what evidence to use as the basis for the 1997 annual standard, EPA placed greater emphasis on the short-term exposure studies, which were judged to be the strongest evidence at that time. The long-term exposure studies available at that time provided only supporting evidence for the annual standard, which was set primarily based on short-term exposure studies.

In addressing the question whether the evidence now available in this review supports consideration of standards that are more protective than the current $PM_{2.5}$ standards, the Staff Paper considered whether (1) statistically significant health effects associations with short-term exposures to fine particles occur in areas that would likely meet the current $PM_{2.5}$ standards, or (2) associations with long-term exposures to fine particles extend down to lower air quality levels than had previously been observed.[11]

In considering the available epidemiologic evidence in this review to address the question of whether more protective standards should be considered, the Staff Paper took a broader approach than was used in the last review. This approach reflects the more extensive and stronger body of evidence now available on health effects related to both short- and long-term exposure to $PM_{2.5}$, and places relatively greater emphasis on evidence from long-term exposure studies than was done in the last review. As discussed below in section II.F, this broader approach was used at the time of proposal to consider the much expanded body of evidence from short-term exposure studies as the principal basis for setting the 24-hour standard to protect against health effects associated with short-term exposures to $PM_{2.5}$, and to consider the stronger and more robust body of evidence from long-term exposure $PM_{2.5}$ studies as the principal basis for setting the annual standard to protect against health effects associated with long-term exposures to $PM_{2.5}$.

In first considering whether areas in which short-term exposure studies have been conducted would likely meet the current $PM_{2.5}$ standards, the focus is principally on comparing the long-term average $PM_{2.5}$ concentration in a study area with the level of the current "generally controlling" annual $PM_{2.5}$ standard. In considering the available epidemiologic evidence related to short-term exposures, the Staff Paper focused on specific epidemiologic studies that show statistically significant associations between $PM_{2.5}$ and health effects for which the Criteria Document judged associations with $PM_{2.5}$ to be likely causal (EPA, 2005, section 5.3.1.1). Many more U.S. and Canadian studies are now available that provide evidence of associations between short-term exposure to $PM_{2.5}$ and serious health effects in areas with air quality at and above the level of the current annual $PM_{2.5}$ standard (15 $\mu g/m^3$). Moreover, a few newly available short-term exposure mortality studies provide evidence of statistically significant associations with $PM_{2.5}$ in areas with air quality levels below the levels of the current $PM_{2.5}$ standards. In considering these studies, the Staff Paper focused on those that include adequate gravimetric $PM_{2.5}$ mass measurements, and noted where the associations are generally robust to alternative model specification and to the inclusion of potentially confounding co-pollutants. Three

[11] In addressing this question, the Criteria Document had recognized that although there are likely biologic threshold levels in individuals for specific health responses, the available epidemiologic evidence neither supports nor refutes the existence of thresholds at the population level for the effects of $PM_{2.5}$ on mortality across the range of concentrations in the studies, for either long-term or short-term $PM_{2.5}$ exposures (EPA, 2004a, section 9.2.2.5).

studies, conducted in Phoenix (Mar *et al.*, 2003), Santa Clara County, CA [Fairley, 2003] and eight Canadian cities [Burnett and Goldberg, 2003], report statistically significant associations between short-term $PM_{2.5}$ exposure and total or cardiovascular mortality in areas in which long-term average $PM_{2.5}$ concentrations ranged between 13 and 14 $\mu g/m^3$ and 98th percentile 24-hour concentrations ranged between 32 and 59 $\mu g/m^3$.[12]

In also considering the new epidemiologic evidence available from U.S. and Canadian studies of long-term exposure to fine particles, the Criteria Document noted that new studies have built upon studies available in the last review and concluded that these studies have confirmed and strengthened the evidence of associations for both mortality and respiratory morbidity (EPA, 2004a, section 9.2.3). For mortality, the Criteria Document placed greatest weight on the reanalyses and extensions of the Six Cities and ACS studies, finding that these studies provide strong evidence for associations with fine particles (EPA, 2004a, p. 9–34), notwithstanding the lack of consistent results in other long-term exposure studies. For morbidity, the Criteria Document found that new studies of a cohort of children in Southern California have built upon earlier limited evidence to provide fairly strong evidence that long-term exposure to fine particles is associated with development of chronic respiratory disease and reduced lung function growth (EPA, 2004a, pp. 9–33 to 9–34). In addition to strengthening the evidence of association, the new extended ACS mortality study [Pope *et al.*, 2002) observed statistically significant associations with cardiorespiratory mortality (including lung cancer mortality) across a range of long-term mean $PM_{2.5}$ concentrations that was lower than was reported in the original ACS study available in the last review.

Beyond the epidemiologic studies using $PM_{2.5}$ as an indicator of fine particles, a large body of newly available evidence from studies that used PM_{10} in areas where fine particles would likely dominate this measurement, as well as other indicators or components of fine particles [e.g., sulfates, combustion-related components], provides additional support for the conclusions reached in the last review as to the likely causal role of ambient PM, and the likely importance of fine particles in contributing to observed health effects. Such studies notably include new multi-city studies, intervention studies [that relate reductions in ambient PM to observed improvements in respiratory or cardiovascular health], and source-oriented studies [e.g., suggesting associations with combustion- and vehicle-related sources of fine particles]. The Criteria Document also noted that new epidemiologic studies of asthma-related increased physician visits and symptoms, as well as new studies of cardiac-related risk factors, suggest likely much larger public health impacts due to ambient fine particles than just those indexed by the mortality and morbidity effects considered in the last review [EPA, 2004a, p. 9–94].

In reviewing this information, the Staff Paper recognized that important limitations and uncertainties associated with this expanded body of evidence for $PM_{2.5}$ and other indicators or components of fine particles need to be carefully considered in determining the weight to be placed on the body of studies available in this review. For example, the Criteria Document noted that although PM-effects associations continue to be observed across most new studies, the newer findings do not fully resolve the extent to which the associations are properly attributed to PM acting alone or in combination with other gaseous co-pollutants or to the gaseous co-pollutants themselves. The Criteria Document concluded, however, that overall the newly available epidemiologic evidence, especially for the more numerous short-term exposure studies, substantiates that associations for various PM indicators with mortality and morbidity are robust to confounding by co-pollutants (EPA, 2004a, p. 9–37).

While the limitations and uncertainties in the available evidence suggest caution in interpreting the epidemiologic studies at the lower levels of air quality observed in the studies, the Staff Paper concluded that the evidence now available provides strong support for considering fine particle standards that would provide increased protection beyond that afforded by the current $PM_{2.5}$ standards. The Staff Paper noted that a more protective suite of $PM_{2.5}$ standards would reflect the generally stronger and broader body of evidence of associations with mortality and morbidity now available in this review, both in short-term exposue studies at levels below the current standards and in long-term exposure studies that extend to lower levels of air quality than in earlier studies, as well as increased understanding of possible underlying mechanisms.

In addition to this evidence-based evaluation, the Staff Paper also considered the extent to which health risks estimated to occur upon attainment of the current $PM_{2.5}$ standards may be judged to be important from a public health perspective, taking into account key uncertainties associated with the quantitative health risk estimates, noted above in section II.A.3. In so doing, the Staff Paper first noted that the risk assessment addressed several key uncertainties through various base case analyses, as well as through sensitivity analyses, as noted above in section II.A.3 and discussed in section II.B of the proposal [71 FR 2637–2641]. In considering the health risks estimated to occur upon attainment of the current $PM_{2.5}$ standards, the Staff Paper focused in particular on a series of base case risk estimates, while recognizing that the confidence ranges in the selected base case estimates do not reflect all the identified uncertainties. These risks were estimated using not only the linear or log-linear concentration-response functions reported in the studies,[13] but also using alternative modified linear functions as surrogates for assumed non-linear functions that would reflect the possibility that thresholds may exist in the reported associations within the range of air quality observed in the studies. Regardless of the relative weight placed on the risk estimates associated with the concentration-response functions reported in the studies or with the modified functions favored by CASAC [discussed above in section II.A.3], the risk assessment indicated the possibility that thousands of premature deaths per year would occur in urban areas across the U.S. upon attainment of the current $PM_{2.5}$

[12] As noted in the Staff Paper, these studies were reanalyzed to address questions about the application of the statistical software used in the original analyses, and the study results from Phoenix and Santa Clara County were little changed in alternative models [Mar *et al.*, 2003; Fairley, 2003], although Burnett and Goldberg [2003] reported that their results were sensitive to using different temporal smoothing methods. Two of these studies also reported significant associations with gaseous pollutants [Mar *et al.*, 2003; Fairley, 2003], and one of these studies included multi-pollutant model results in reanalyses, reporting that associations with $PM_{2.5}$ remained significant with gaseous pollutants [Fairley, 2003]. The 98th percentile 24-hour concentrations were approximately 59 $\mu g/m^3$ in Fairley *et al.* [2003], 39 $\mu g/m^3$ in Burnett and Goldberg [2003], and 32 $\mu g/m^3$ in Mar *et al.* [2003].

[13] As noted in section II.B of the proposal, the reported linear or log-linear concentration-response functions were applied down to 7.5 $\mu g/m^3$ in estimating risk associated with long-term exposure [i.e., the lowest measured level in the extended ACS study], and down to the estimated policy-relevant background level in estimating risk associated with short-term exposure [i.e., 3.5 $\mu g/m^3$ for eastern urban areas and 2.5 $\mu g/m^3$ for western urban areas].

standards.[14] Beyond the estimated incidences of premature mortality, the Staff Paper also recognized that similarly substantial numbers of incidences of hospital admissions, emergency room visits, aggravation of asthma and other respiratory symptoms, and increased cardiac-related risk are also likely in many urban areas, based on risk assessment results (EPA, 2005, Chapter 4) and on the discussion related to this "pyramid of effects" in the Criteria Document (EPA, 2004a, section 9.2.5). Based on these considerations, the Staff Paper concluded that the estimates of risks likely to remain upon attainment of the current $PM_{2.5}$ standards are indicative of risks that can reasonably be judged to be important from a public health perspective (EPA, 2005, section 5.3.1.).

In considering available evidence, risk estimates, and related limitations and uncertainties, the Staff Paper concluded that the available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards and provides strong support for revising the current suite of $PM_{2.5}$ standards to provide increased public health protection. Also, taking into account these considerations, the CASAC advised the Administrator that a majority of CASAC Panel members were in agreement that the primary 24-hour and annual $PM_{2.5}$ standards "should be modified to provide increased public health protection" (Henderson, 2005a). The CASAC further advised that changes to either the annual standard or the 24-hour standard, or both, could be recommended, and expressed reasons that formed the basis for the consensus among the Panel members for placing more emphasis on lowering the 24-hour standard (Henderson, 2005a).[15]

At the time of proposal, in considering whether the suite of $PM_{2.5}$ standards should be revised to provide requisite public health protection, the Administrator carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator placed primary consideration on the evidence obtained from the studies, and provisionally found the evidence of serious health effects reported in short-term exposure studies conducted in areas that would attain the current standards to be compelling, especially in light of the extent to which such studies are part of an overall pattern of positive and frequently statistically significant associations across a broad range of studies that collectively represent a strong and robust body of evidence. As discussed in the Criteria Document and Staff Paper, the Administrator recognized that much progress has been made since the last review in addressing some of the key uncertainties that were important considerations in establishing the current suite of $PM_{2.5}$ standards. For example, progress made since the last review provides increased confidence in the long-term exposure studies as a basis for considering whether any revision of the annual standard is appropriate and increased confidence in the short-term exposure studies as a basis for considering whether any revision of the 24-hour standard is appropriate.[16] In considering the risk assessment presented in the Staff Paper, the Administrator noted that the assessment contained a sensitivity analysis but not a formal uncertainty analysis, making it difficult to use the risk assessment to form a judgment of the probability of various risk estimates. Instead, the Administrator viewed the risk assessment in light of his evaluation of the underlying studies. Seen in this light, the risk assessment informs the determination of the public health significance of risks to the extent that the evidence is judged to support an effect at a particular level of air quality. Based on these considerations, the Administrator provisionally concluded that the current $PM_{2.5}$ standards, taken together, are not requisite to protect public health with an adequate margin of safety and that revision is needed to provide increased public health protection.

2. Comments on the Need for Revision

General comments based on relevant factors that either support or oppose any change to the current suite of $PM_{2.5}$ primary standards are addressed in this section. Comments on specific short- and long-term exposure studies that relate to consideration of the appropriate levels of the 24-hour and annual $PM_{2.5}$ standards are addressed below in sections II.F.1 and II.F.2, respectively. General comments based on implementation-related factors that are not a permissible basis for considering the need to revise the current standards are addressed in the Response to Comments document.

Many public comments received on the proposal asserted that the current $PM_{2.5}$ standards are insufficient to protect public health with an adequate margin of safety and revisions to the standards are appropriate. Among those calling for revisions to the current standards are medical groups, including the American Medical Association, the American Thoracic Society, the American Academy of Pediatrics, and the American College of Cardiology, as well as medical doctors and academic researchers. For example, the American Medical Association stated that PM air pollution is "a national public health problem" and supported more stringent standards based on studies that provide evidence of associations between $PM_{2.5}$ and serious health effects in areas with $PM_{2.5}$ concentrations that are below the 1997 standards. Other medical associations offered the following views in support of more protective standards:

> As professional organizations that represent physicians treating patients with diseases either caused by or exacerbated by air pollution, we are keenly aware of the impact air quality has on the individual health of our patients. As such we are committed to supporting a standard for PM that is protective of the health of vulnerable populations including children, seniors and patients with respiratory and cardiac conditions * * *. In short, a significant body of research has described potential mechanisms for and the range of health effects caused by PM air pollution. The undersigned physician organizations find the body of scientific evidence to be rigorous, comprehensive and compelling enough to justify a significant tightening of the existing NAAQS PM standards. [American Thoracic Society et al.]

In a letter signed from environmental health researchers and physicians, similar conclusions were drawn:

> More than 2,000 peer-reviewed studies have been published since 1996 * * *. These studies, as discussed and interpreted in the 2004 EPA Criteria Document, validate earlier epidemiologic studies linking both acute and chronic fine particle pollution with serious morbidity and mortality. The newer research has also expanded the list of health effects associated with PM, and has identified health effects at lower exposure levels than

[14] The Staff Paper recognized how highly dependent any specific risk estimates are on the assumed shape of the underlying concentration-response functions, noting nonetheless that mortality risks are not completely eliminated when current $PM_{2.5}$ standards are met in a number of example urban areas even using the highest assumed cutpoint levels considered in the risk assessment (EPA, 2005, p. 5–15).

[15] Of the individual Panel members who submitted written comments expressing views on appropriate levels of the $PM_{2.5}$ standards, only one did not support changes to either the 24-hour or annual standard to provide additional public health protection (Henderson, 2005a).

[16] The EPA notes that this increased confidence in the long- and short-term associations generally reflects less uncertainty as to the likely causal nature of such associations, but does not address directly the question of the extent to which such associations remain toward the lower end of the range of ambient $PM_{2.5}$ concentrations. This question is central to the Agency's evaluation of the relevant evidence to determine appropriate standards levels, as discussed below in section II.F.

previously reported. In fact, the science is now sufficiently strong that it is appropriate to conclude that $PM_{2.5}$ is causally associated with numerous adverse health effects in humans, at exposure levels far below the current standards. [Schwartz *et al.*, 2005]

Similar conclusions were also reached in comments by many national, state, and local public health organizations, including, for example, the American Lung Association, the American Heart Association, the American Cancer Society, the American Public Health Association, and the National Association of Local Boards of Health, as well as in letters to the Administrator from EPA's advisory panel on children's environmental health (Children's Health Protection Advisory Committee, 2005, 2006). All of these medical and public health commenters stated that the current $PM_{2.5}$ standards need to be revised, and that even more protective standards than those proposed by EPA are needed to protect the health of sensitive population groups. Many individual commenters also expressed such views.

State and local air pollution control authorities who commented on the $PM_{2.5}$ standards supported revision of the suite of current $PM_{2.5}$ standards, as did the National Tribal Air Association. The State and Territorial Air Pollution Program Administrators and the Association of Local Air Pollution Control Officials (STAPPA/ALAPCO) urged that EPA revise the $PM_{2.5}$ standards in accordance with the recommendations of CASAC. Each of the individual State environmental/public health agencies that commented on the $PM_{2.5}$ standards supported revisions to the current standards, with most supporting standards consistent with CASAC's recommendations. The Northeast States for Coordinated Air Use Management (NESCAUM) argued for even more stringent revisions to the standards.

The commenters noted above primarily based their views on the body of evidence assessed in the Criteria Document, finding it to be stronger and more compelling than in the last review. These commenters generally placed much weight on CASAC's interpretation of the body of available evidence and the results of EPA's risk assessment, both of which formed the basis for CASAC's recommendation to revise the $PM_{2.5}$ standards to provide increased public health protection was based.

Some of these commenters specifically mentioned the independent reanalysis of the original ACS and Six Cities long-term exposure studies conducted by HEI (Krewski *et al.*, 2000) that concluded that the original data were of high quality, the original results could be fully replicated, and the results were robust to alternative model specifications. Some also mentioned the ACS extended study (Pope *et al.*, 2002) and the Southern California children's cohort study (Gauderman *et al.*, 2002) as providing evidence of mortality and morbidity effects associated with long-term exposures to $PM_{2.5}$ at lower levels than had previously been studied. A number of short-term exposure studies were also cited by some of these commenters as providing evidence of mortality and morbidity effects at levels well below the level of the current 24-hour $PM_{2.5}$ standard. In addition, many of these commenters generally concluded that progress had been made in reducing many of the uncertainties identified in the last review and in better understanding mechanisms by which $PM_{2.5}$ may be causing the observed health effects.

Some of these commenters also noted the results of EPA's risk assessment, concluding that it showed that the risks estimated to remain when the current standards are met are large and important from a public health perspective and warrant increased protection. Some of these commenters expressed the view that $PM_{2.5}$-related risks are likely larger than those estimated in EPA's risk assessment, in part because EPA based its risk assessment on the ACS extended study which had greater exposure measurement error than other studies, leading to an underestimate of the relative risk, and because EPA incorporated an assumed "cutpoint" in its assessment that is not supported by studies that find no evidence of a threshold.

In general, all of these commenters agreed on the importance of results from the large body of scientific studies reviewed in the Criteria Document and on the need to revise the suite of $PM_{2.5}$ standards as articulated in EPA's proposal, while generally differing with EPA's proposed judgments about the extent to which the standards should be revised based on this evidence. The EPA generally agrees with these commenters' conclusion regarding the need to revise the current suite of $PM_{2.5}$ standards. The scientific evidence noted by these commenters was generally the same as that assessed in the Criteria Document and the Staff Paper, and EPA agrees that this evidence provides a basis for concluding that the current $PM_{2.5}$ standards, taken together, are not adequately protective of public health. For reasons discussed below in section II.F, however, EPA disagrees with aspects of these commenters' views on the level of protection that is appropriate and supported by the available scientific information.

Some of these commenters also identified "new" studies that were not included in the Criteria Document as providing further support for the need to revise the $PM_{2.5}$ standards. As discussed above in section I.C, EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), EPA notes that its provisional assessment of "new" science found that such studies did not materially change the conclusions in the Criteria Document.

Another group of commenters representing industry associations and businesses opposed revising the current $PM_{2.5}$ standards. These views are most extensively presented in comments from the Utility Air Regulatory Group (UARG), representing a group of electric generating companies and organizations and several national trade associations, and from Pillsbury, Winthrop, Shaw and Pittman (Pillsbury *et al.*) on behalf of 19 industry and business associations (including, for example, the Alliance of Automobile Manufacturers, the American Iron and Steel Institute, the National Association of Manufacturers, the American Petroleum Institute, and the U.S. Chamber of Commerce).

These and other commenters in this group generally mentioned many of the same studies that were cited by the commenters who supported revising the standards, as well as other studies, but highlighted different aspects of these studies in reaching substantially different conclusions about their strength and the extent to which progress has been made in reducing uncertainties in the evidence since the last review. These commenters generally expressed the view that the current standards provide the requisite degree of public health protection. They then considered whether the evidence that has become available since the last review has established a more certain risk or a risk of effects that are significantly different in character to those that provided a basis for the current standards, or whether the evidence demonstrates that the risk to public health upon attainment of the current standards would be greater than

was understood when EPA established the current standards in 1997.

In supporting their view that the present suite of primary $PM_{2.5}$ standards continues to provide the requisite public health protection and should not be revised, UARG and others generally stated: (1) That the effects of concern have not changed significantly since 1997; (2) that the uncertainties in the underlying health science are as great or greater than in 1997; (3) that the estimated risk upon attainment of the current $PM_{2.5}$ standards has decreased since 1997; and (4) that "new" studies not included in the Criteria Document continue to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$. These comments are discussed in turn below.

(1) In asserting that effects of concern have not changed significantly since 1997, some of these commenters stated that more subtle physiological changes in the cardiovascular system are the only type of new PM-related effect identified in this review. They stated that such subtle effects are far less serious than the cardiovascular effects such as aggravation of cardiovascular disease that had been considered in the last review. The EPA disagrees with the assertion that subtle changes in the cardiovascular system are the only type of new PM-related effect identified in this review. Further, EPA believes that evidence of physiological changes in the cardiovascular system is important in that it increases confidence in inferences about the causal nature of the associations between fine particles and cardiovascular-related mortality and hospital admissions.

As discussed in the Criteria Document (EPA, 2004a, p. 9–75), epidemiologic studies published since the last review have expanded upon and extended the evidence examining possible links between long-term exposures to fine particles and increased risk of lung cancer incidence and mortality, which was considered to be insufficient to support such a linkage in the last review. In this review, however, the epidemiologic evidence now available "support(s) an association between long-term exposure to fine particles and lung cancer mortality; and the new toxicological studies provide credible evidence for the biological plausibility of these associations" (EPA, 2004a, p. 9–76). More specifically, the Criteria Document highlighted "the newer results of the extension of the ACS study analyses (that include more years of participant follow-up and address previous criticisms of the earlier ACS analyses), which indicate that long-term ambient PM exposures are associated with increased risk of lung cancer. That increased risk appears to be in about the same range as that seen for a nonsmoker residing with a smoker, with any consequent life-shortening due to lung cancer" (EPA 2004a, p. 9–94).

In addition, as noted earlier, the Criteria Document identified increased nonhospital medical visits (physician visits) and aggravation of asthma associated with short-term exposure to $PM_{2.5}$ as being newly identified effects since the last review, and concluded that findings of such effects "suggest likely much larger health impacts and costs to society due to ambient PM than just those indexed either by just hospital admissions/visits and/or mortality." *Id.* Further, the Criteria Document (EPA, 2004a, p. 9–79) noted that there may be PM-related health effects in infants and children, although only very limited evidence of such effects exists.

(2) In asserting that the uncertainties in the underlying health science are as great or greater than in 1997, commenters in this group variously discussed a number of issues including: The lack of demonstrated mechanisms by which $PM_{2.5}$ may be causing mortality and morbidity effects; uncertainty in the shape of the concentration-response functions; the potential for co-pollutant confounding; uncertainty in the role of individual constituents of fine particles; and the sensitivity of epidemiological results to statistical model specification. Each of these issues is addressed below. In summary, these commenters concluded that the substantial uncertainties present in the last review have not been resolved, that a previously unrecognized sensitivity to model specification has been newly identified, and/or that the uncertainty about the possible health risks associated with $PM_{2.5}$ exposure has not diminished. As discussed below, although EPA agrees that important uncertainties remain, and that future research directed toward addressing these uncertainties is warranted, EPA believes that overall uncertainty about possible health risks associated with both short- and long-term $PM_{2.5}$ exposure has diminished since the last review. As noted above, the greater confidence in short-term exposure studies supports the Administrator's increased reliance on those studies as the basis for the 24-hour standard, and greater confidence in long-term exposure studies supports the Administrator's increased reliance on those studies as the basis for the annual $PM_{2.5}$.[17]

With regard to the issue of mechanisms, these commenters noted that although EPA recognizes that new evidence is now available on potential mechanisms and plausible biological pathways, the evidence still does not resolve all questions about how $PM_{2.5}$ at ambient levels could produce the effects in question in this review. They further assert that even if more recent information has advanced our understanding of such mechanisms, it would not justify revision of the standard. The EPA notes that in the last review, the Agency considered the lack of demonstrated biologic mechanisms for the varying effects observed in epidemiologic studies to be an important caution in its integrated assessment of the health evidence, upon which the standards were based. Since the last review, there has been a great deal of research directed toward advancing our understanding of biologic mechanisms. While this research has not resolved all questions, and further research is warranted, it has provided important insights as discussed in section II.A.1 of the proposal (71 FR 2626–2627). As noted there, the findings from this new research indicate that different health responses are linked with different particle characteristics and that both individual components and complex particle mixtures appear to be responsible for many biologic responses relevant to fine particle exposures. The Criteria Document (EPA, 2004a, p. 7–206) concluded: "Thus, there appear to be multiple biologic mechanisms that may be responsible for observed morbidity/mortality due to exposure to ambient PM. It also appears that many biological responses are produced by PM whether it is composed of a single component or a complex mixture." Further, EPA believes that progress made in gaining insights into potential mechanisms lends support to the biologic plausibility of results observed in epidemiologic studies (71 FR 2636). The mechanistic evidence now available, taken together with newly available epidemiologic evidence, increases the Agency's confidence that observed associations are causal in nature, such that the risks of health effects attributed to short- and long-term exposure to $PM_{2.5}$, acting alone and/or in combination with gaseous co-pollutants, are now more

[17] As noted above, this increased confidence in the long- and short-term associations generally reflects less uncertainty as to the likely causal nature of such associations, but does not address directly the question of the extent to which such associations remain toward the lower end of the range of ambient $PM_{2.5}$ concentrations. This question is central to the Agency's evaluation of the relevant evidence to determine appropriate standards levels, as discussed below in section II.F.

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certain than was understood in the last review.

With regard to uncertainty in concentration-response functions, these commenters concluded that "because the actual shape of this function remains unknown, this uncertainty has not been reduced since 1997" (UARG, p. 17). The EPA notes that, in contrast to the last review when few studies had quantitatively assessed the form of the concentration-response function or the potential for a threshold, several new studies available in this review have used different methods to examine this question, and most have been unable to detect threshold levels in time-series mortality studies. The Criteria Document (EPA, 2004a, p. 9–44) recognized that in multi-city and most single-city time-series studies, statistical tests comparing linear and various nonlinear or threshold models have not shown statistically significant distinctions between them; where potential threshold levels have been suggested in single-city studies, they are at fairly low levels (*Id.* at p. 9–45). Further, the shape of concentration-response functions for long-term exposure to $PM_{2.5}$ was evaluated using data from the ACS cohort, with the HEI reanalysis finding near-linear increasing trends through the range of particle levels observed in this study, and the extended ACS study reporting that the various mortality associations were not significantly different from linear (71 FR 2635).[16] However, EPA agrees that uncertainties remain in our understanding of the shape of concentration-response functions, and, consistent with the conclusion in the Criteria Document, has concluded that the available evidence does not either support or refute the existence of population thresholds for effects associated with short- or long-term exposures to PM across the range of concentrations in the studies. Even while recognizing that uncertainties remain, EPA believes that our understanding of this issue for both short- and long-term exposure studies has been advanced since the last review.

With regard to co-pollutant confounding, these commenters asserted that EPA has been "dismissive" of this issue in assessing the epidemiologic evidence of associations between PM and mortality and morbidity endpoints (UARG, p. 18). These commenters asserted that EPA has inappropriately concluded that PM-related mortality and morbidity associations are generally robust to confounding, which is one of the criteria considered in drawing inferences about the extent to which observed statistical associations are likely causal in nature. The commenters focused on an examination of the extent to which statistically significant $PM_{2.5}$ associations based on one-pollutant models in a number of time-series studies, and in an analysis of associations with long-term exposures in the ACS cohort studies, often did not remain statistically significant in two-pollutant models.

In general, EPA does not believe that the examination of this issue put forward by these commenters reflects the complexities inherent in assessing the issue of co-pollutant confounding. As discussed in the proposal (71 FR 2634) and more fully in the Criteria Document (EPA, 2004a, section 8.4.3; chapter 9, section 9.2.2.2.2), although multi-pollutant models may be useful tools for assessing whether gaseous co-pollutants may be *potential* confounders, such models cannot determine whether in fact they are. Interpretation of the results of multi-pollutant models is complicated by correlations that often exist among air pollutants, by the fact that some pollutants play a role in the atmospheric reactions that form other pollutants such as secondary fine particles, and by the inherent statistical power of the studies in question. While single-city multi-pollutant models have received a great deal of attention during this review, the Criteria Document also noted several other approaches to examining the question, including a more careful examination of personal exposures to PM and co-pollutants, the use of factor or principal component analyses, and the use of intervention studies (EPA, 2004a, pp. 8–245 to 8–246). The Criteria Document also recognized that it is important to consider the issue of potential co-pollutant confounding in the context of the more recent evidence available about the biological plausibility of associations between the various pollutants and health outcomes, model specification, and exposure error (EPA, 2004a, p. 8–254).

An example of other approaches to examining potential co-pollutant confounding is the study of personal exposure to fine particles and co-pollutant gases done in Baltimore (Sarnat *et al.*, 2001). This study found that day-to-day variations in monitored ambient gases were not associated with day-to-day changes in personal exposures to those gases, but they were associated with day-to-day changes in personal exposure to $PM_{2.5}$. One reasonable interpretation of this study is that for cities like Baltimore, changes in model results when ambient gases are included in multi-pollutant models may stem from such gases being surrogates for exposures to particles and not confounders at all.

The broader examination of this issue in the Criteria Document included a focus on evaluating the stability of the size of the effect estimates in time-series studies using single- and multi-pollutant models, as illustrated in Figures 8–16 through 8–19 (EPA, 2004a, pp. 8–248 to 8–251). This examination found that for most time-series studies, there was little change in effect estimates based on single- and multi-pollutant models, although recognizing that in some cases, the PM effect estimates were markedly reduced in size and lost statistical significance in models that included one or more gaseous pollutants. The Criteria Document also noted that PM and the gaseous co-pollutants were often highly correlated, and it is generally the case that high correlations existed between pollutants where PM effect estimates were reduced in size with the inclusion of gaseous co-pollutants. With regard to the analysis of multiple pollutants from the ACS cohort, it is important to note that the effects estimates for fine particles actually increased in two pollutant models that incorporated CO, NO_2, and ozone, and were reduced only for models that incorporated SO_2. The Criteria Document recognized, however, that SO_2 is a precursor for fine particle sulfates, which complicates the interpretation of multi-pollutant model results, and that mortality may be associated with not only $PM_{2.5}$ but also with other components of the mix of ambient pollutants in this long-term exposure study.

Far from being dismissive, EPA has examined this issue in detail based on the much more extensive body of relevant evidence available in this review. This Criteria Document concluded that "the most consistent findings from amidst the diversity of multi-pollutant evaluation results for different sites is [sic] that the PM signal most often comes through most clearly." (EPA, 2004a, p. 8–254.) While acknowledging that these analyses have not fully disentangled the relative role of co-pollutants, EPA believes that this examination provides greater confidence than in the last review that

[16] In assessing such uncertainties in this review relative to the last review, EPA notes that in the last review the level of uncertainty associated with long-term exposure studies was such that they were not relied on as the primary basis for the annual standard. In the last review, relative risk estimates from long-term exposure studies were deemed "highly uncertain" (62 FR 38668) and health effects from long-term exposure were characterized as "potentially independent" (*Id.*) from those associated with short-term exposure.

observed effects can be attributed to short- and long-term exposures to $PM_{2.5}$, alone and in combination with other pollutants, while recognizing that potential confounding by co-pollutants remains a very challenging issue to address, even with well-designed studies.

With regard to questions about the role of individual constituents within the mix of fine particles, these commenters pointed out that EPA recognized this issue as an important uncertainty in the last review and did so again in this review. These commenters then expressed the view that such continued uncertainty provides no grounds for reconsidering the Agency's 1997 conclusion that the current $PM_{2.5}$ standards provide the requisite protection. As a general matter, EPA agrees that although new research directed toward this question has been conducted since the last review, important questions remain and the issue remains an important element in the Agency's ongoing research program. The EPA does not agree, however, that continued uncertainty with regard to the relative toxicity of components within the mix of fine particles, in and of itself, provides grounds for not revising the suite of $PM_{2.5}$ standards. Rather, the full body of health effects evidence that has become available since the last review provides a basis for concluding that additional public health protection is warranted to protect against health effects that have been associated with exposure to fine particles measured as $PM_{2.5}$ mass.

At the time of the last review, the Agency determined that it was appropriate to control fine particles as a group, as opposed to singling out any particular component or class of fine particles. This distinction was based largely on epidemiologic evidence of health effects using various indicators of fine particles in a large number of areas that had significant contributions of differing components or sources of fine particles, together with some limited experimental studies that provided some evidence suggestive of health effects associated with high concentrations of numerous fine particle components. In this review, as discussed in section II.D of the proposal (71 FR 2643–2645) and below in section II.C, while most epidemiologic studies continue to be indexed by $PM_{2.5}$, some epidemiologic studies also have continued to implicate various components within the mix of fine particles that have been more commonly studied (*e.g.*, sulfates, nitrates, carbon, organic compounds, and metals) as being associated with adverse effects (EPA, 2004a, p. 9–31, Table 9–3). In addition, several recent epidemiologic studies included in the Criteria Document have used $PM_{2.5}$ speciation data to evaluate associations between mortality and fine particles from different sources, and some toxicologic studies have provided evidence for effects associated with various fine particle components or size-differentiated subsets of fine particles.

The available information continues to suggest that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, effects associated with $PM_{2.5}$. Consequently, there continues to be no basis to conclude that any individual fine particle component cannot be associated with adverse health effects (EPA, 2005, p. 5–17). This information is relevant to the Agency's decision to retain PM2.5 as the indicator for fine particles (as discussed below in section II.C). The EPA also believes that it is relevant to the Agency's conclusion as to whether revision of the suite of $PM_{2.5}$ standards is appropriate. Furthermore, while there remains uncertainty about the role and relative toxicity of various components of fine PM, the current evidence continues to support the view that fine particles should be addressed as a group for purposes of public health protection, and the remaining uncertainty does not call for delaying any increase in public health protection that other evidence indicates may be warranted.

With regard to the sensitivity of epidemiologic associations to the use of different statistical models and different approaches to model specification used by researchers, these commenters identified this issue of model sensitivity as an area in which uncertainty in interpreting epidemiologic evidence has increased since the last review. Comments from UARG, Pillsbury *et al.*, the Annapolis Center and others pointed to examples where individual study results are sensitive to the use of alternative models, and to reviews that recommend further exploration of this issue in future research, as a basis for asserting that current modeling approaches are too uncertain to use the available epidemiologic studies as a basis for revising the current $PM_{2.5}$ standards. The EPA agrees that recent work on model sensitivity has raised new concerns and the Agency has given much attention to this issue. In so doing, EPA recognizes, as does the HEI and other researchers, that there is no clear consensus at this time as to what constitutes appropriate control of weather and temporal trends in time-series studies, and that no single statistical modeling approach is likely to be most appropriate in all cases (EPA 2004a, p. 8–238).

While recognizing the need for further research on this issue, EPA believes that the body of time-series epidemiologic studies considered in this review[19] provides an appropriate basis for informing the Agency's decisions on whether to revise the 24-hour $PM_{2.5}$ standard, consistent with the conclusion of the HEI review panel ["* * * the revised findings will continue to help inform regulatory decisions regarding PM." HEI, 2003; EPA, 2004a, p. 8–237). More specifically, as discussed in the proposal (71 FR 2633–2634), the recent time-series epidemiologic studies evaluated in the Criteria Document have included some degree of control for variations in weather and seasonal variables. However, as summarized in the HEI review panel commentary, selecting a level of control to adjust for time-varying factors, such as temperature, in time-series epidemiologic studies involves a trade-off. For example, if the model does not sufficiently adjust for the relationship between the health outcome and temperature, some effects of temperature could be falsely ascribed to the pollution variable. Conversely, if an overly aggressive approach is used to control for temperature, the result would possibly underestimate the pollution-related effect and compromise the ability to detect a small but true pollution effect (EPA, 2004a, p. 8–236; HEI, 2003, p. 266). The selection of approaches to address such variables depends in part on prior knowledge and judgments made by the investigators, for example, about weather patterns in the study area and expected relationships between weather and other time-varying factors and health outcomes considered in the study.

The HEI commentary also reached several other relevant conclusions about the reanalysis of time-series studies: upon reanalysis, the PM effect persisted in the majority of studies; in some of the large number of studies in which the PM effect persisted, the estimates of PM effects were substantially reduced; in the few studies in which further sensitivity analyses were performed, some showed marked sensitivity of the PM effect estimate to the degree of smoothing and/or the specification of

[19] As discussed in section II.A.2.a of the proposal (71 FR 2629–2630, 2633), this body of studies includes those that did not use generalized additive models or were reanalyzed to address problems with applications of statistical software used in a number of important studies, as noted above in section I.C.

weather; and, in most studies, parametric smoothing approaches used to obtain correct standard errors of the PM effect estimates produced slightly larger standard errors than with the use of generalized additive models. However, the impact of these larger standard errors on the level of statistical significance of the PM effect was minor (EPA, 2004a, pp. 8–237 to 8–238). While recognizing the need for further exploration of alternative modeling approaches for time-series analyses, the Criteria Document found that the studies included in this part of the reanalysis, in general, continued to demonstrate associations between PM and mortality and morbidity beyond those attributable to weather variables alone (EPA, 2004a, pp. 8–340, 8–341).

For long-term exposure to fine particles, the reanalysis and extended analyses of data from prospective cohort studies have shown that reported associations between mortality and long-term exposure to fine particles are robust to alternative modeling strategies (Krewski *et al.*, 2000). As stated in the reanalysis report, "The risk estimates reported by the Original Investigators were remarkably robust to alternative specifications of the underlying risk models, thereby strengthening confidence in the original findings' (Krewski *et al.*, 2000, p. 232). In the extended analysis, Krewski *et al.* (2000) did identify model sensitivities related to education level and spatial patterns in the data (*e.g.*, correlations in air pollutant concentrations between cities within a region of the country). However, these model sensitivities do not invalidate the findings of statistically significant associations between long-term exposure to $PM_{2.5}$ and mortality. For example, while the association was stronger for the subset of the ACS cohort with the least education, there was an association with cardiorespiratory mortality in the entire population.[20]

In considering these issues related to uncertainties in the underlying health science, on balance, EPA believes that the available evidence interpreted in light of these remaining uncertainties does provide increased confidence relative to the last review in the reported associations between short- and long-term $PM_{2.5}$ exposures and mortality and morbidity effects, alone and in combination with other pollutants, and generally supports stronger inferences as to the causal nature of the associations. The EPA also believes that this increased confidence, when taken in context of the entire body of available health effects evidence and in light of the evidence from short-term exposure studies of associations observed in areas meeting the current suite of $PM_{2.5}$ standards, adds support to its conclusion that the current suite of $PM_{2.5}$ standards needs to be revised to provide increased public health protection. This increased confidence also adds support to the Administrator's decision to place greater reliance on the long-term exposure studies as the basis for the annual $PM_{2.5}$ standard and to place greater reliance on the short-term exposure studies as the basis for the 24-hour $PM_{2.5}$ standard.

(3) In asserting that the estimated risk upon attainment of the current $PM_{2.5}$ standards has decreased since 1997 (UARG, p. 23), these commenters compared results of EPA's risk assessment done in the last review with those from the Agency's risk assessment done as part of this review, and they concluded that risks upon attainment of the current $PM_{2.5}$ standards "are almost surely far below those that were predicted in 1997" (UARG, p. 25). These commenters used this conclusion as the basis for a claim that there is no reason to revise the current $PM_{2.5}$ standards. In particular, UARG and other commenters claimed that based on this purported reduction in risk estimates EPA cannot reconcile a decision to provide a greater level of health protection now than that afforded by the current standards with the "not lower or higher than is necessary" standard articulated by the Supreme Court in *Whitman*.

The EPA believes that this claim is fundamentally flawed for three reasons, as discussed in turn below: (i) It mischaracterizes the use of the quantitative risk assessment in the 1997 rulemaking; (ii) it is factually incorrect in comparing the quantitative risks estimated in 1997 with those estimated in the current rulemaking; and (iii) it fails to take into account that with similar risks, increased certainty in the risks presented by $PM_{2.5}$ implies greater concern than in the last review.

First, this claim mischaracterizes EPA's use of the risk assessment in 1997 in part by not recognizing that the illustrative risk assessment conducted for portions of two cities (Philadelphia and Los Angeles) in the last review was only used qualitatively to assess the need to revise the then-current PM_{10} standards. The EPA used the 1997 risk assessment estimates to confirm the conclusions drawn primarily from the epidemiological studies that ambient $PM_{2.5}$ levels allowed under the then current PM_{10} standards presented a serious public health problem. EPA did not use it as a basis for selecting the level of the 1997 PM standards. See 62 *FR* at 38656, 65; *ATA III*, 283 F. 3d at 373–74 (noting that EPA did not base the level of the standards on the numerical results of the risk assessment). In so doing, the Administrator concurred with CASAC's judgment that the quantitative risk estimates at the time were too uncertain for EPA to rely on in deciding the appropriate levels for the $PM_{2.5}$ NAAQS. Therefore, the final decision on the level of the NAAQS was not based on the absolute or relative risk reductions estimated in the quantitative risk assessment. Instead, the decision was based on a direct assessment of the available epidemiological studies and the concentration levels observed in urban areas examined in the studies where statistically significant effects had been observed. Since EPA did not rely on the 1997 quantitative risk estimates in setting the level of the 1997 standards, the 1997 estimates associated with those levels do not represent a decision on a requisite level of quantified risk from PM exposure, and therefore do not support the argument that a lower estimated risk is more than is necessary to provide the requisite level of protection. As a result, the suggested quantitative comparison between the 1997 estimates and the current estimates of risks at the levels of the current standards is not an appropriate basis for determining whether the current suite of $PM_{2.5}$ standards needs to be revised.

Second, EPA relies on the current risk estimates associated with meeting the current standards in a qualitative manner, as in 1997, to inform the conclusions drawn primarily from the epidemiological studies on whether ambient $PM_{2.5}$ levels allowed under the current suite of $PM_{2.5}$ standards present a serious public health problem warranting revision of the suite of $PM_{2.5}$ standards. The 1997 estimate of these risks, or any comparison of the 1997 risk estimates to the current estimates, are irrelevant for that purpose, as the 1997 estimates reflect an outdated analysis that has been updated in this review to reflect the current science.

Further, even if the 1997 and current risk assessments were legitimately comparable for decision-making purposes, it would still be factually

[20] More specifically, in multivariate models, the association found between mortality and long-term $PM_{2.5}$ exposure was little changed with addition of education level to the model (Krewski *et al.*, 2000, p. 184). This indicates that education level was not a confounder in the relationship between fine particles and mortality, but the relationship between fine particles and mortality is larger in the population subsets with lower education in this study and not statistically significant in the population subset with the highest education (EPA, 2004, p. 8–100).

incorrect to conclude that EPA accepted significantly greater risk in 1997 than is now estimated to be associated with the 1997 standards based on the most recent risk assessment. It is important to note that a very large proportion of the quantitative risks estimated in 1997 and today comes from long-term exposure mortality. The primary estimates from the current risk assessment (which assume a potential threshold of 10 μg/m³, as recommended by CASAC) result in residual risks in terms of percent of total incidence that are about the same in the current review as they were in the last review for both Philadelphia and Los Angeles.

Third, it is important to take into account EPA's increased level of confidence in the associations between short- and long-term $PM_{2.5}$ exposures and mortality and morbidity effects. In comparing the scientific understanding of the risk presented by exposure to $PM_{2.5}$ between the last and current reviews, one must examine not only the quantitative estimate of risk from those exposures (e.g. the numbers of premature deaths or increased hospital admissions at various levels), but also the degree of confidence that the Agency has that the observed health effects are causally linked to $PM_{2.5}$ exposure at those levels. As documented in the Criteria Document and the recommendations and conclusions of CASAC, EPA recognizes significant advances in our understanding of the health effects of $PM_{2.5}$, based on reanalyses, extended analyses and new epidemiology studies, new human and animal studies documenting effects of concentrated ambient particles, new laboratory studies identifying and investigating biological mechanisms of PM toxicity, and new studies addressing the utility of using ambient monitors to assess population exposures to particles of outdoor origin. As a result of these advances, EPA is now more certain that fine particles, alone or in combination with other pollutants, present a significant risk to public health at levels at or above the range of levels that the Agency had considered for these standards in 1997. From this more comprehensive perspective, since the risks presented by $PM_{2.5}$ are more certain and the overall current quantitative risk estimates are about the same as in 1997, $PM_{2.5}$-related risks are now of greater concern than in the last review.

In sum, quantitative risk estimates were not a basis for EPA's decision in setting a level for the $PM_{2.5}$ standards in 1997, and they do not set any quantified "benchmark" for the Agency's decision to revise the $PM_{2.5}$ standards at this time. In any case, there is not a significant difference in the risk estimates from 1997 to now. Finally, EPA believes that confidence in the causal relationships between short- and long-term exposures to fine particles and various health effects has increased markedly since 1997. Therefore, similar or even somewhat lower quantitative risk estimates today would not be a basis to conclude that no revision to the suite of $PM_{2.5}$ standards is "requisite" to protect public health with an adequate margin of safety.

[4] Some of these commenters also identified "new" studies that were not included in the Criteria Document as showing "continued erosion of the hypothesis that there is a causal connection between fine PM mass and health effects" and further supporting "the conclusion that more stringent $PM_{2.5}$ standards are not justified" [Pillsbury *et al.*, p. 14]. As discussed above in section I.C, EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review, and will consider newly published studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), EPA notes that its provisional assessment of "new" science found that such studies did not materially change the conclusions in the Criteria Document.

3. Conclusions Regarding the Need for Revision

Having carefully considered the public comments, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of $PM_{2.5}$ reached in the Criteria Document and Staff Paper, discussed above in section II.B.1, remain valid. In considering whether the suite of primary $PM_{2.5}$ standards should be revised, the Administrator places primary consideration on the evidence obtained from the epidemiologic studies, and finds the evidence of serious health effects reported in short-term exposure studies conducted in areas that would meet the current suite of $PM_{2.5}$ standards to be compelling, especially in light of the extent to which such studies are part of an overall pattern of positive and frequently statistically significant associations across a broad range of studies. The Administrator believes that this literature collectively represents a strong and generally robust body of evidence of serious health effects associated with both short- and long-term exposures to $PM_{2.5}$. Further, the Administrator believes that the increased confidence in the evidence of health effects associated with long-term exposure to $PM_{2.5}$ supports relying on long-term exposure studies as the basis for setting the annual standard in this review. This is in contrast to 1997 when EPA relied primarily on evidence from the then-available short-term exposure studies as the primary basis for setting the annual standard. As discussed in the Criteria Document and Staff Paper, the Administrator believes that much progress has been made since the last review in reducing some of the major uncertainties that were important considerations in establishing the current suite of $PM_{2.5}$ standards.

Extensive critical review of this body of evidence, the quantitative risk assessment, and related uncertainties during the criteria and standards review process, including review by CASAC and the public of the basis for EPA's proposed decision to revise the suite of primary $PM_{2.5}$ standards, has identified a number of issues about which different reviewers disagree and for which additional research is warranted. Nonetheless, on balance, the Administrator believes that the remaining uncertainties in the available evidence do not diminish confidence in the associations between serious mortality and morbidity effects and exposure to fine particles, in particular as reported in peer-reviewed short-term exposure studies at levels allowed by the current standards. In this regard, the Administrator agrees with CASAC and the majority of public commenters that revision of the current suite of $PM_{2.5}$ standards to provide increased public health protection is both appropriate and necessary. Based on these considerations, the Administrator concludes that the current suite of primary $PM_{2.5}$ standards, taken together, is not sufficient and thus not requisite to protect public health with an adequate margin of safety, and that revision is needed to provide increased public health protection.

It is important to note that this conclusion, and the reasoning on which it is based, do not address the question of what specific revisions are appropriate. That requires looking specifically at the current indicator, averaging time, form, and level of the 24-hour and annual $PM_{2.5}$ standards, and evaluating the evidence relevant to determining whether any of those elements should be revised. The analyses discussed above concerning the need to revise the current standards

go no further than determining whether the evidence, taken as a whole, indicates that greater public health protection is needed than that provided by the current suite of $PM_{2.5}$ standards.

C. Indicator for Fine Particles

In 1997, EPA established $PM_{2.5}$ as the indicator for fine particles. In reaching this decision, the Agency first considered whether the indicator should be based on the mass of a size-differentiated sample of fine particles or on one or more components within the mix of fine particles. Second, in establishing a size-based indicator, a size cut needed to be selected that would appropriately distinguish fine particles from particles in the coarse mode.

In addressing the first question in the last review, EPA determined that it was appropriate to control fine particles as a group, as opposed to singling out any particular component or class of fine particles. Community health studies had found significant associations between various indicators of fine particles (including $PM_{2.5}$ or PM_{10} in areas dominated by fine particles) and health effects in a large number of areas that had significant mass contributions of differing components or sources of fine particles, including sulfates, wood smoke, nitrates, secondary organic compounds and acid sulfate aerosols. In addition, a number of animal toxicologic and controlled human exposure studies had reported health effects associations with high concentrations of numerous fine particle components (*e.g.*, sulfates, nitrates, transition metals, organic compounds), although such associations were not consistently observed. It also was not possible to rule out any component within the mix of fine particles as not contributing to the fine particle effects found in epidemiologic studies. For these reasons, EPA concluded that total mass of fine particles was the most appropriate indicator for fine particle standards rather than an indicator based on PM composition (62 FR 38667).

Having selected a size-based indicator for fine particles, the Agency then based its selection of a specific size cut on a number of considerations. In focusing on a size cut within the size range of 1 to 3 μm (*i.e.*, the intermodal range between fine and coarse mode particles), the Agency noted that the available epidemiologic studies of fine particles were based largely on $PM_{2.5}$; only very limited use of PM_1 monitors had been made. While it was recognized that using PM_1 as an indicator of fine particles would exclude the tail of the coarse mode in some locations, in other locations it would miss a portion of the fine PM, especially under high humidity conditions, which would result in falsely low fine PM measurements on days with some of the highest fine PM concentrations. The selection of a 2.5 μm size cut reflected the regulatory importance that was placed on defining an indicator for fine particle standards that would more completely capture fine particles under all conditions likely to be encountered across the U.S., especially when fine particle concentrations are likely to be high, while recognizing that some small coarse particles would also be captured by $PM_{2.5}$ monitoring. Thus, EPA's selection of 2.5 μm as the size cut for the fine particle indicator was based on considerations of consistency with the epidemiologic studies, the regulatory importance of more completely capturing fine particles under all conditions, and the potential for limited intrusion of coarse particles in some areas; it also took into account the general availability of monitoring technology (62 FR 38668).

In this current review, the same considerations continue to apply for selection of an appropriate indicator for fine particles. As an initial matter, the available epidemiologic studies linking mortality and morbidity effects with short- and long-term exposures to fine particles continue to be largely indexed by $PM_{2.5}$. Some epidemiologic studies also have continued to implicate various components within the mix of fine particles that have been more commonly studied (*e.g.*, sulfates, nitrates, carbon, organic compounds, and metals) as being associated with adverse effects (EPA, 2004a p. 9–31, Table 9–3). In addition, several recent studies have used $PM_{2.5}$ speciation data to evaluate the association between mortality and particles from different sources (Schwartz, 2003; Mar *et al.*, 2003; Tsai *et al.*, 2000; EPA, 2004a, section 8.2.2.5). Schwartz (2003) reported statistically significant associations for mortality with factors representing fine particles from traffic and residual oil combustion that were little changed in reanalysis to address statistical modeling issues, and also an association between mortality and coal combustion-related particles that was reduced in size and lost statistical significance in reanalysis. In Phoenix, significant associations were reported between mortality and fine particles from traffic emissions, vegetative burning, and regional sulfate sources that remained unchanged in reanalysis models (Mar *et al.*, 2003).[21] Finally, a small study in three New Jersey cities reported significant associations between mortality and fine particles from industrial, oil burning, motor vehicle and sulfate aerosol sources, though the results were somewhat inconsistent between cities (Tsai *et al.*, 2000).[22] No significant increase in mortality was reported with a source factor representing crustal material in fine particles (EPA, 2004a, p. 8–85). Recognizing that these three studies represent a very preliminary effort to distinguish effects of fine particles from different sources, and that the results are not always consistent across the cities, the Criteria Document found that these studies indicate that exposure to fine particles from combustion sources, but not crustal material, is associated with mortality (EPA, 2004a, p. 8–77). Animal toxicologic and controlled human exposure studies have continued to link a variety of PM components or particle types (*e.g.*, sulfates, notably primary metal sulfate emissions from residual oil burning, metals, organic constituents, bioaerosols, diesel particles) with health effects, though often at high concentrations (EPA, 2004a, section 7.10.2). In addition, some recent studies have suggested that the ultrafine subset of fine particles (generally including particles with a nominal aerodynamic diameter less than 0.1 μm) may also be associated with adverse effects (EPA, 2004a, pp. 8–67 to 8–68).

The Criteria Document recognized that, for a given health response, some fine particle components are likely to be more closely linked with that response than others. The presumption that different PM constituents may have differing biological responses is toxicologically plausible and an important source of uncertainty in interpreting such epidemiologic evidence. For specific effects there may be stronger correlation with individual PM components than with aggregate particle mass. In addition, particles or particle-bound water can act as carriers to deliver other toxic agents into the respiratory tract, suggesting that

[21] Mar *et al.* (2006) noted that sulfate alone in a single-pollutant model was not associated with cardiovascular mortality, but that the sulfate "factor," which was so associated, contained elevated levels of lead and bromine. The authors state that the health association with the sulfate (S) factor "may be reflective of the contribution of Pb [lead] and Br [bromine] to the S factor." Mar *et al.* (2003) did not provide information about single-pollutant analysis of sulfate or about contribution of Pb and Br to the S factor.

[22] More specifically, statistically significant associations were reported with factors representing fine particles from oil burning, industrial and sulfate aerosol sources in Newark and with particles from oil burning and motor vehicle sources in Camden, and no statistically significant associations were reported in Elizabeth.

exposure to particles may elicit effects that are linked with a mixture of components more than with any individual PM component (EPA, 2004a, section 9.2.3.1.3).

Thus, epidemiologic and toxicologic studies have provided evidence for effects associated with various fine particle components or size-differentiated subsets of fine particles. The Criteria Document concluded: "These studies suggest that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, mortality, either independently or in combinations" (EPA, 2004a, p. 9–31). Conversely, the Criteria Document provided no basis to conclude that any individual fine particle component cannot be associated with adverse health effects (EPA, 2005, p. 5–17). In short, there is not sufficient evidence that would lead toward the selection of one or more PM components as being primarily responsible for effects associated with fine particles, nor is there sufficient evidence to suggest that any component should be eliminated from the indicator for fine particles. The Staff Paper continued to recognize the importance of an indicator that not only captures all of the most harmful components of fine particles (i.e., an effective indicator), but also emphasizes control of those constituents or fractions, including sulfates, transition metals, and organics that have been associated with health effects in epidemiologic and/or toxicologic studies, and is thus most likely to result in the largest risk reduction (i.e., an efficient indicator). Taking into account the above considerations, the Staff Paper concluded that it remains appropriate to control fine particles as a group; i.e., that total mass of fine particles is the most appropriate indicator for fine particle standards (EPA, 2005, p. 5–17).

With regard to an appropriate size cut for a size-based indicator of total fine particle mass, the Criteria Document concluded that advances in our understanding of the characteristics of fine particles continue to support the use of particle size as an appropriate basis for distinguishing between these subclasses, and that a nominal size cut of 2.5 μm remains appropriate (EPA, 2004a, p. 9–22). This conclusion followed from a recognition that within the intermodal range of 1 to 3 μm there is no unambiguous definition of an appropriate size cut for the separation of the overlapping fine and coarse particle modes. Within this range, the Staff Paper considered size cuts of both 1 μm and 2.5 μm. Consideration of these two size cuts took into account that there is generally very little mass in this intermodal range, although in some circumstances (e.g., windy, dusty areas) the coarse mode can extend down to and below 1 μm, whereas in other circumstances (e.g., high humidity conditions, usually associated with very high fine particle concentrations) the fine mode can extend up to and above 2.5 μm. The same considerations that led to the selection of 2.5 μm size cut in the last review—that the epidemiologic evidence was largely based on $PM_{2.5}$ and that it was more important from a regulatory perspective to capture fine particles more completely under all conditions likely to be encountered across the U.S. (especially when fine particle concentrations are likely to be high) than to avoid some coarse-mode intrusion into the fine fraction in some areas—led to the same recommendation in the Staff Paper (EPA, 2005, p. 5–18), which was endorsed by CASAC in its recommendations for $PM_{2.5}$ standards (Henderson, 2005a, p. 6). In addition, the Staff Paper recognized that particles can act as carriers of water, oxidative compounds, and other components into the respiratory system, which adds to the importance of ensuring that larger accumulation-mode particles are included in the fine particle size cut (EPA, 2005, p. 5–18).

Consistent with the Staff Paper and CASAC recommendations, the Administrator proposed to retain $PM_{2.5}$ as the indicator for fine particles. Further, the Administrator provisionally concluded that currently available studies do not provide a sufficient basis for supplementing mass-based fine particle standards with standards for any specific fine particle component or subset of fine particles, or for eliminating any individual component or subset of components from fine particle mass standards. Addressing the current uncertainties in the evidence of effects associated with various fine particle components and types of source categories is an important element in EPA's ongoing PM research program.

In so doing, the Administrator also noted that some commenters had expressed views about the importance of evaluating health effect associations with various fine particle components and types of source categories as a basis for focusing ongoing and future research to reduce uncertainties in this area and for considering whether alternative indicator(s) are now or may be appropriate for standards intended to protect against the array of health effects that have been associated with fine particles as indexed by $PM_{2.5}$. Information from such studies could also help inform the development of strategies that emphasize control of specific types of emission sources so as to address particles of greatest concern to public health. While recognizing that the studies evaluated in the Criteria Document provided some limited evidence of such associations that is helping to focus research activities, the Administrator solicited broad public comment on issues related to studies of fine particle components and types of source categories and their usefulness as a basis for consideration of alternative indicator(s) for fine particle standards. In general, comment was solicited on relevant new published research, recommendations for studies that would be appropriate for inclusion in future research activities, and approaches to assessing the available and future research results to determine whether alternative indicators for fine particles are warranted to provide effective protection of public health from effects associated with long- and short-term exposure to ambient fine particles (71 FR at 2645). More specifically, the proposal solicited comment on a number of related issues, including the extent to which reducing particular types of PM (differentiated by either size or chemistry) might alter the size and toxicity of remaining particles; the extent to which fine particles in urban and rural areas can be differentiated by size or chemistry; the extent to which the latest scientific information can be used to improve our understanding of the relationship of monitored pollution levels to human exposure; and on studies using concentrated ambient particles (CAPs) and their use in examining the toxicity of specific mixtures of pollutants or of particular source categories.

The EPA received comparatively few public comments on issues related to the indicator for fine particles.[22] Public comments from all major public and private sector groups received on the proposal were overwhelmingly in favor of EPA's proposal to retain $PM_{2.5}$ as the indicator for fine particles. Commenters who supported retaining $PM_{2.5}$ as an indicator argued that current scientific evidence does not identify specific components or sources of concern and therefore, that a mass-based indicator remains the appropriate indicator for fine particles (Engine Manufacturers Association; American Lung Association *et al.*). Some commenters emphasized the need to conduct additional research to more fully

[22] No public comments were submitted regarding the use of a different size for fine particles.

understand the effect of specific PM components and/or sources on public health. For example, the Electric Power Research Institute highlighted specific new research studies that had been completed since the close of the Criteria Document addressing issues related to fine particle components and source apportionment, and noted its ongoing research on component-related health effects that includes coordinated epidemiology, toxicology, and exposure assessment studies. The Administrator recognizes the work of the Electric Power Research Institute and agrees that additional research is important to improve future understanding of the role of specific fine particle components and/or sources of fine particles. The Administrator also recognizes the ongoing efforts of HEI to conduct additional multidisciplinary research targeted at expanding the available data on the health effects associated with specific PM components (HEI, 2005).

Having considered the public comments on this issue, the Administrator concurs with the Staff Paper and CASAC recommendations and concludes that it is appropriate to retain $PM_{2.5}$ as the indicator for fine particles.

D. Averaging Time of Primary $PM_{2.5}$ Standards

In the last review, EPA established two $PM_{2.5}$ standards, based on annual and 24-hour averaging times, respectively (62 FR 38668–70). This decision was based in part on evidence of health effects related to both short-term (from less than 1 day to up to several days) and long-term (from a year to several years) measures of PM. The EPA noted that the large majority of community epidemiologic studies reported associations based on 24-hour averaging times or on multiple-day averages. Further, EPA noted that a 24-hour standard could also effectively protect against episodes lasting several days, as well as providing some degree of protection from potential effects associated with shorter duration exposures. The EPA also recognized that an annual standard would provide effective protection against both annual and multi-year, cumulative exposures that had been associated with an array of health effects, and that a much longer averaging time would complicate and unnecessarily delay control strategies and attainment decisions. The EPA considered the possibility of seasonal effects, although the very limited available evidence of such effects and the seasonal variability of sources of fine particle emissions across the country did not provide an adequate basis for establishing a seasonal averaging time.

In considering whether the information available in this review supported consideration of different averaging times for $PM_{2.5}$ standards, the Staff Paper concluded that the available information is generally consistent with and supportive of the conclusions reached in the last review to set $PM_{2.5}$ standards with both annual and 24-hour averaging times. In considering the new information, the Staff Paper made the following observations (EPA, 2005, section 5.3.3):

(1) There is a growing body of studies that provide additional evidence of effects associated with exposure periods shorter than 24-hours (e.g., one to several hours) (EPA, 2004a, section 3.5.5.1). While the Staff Paper concluded that this information remains too limited to serve as a basis for establishing a shorter-than-24-hour fine particle primary standard at this time, it also noted that this information gives added weight to the importance of a standard with a 24-hour averaging time.

(2) Some recent PM_{10} studies have used a distributed lag over several days to weeks preceding the health event, although this modeling approach has not been extended to studies of fine particles (EPA, 2004a, section 3.5.5). While such studies continue to suggest consideration of a multiple day averaging time, the Staff Paper noted that limiting 24-hour concentrations of fine particles will also protect against effects found to be associated with PM averaged over many days in health studies. Consistent with the conclusion reached in the last review, the Staff Paper concluded that a multiple-day averaging time would add complexity without providing more effective protection than a 24-hour average.

(3) While some newer studies have investigated seasonal effects (EPA, 2004a, section 3.5.5.3), the Staff Paper concluded that currently available evidence of such effects is still too limited to serve as a basis for considering seasonal standards.

Based on the above considerations, the Staff Paper and CASAC (Henderson, 2005a, p. 6) recommended retaining the current annual and 24-hour averaging times for $PM_{2.5}$ primary standards. The Administrator concurred with the staff and CASAC recommendations and proposed that averaging times for $PM_{2.5}$ standards should continue to include annual and 24-hour averages to protect against health effects associated with short-term (hours to days) and long-term (seasons to years) exposure periods.

The EPA received very limited public comment on the issue of averaging time for the $PM_{2.5}$ primary standards. A group of public health and environmental organizations agreed that "the EPA has selected the appropriate averaging times for the fine particle standards" (American Lung Association *et al.*).

Having considered the public comments on this issue, the Administrator concurs with the recommendations presented in the Staff Paper and recommendations made by CASAC (Henderson, 2005a) and concludes, as proposed, that it is appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards to protect against health effects associated with short-term and long-term exposure periods.

E. Form of Primary $PM_{2.5}$ Standards

1. 24-Hour $PM_{2.5}$ Standard

In 1997 EPA established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of the annual 24-hour concentrations at each population-oriented monitor within an area, averaged over three years (62 FR 38671–74). EPA found that, as compared to an exceedance-based form used in earlier PM standards, a concentration-based form is more reflective of the health risk posed by elevated $PM_{2.5}$ concentrations because it gives proportionally greater weight to days when concentrations are well above the level of the standard than to days when the concentrations are just above the standard. Further, a concentration-based form better compensates for missing data and less-than-every-day monitoring; and, when averaged over 3 years, it has greater stability and, thus, facilitates the development of more stable implementation programs. After considering a range of concentration percentiles from the 95th to the 99th, EPA selected the 98th percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability and robustness. Further, by basing the form of the standard on concentrations measured at population-oriented monitoring sites (as specified in 40 CFR part 58), EPA intended to provide protection for people residing in or near localized areas of elevated concentrations.

In this review, the Staff Paper concluded that it is appropriate to retain a concentration-based form that is defined in terms of a specific percentile of the distribution of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area, averaged over 3 years. This staff

recommendation was based on the same reasons that were the basis for EPA's selection of this type of form in the last review. As to the specific percentile value to be considered, the Staff Paper took into consideration (1) the relative risk reduction afforded by alternative forms at the same standard level, (2) the relative year-to-year stability of the air quality statistic to be used as the basis for the form of a standard, and (3) the implications from a public health communication perspective of the extent to which either form allows different numbers of days in a year to be above the level of the standard in areas that attain the standard. Based on these considerations, the Staff Paper recommended either retaining the 98th percentile form or revising it to be based on the 99th percentile form, and noted that primary consideration should be given to the combination of form and level, as compared to looking at the form in isolation (EPA, 2005, p. 5–44).

In considering the information provided in the Staff Paper, most CASAC Panel members favored continued use of the 98th percentile for a concentration-based form because it is more robust than the 99th percentile, such that it would provide more stability to prevent areas from moving in and out of attainment from year to year (Henderson 2005a). In recommending retention of the 98th percentile form, the CASAC Panel recognized that it is the link between the form and level of a standard that determines the degree of public health protection the standard affords.

In considering the available information and the Staff Paper and CASAC recommendations, the Administrator proposed to retain the form for the 24-hour standard. In so doing, the Administrator focused on the relative stability of the 98th and 99th percentile forms as a basis for selecting the 98th percentile form, while recognizing that the degree of public health protection likely to be afforded by a standard is a result of the combination of the form and the level of the standard.

None of the public commenters raised objections to continuing the use of a concentration-based form for the 24-hour standard. Many of the individuals and groups who supported a more stringent 24-hour $PM_{2.5}$ standard noted above in Section II.B, however, recommended a more restrictive concentration-based percentile form, specifically a 99th percentile form. The limited number of these commenters who provided a specific rationale for this recommendation generally expressed their concern that the 98th percentile form could allow too many days where concentrations exceeded the level of the standard, and thus fail to adequately protect public health. The EPA received comparatively few public comments from State and local air pollution control authorities and tribal organizations on the form of the 24-hour $PM_{2.5}$ standard. Of the limited number of state air pollution control authorities that commented on the form of the 24-hour $PM_{2.5}$ standard, all supported retaining the 98th percentile form. Of the limited number of local air pollution control authorities and tribal organizations that commented on the form of the 24-hour $PM_{2.5}$ standard, some supported retaining the 98th percentile form while others supported the 99th percentile form. Beyond their support for retaining the current 24-hour $PM_{2.5}$ standard, which has a 98th percentile form, commenters representing industry associations and businesses provided no specific comments regarding the form of the 24-hour $PM_{2.5}$ standard.

The EPA notes that the viewpoints represented in this review are similar to comments submitted in the last review and through various NAAQS reviews. The EPA recognizes that the selection of the appropriate form includes maintaining adequate protection against peak 24-hour values while also providing a stable target for risk management programs, which serves to provide for the most effective public health protection in the long run.[24] Nothing in the commenters' views has provided a reason to change the Administrator's previous conclusion regarding the appropriate balance represented in the proposed form of the 24-hour $PM_{2.5}$ standard. Therefore, the Administrator concurs with CASAC recommendations and concludes that it is appropriate to retain the 98th percentile form for the 24-hour $PM_{2.5}$ standard.

In reaching this conclusion, EPA also recognizes that several states that otherwise supported EPA's proposal to retain the 98th percentile form of the 24-hour $PM_{2.5}$ standard raised concerns regarding a technical problem associated with a potential bias in the method used to calculate the 98th percentile concentration for this form. NESCAUM, in particular, noted that "the existing and proposed methodology yields a lower (*i.e.*, less stringent) value on average for a 1 in 3 day frequency sample data-set compared to a daily sample data-set by approximately 1 $\mu g/m^3$" (NESCAUM, p. 3), and recommended revisions to the methodology such that "the calculation becomes insensitive to data capture rate or sampling frequency" (NESCAUM, Attachment A, p.7). Another state commenter suggested the issue could be addressed by "the addition of language that requires areas that are near the daily NAAQS to continue to use every day FRM/FEM sampling" (Delaware Department of Natural Resources, p. 4). The EPA agrees with these commenters that the potential bias in calculating the design value of the 24-hour $PM_{2.5}$ standard is a concern. To reduce this bias, EPA had proposed to increase the sampling frequency for monitoring sites that were within 10 percent of the standard to 1 in 3 day sampling (Part 58 section 12(d)(1)). The EPA is persuaded by these comments that it is appropriate to adjust the proposed sampling frequency requirements in order to further reduce this bias. Accordingly, EPA is modifying the final monitoring requirements such that areas that are within 5 percent of the standard will be required to increase the frequency of sampling to every day (Part 58 section 12(d)(1).[25]

2. Annual $PM_{2.5}$ Standard

In 1997 EPA established the form of the annual $PM_{2.5}$ standard as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors. This form of the annual standard was intended to represent a relatively stable measure of air quality and to characterize area-wide $PM_{2.5}$ concentrations in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ levels. The current annual $PM_{2.5}$ standard level is to be compared to measurements made at the community-oriented monitoring site recording the highest level, or, if specific constraints are met, measurements from multiple community-oriented monitoring sites may be averaged (Part 50 Appendix N section 1.0(c) and 2.1(a) and (b) and Part 58 Appendix D section 2.8.1.6.1; 62 FR 38672). Community-oriented monitoring sites were specified to be consistent with the intent that a spatially averaged annual standard protect persons living in smaller communities, as well as those in larger population centers. The constraints on allowing the use of spatially averaged measurements were

[24] See *ATA III*, 283 F. 3d at 374–375 which concludes it is legitimate for EPA to consider promotion of overall effectiveness of NAAQS implementation programs, including their overall stability, in setting a standard that is requisite to protect the public health.

[25] See final rulemaking notice regarding revisions to ambient air monitoring requirements, elsewhere in today's Federal Register.

intended to limit averaging across poorly correlated or widely disparate air quality values.[26] This approach was judged to be consistent with the short-term epidemiologic studies on which the annual $PM_{2.5}$ standard was primarily based, in which air quality data were generally averaged across multiple monitors in an area or were taken from a single monitor that was selected to represent community-wide exposures, not localized "hot spots" (62 FR 38672). These criteria and constraints were intended to ensure that spatial averaging would not result in inequities in the level of protection afforded by the $PM_{2.5}$ standards (*Id.*).

In this review, there now exists a much larger set of $PM_{2.5}$ air quality data than was available in the last review. Consideration in the Staff Paper of the spatial variability across urban areas that is revealed by this new data base has raised questions as to whether an annual standard that allows for spatial averaging, within currently specified or alternative constraints, would provide appropriate public health protection. Analyses in the Staff Paper to assess these questions, as discussed below, took into account both aggregate population risk across an entire urban area and the potential for disproportionate impacts on potentially vulnerable subpopulations within an area.

The effect of allowing the use of spatial averaging on aggregate population risk was considered in sensitivity analyses included in the health risk assessment (EPA, 2005, section 4.4.3.2). In particular, this included analyses of several urban areas that compared estimated mortality risks based on calculating compliance with alternative standards (1) using air quality values from the highest community-oriented monitor in an area and (2) using air quality values averaged across all such monitors within the constraints on spatial averaging allowed by the current standard.[27] As expected, estimated risks associated with long-term exposures that remain upon just meeting the current annual standard are greater when spatial averaging is used than when the highest monitor is used (i.e., the estimated reductions in risk associated with just attaining the current or alternative annual standards are less when spatial averaging is used), as the use of the highest monitor leads to greater modeled reductions in ambient $PM_{2.5}$ concentrations.[28]

In considering the potential for disproportionate impacts on potentially vulnerable subpopulations, EPA assessed whether any such groups are more likely than the general population to live in census tracts in which the monitors recording the highest air quality values in an area are located. Data used in this analysis included demographic parameters measured at the census tract level, including education level, income level, and percent minority population. Data from the census tract in each area in which the highest air quality value was monitored were compared to the area-wide average value (consistent with the constraints on spatial averaging provided by the current standard) in each area (Schmidt *et al.*, 2005). Recognizing the limitations of such cross-sectional analyses, the Staff Paper observed that the results suggest that the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding population is more likely to have lower education and income levels, and higher percentages of minority populations (EPA, 2005, p. 5–41).[29] Noting the intended purposes of the form of the annual standard, as discussed above, the Staff Paper concluded that the existing constraints on spatial averaging may not be adequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on these potentially vulnerable subpopulations.

In considering whether more stringent constraints on the use of spatial averaging may be appropriate, the Staff Paper presented results of an analysis of recent air quality data which assessed correlations and differences between monitor pairs in metropolitan areas across the country (Schmidt *et al.*, 2005). For all pairs of $PM_{2.5}$ monitors, the median correlation coefficient based on annual air quality data is approximately 0.9, which is substantially higher than the current criterion (in Appendix D of Part 58, section 2.8.1.6.1) of a minimum correlation of at least 0.6, which was met by nearly all monitor pairs. The current criterion that differences in mean air quality values between individual monitors and the corresponding multi-site spatial average not exceed 20 percent on an annual basis also was met for most monitor pairs, while the actual annual median and mean differences for all monitor pairs were 5 percent and 8 percent, respectively. This analysis also showed that in some areas with highly seasonal air quality patterns (e.g., due to seasonal wood smoke emissions), substantially lower seasonal correlations and larger seasonal differences can occur relative to those observed on an annual basis. This analysis provided some perspective on the constraints on spatial averaging that were adopted in the last review before data were widely available on spatial distributions of $PM_{2.5}$ air quality levels.

In considering the results of the analyses discussed above, the Staff Paper concluded that it is appropriate to consider either eliminating the provision that allows for spatial averaging from the form of an annual $PM_{2.5}$ standard or narrowing the constraints on spatial averaging to be based on more restrictive criteria. More specifically, based on the analyses discussed above, the Staff Paper recommended consideration of revised criteria such that the correlation coefficient between monitor pairs to be averaged be at least 0.9, determined on a seasonal basis, and annual mean differences between individual monitors and corresponding spatial averages not exceed 10 percent (EPA, 2005, p. 5–42).[30]

[26] The current constraints include the criteria that the correlation coefficient between monitor pairs to be averaged be at least 0.6, and that differences in mean air quality values between monitors to be averaged not exceed 20 percent and that areas in which monitoring results may be averaged should principally be affected by the same major emission source of $PM_{2.5}$ (Part 58 App. D section 2.8.1.6.1).

[27] As discussed in the Staff Paper (EPA, 2005; section 4.2.2), the monitored air quality values were used to determine the design value for the annual standard in each area, as applied to a "composite" monitor to reflect area-wide exposures. Changing the basis of the annual standard design value from the concentration at the highest monitor to the average concentration across all monitors changes the amount of reduction in $PM_{2.5}$ levels that is needed to just meet the current or alternative annual standards. With averaging, less overall reduction in ambient $PM_{2.5}$ is needed to just meet the standards.

[28] For example, based on analyses conducted in three example urban areas, estimated mortality incidence associated with long-term exposure based on the use of spatial averaging is about 10 to more than 40 percent higher than estimated incidence based on the use of the highest monitor (EPA, 2005, p.5–41).

[29] As summarized in section II.A.4 of the proposal, the Criteria Document notes that some epidemiologic study results, most notably the associations between total mortality and long-term $PM_{2.5}$ exposure in the ACS cohort, have shown larger effect estimates in the cohort subgroup with lower education levels (EPA, 2004a, p. 8–103). The Criteria Document also notes that lower education level can be a marker for lower socioeconomic status that may be related to increased vulnerability to the effects of fine particle exposures, for example, as a result of greater exposure from proximity to sources such as roadways and industry, as well as other factors such as poorer health status and access to health care (EPA, 2004a, section 9.2.4.3).

[30] In CASAC's review of the Second Draft Staff Paper, most of the members of the CASAC Review Panel found the fine particle sections to be "generally well-written and scientifically well-reasoned" but, beyond their recommendation that the primary $PM_{2.5}$ standards should be strengthened, CASAC provided no specific

In considering the Staff Paper recommendations based on the results of the analyses discussed above, and focusing on a desire to be consistent with the epidemiologic studies on which the $PM_{2.5}$ health effects are based and concern over the evidence of potential disproportionate impact on potentially vulnerable subpopulations, the Administrator proposed to revise the form of the annual $PM_{2.5}$ standard consistent with the Staff Paper recommendation to change two of the criteria for use of spatial averaging such that the correlation coefficient between monitor pairs must be at least 0.9, determined on a seasonal basis, with differences between monitor values not to exceed 10 percent (71 FR 2647). The Administrator also solicited comment on the other Staff Paper-recommended alternative of revising the form of the annual $PM_{2.5}$ standard to one based on the highest community-oriented monitor in an area, with no allowance for spatial averaging (*Id.* at 2647–48).

Relatively few public comments were received on the form of the annual $PM_{2.5}$ standard. Of the commenters noted above in Section II.B who supported a more stringent annual $PM_{2.5}$ standard, those who commented on the form of the annual $PM_{2.5}$ standard argued that the EPA analyses described above demonstrated that the current form of the standard results in uneven public health protection leading to disproportionate impacts on potentially vulnerable subpopulations, and thus a change in the form of the standard is needed. However, these commenters argued that the proposed modifications to the spatial averaging criteria were not stringent enough and, in order to reduce the possibility of pollution hotspots and disproportionate impacts, especially in areas meeting the annual $PM_{2.5}$ standard, spatial averaging should be eliminated (American Lung Association *et al.*, 2006, pp. 44–47; Schwartz, 2005, p. 2). Of the commenters noted above in Section II.B who supported retaining the current annual $PM_{2.5}$ standard, those who commented specifically on the form of the standard supported retaining the current spatial averaging criteria. These views are most extensively presented in comments from UARG who argued that changes to the spatial averaging criteria, effectively increasing the stringency of the standard, are not needed as the current standards provide the requisite degree of public health protection [UARG, 2006, pp. 33–36]. In addition, one state air pollution control agency supported a more stringent level for the annual $PM_{2.5}$ standard in the range recommended by CASAC but also supported retaining the option for spatial averaging for the form of the standard arguing that "rarely is one monitor representative of an entire nonattainment area" especially in the western U.S. (Utah Department of Environmental Quality, 2006, p. 2).

The Administrator emphasizes that the intent of the current spatial averaging criteria, as defined in 1997 based on a limited set of $PM_{2.5}$ air quality data, was to ensure that spatial averaging would not result in inequities in the level of protection provided by the $PM_{2.5}$ standards against health effects associated with short- and long-term exposures to $PM_{2.5}$. Based on the analyses described above (Schmidt *et al.*, 2005), which are based on the much larger set of air quality data that has become available since the last review, EPA now believes that tighter constraints on spatial averaging are necessary to address concerns over potential disproportionate impacts on the populations that EPA has identified as being potentially vulnerable to $PM_{2.5}$-related health effects. The EPA believes that current information and analyses indicate that application of the current form has the clear potential to result in disproportionate impacts on potentially vulnerable subpopulations in some areas. The EPA recognizes that the proposed constraints have the potential to increase the stringency of the annual $PM_{2.5}$ standard in some areas in which a State might choose to use spatial averaging. The EPA believes that in such cases this increased stringency is warranted so as to address possible disproportionate impacts on potentially vulnerable populations and more generally to avoid inequities across all population groups. The EPA disagrees with those commenters who support eliminating spatial averaging altogether. The EPA believes that the proposed narrowing of the spatial averaging criteria will adequately address the concerns about disproportionate impact raised by some commenters, as analyzed in the Staff Paper, by substantially reducing the amount of spatial variation in long-term ambient levels that will be allowed to be averaged together in determining compliance with the standard. Therefore, the Administrator concludes that the current form of the standard should be retained with the proposed modifications. The form of the annual $PM_{2.5}$ standard is retained as an annual arithmetic mean, averaged over 3 years; however, the following two aspects of the spatial averaging criteria are narrowed: (1) The annual mean concentration at each site shall be within 10 percent of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.9 for each calendar quarter.

F. Level of Primary $PM_{2.5}$ Standards

In the last review, having concluded that it was appropriate to establish both 24-hour and annual $PM_{2.5}$ standards, EPA selected a level for each standard that was appropriate for the function to be served by each (62 FR 38674, 38676–77). As noted above, EPA concluded at that time that the suite of $PM_{2.5}$ standards could most effectively and efficiently protect public health by treating the annual standard as the generally controlling standard for lowering both short- and long-term $PM_{2.5}$ concentrations.[31] In conjunction with such an annual standard, the 24-hour standard was intended to provide protection against days with high peak $PM_{2.5}$ concentrations, localized "hotspots," and risks arising from seasonal emissions that would not be well controlled by an annual standard.[32]

In selecting the level for the annual standard in the last review, EPA used an evidence-based approach that considered the evidence from both short- and long-term exposure studies. The risk assessment conducted in the last review, while providing qualitative insights about the distribution of risks, was considered by EPA to be too limited to serve as a quantitative basis for decisions on the standard levels. In accordance with Staff Paper and CASAC views on the relative strengths of the short- and long-term exposure studies, EPA placed greater emphasis on the short-term exposure studies. In so doing, EPA first determined a level for the annual standard based on the short-term exposure studies, and then considered whether the long-term exposure studies suggested the need for a lower level. While recognizing that health effects could occur over the full range of concentrations observed in the studies, EPA concluded that the

comments regarding the form of the annual standard (Henderson, 2005a, pp. 1–2).

[31] In so doing, EPA noted that an annual standard would focus control programs on annual average $PM_{2.5}$ concentrations, which would generally control the overall distribution of 24-hour exposure levels, as well as long-term exposure levels, and would also result in fewer and lower 24-hour peak concentrations. Alternatively, a 24-hour standard that focused controls on peak concentrations could also result in lower annual average concentrations. Thus, EPA recognized that either standard could provide some degree of protection from both short- and long-term exposures, with the other standard serving to address situations where the daily peaks and annual averages are not consistently correlated (62 FR 38662).

[32] *See also ATA III*, 283 F.3d at 373 (endorsing this reasoning).

strongest evidence for short-term $PM_{2.5}$ effects occurs for air quality distributions with long-term concentrations near the long-term (e.g., annual) average in those studies reporting statistically significant health effects. Thus, in the last review, EPA selected a level for the annual standard that was somewhat below the lowest long-term average $PM_{2.5}$ concentration in a short-term exposure study that reported statistically significant health effects. Further consideration of the average $PM_{2.5}$ concentrations across the cities in the key long-term exposure studies available at that time did not provide a basis for establishing a lower annual standard level.

In this review, the approach used in the Staff Paper as a basis for staff recommendations on standard levels built upon and broadened the general approach used by EPA in the last review. This broader approach reflected the more extensive and stronger body of evidence now available on health effects related to both short- and long-term exposure to $PM_{2.5}$, together with the availability of much more extensive $PM_{2.5}$ air quality data. This newly available information was used to conduct a more comprehensive risk assessment for $PM_{2.5}$. As a consequence, the broader approach used in the Staff Paper discussed ways to take into account both evidence-based and quantitative risk-based considerations and placed relatively greater emphasis on evidence from long-term exposure studies than was done in the last review.

Given the extensive body of new evidence based specifically on $PM_{2.5}$ that is now available, and the resulting broader approach presented in the Staff Paper, the Administrator considered it appropriate to use a somewhat different evidence-based approach from that used in the last review to propose appropriate standard levels. In the Administrator's view, the very large numbers of $PM_{2.5}$ health effect studies that now make up the available body of evidence provide the most reliable basis for determining the level of the standards. More specifically, EPA's proposal relied on an evidence-based approach that considered the much expanded body of evidence from short-term exposure $PM_{2.5}$ studies as the principal basis for selecting the level of the 24-hour standard, with such standard aimed at protecting against health effects associated with short-term exposures to $PM_{2.5}$. Likewise, the stronger and more robust body of evidence from the long-term exposure $PM_{2.5}$ studies was considered as the principal basis for selecting the level of the annual standard, with such standard aimed at protecting against health effects associated with long-term exposures to $PM_{2.5}$.

With respect to the quantitative risk assessment, the Administrator recognized at proposal that it rests on a more extensive body of data and is more comprehensive in scope than the assessment conducted in the last review, but was mindful that significant uncertainties continue to underlie the resulting risk estimates. Such uncertainties generally relate to a lack of clear understanding of a number of important factors, including, for example, the shape of concentration-response functions, particularly when, as here, effect thresholds can neither be discerned nor determined not to exist; issues related to selection of appropriate statistical models for the analysis of the epidemiologic data; the role of potentially confounding and modifying factors in the concentration-response relationships; issues related to simulating how $PM_{2.5}$ air quality distributions will likely change in any given area upon attaining a particular standard, since strategies to reduce emissions are not yet defined; and whether there would be differential reductions in the many components within $PM_{2.5}$ and, if so, whether this would result in differential reductions in risk. In the case of fine particles, the Administrator recognized that for purposes of developing quantitative risk estimates such uncertainties are likely to amplified by the complexity in the composition of the mix of fine particles generally present in the ambient air. Further, in the Administrator's view, this risk assessment, which is based on studies that do not resolve the issue of a threshold, has important limitations as a basis for standard setting, since if no threshold is assumed the assessment necessarily predicts that ever lower standards result in ever lower risks. This has the effect of masking the increasing uncertainty in the risk estimates that exists as lower levels are considered, even when a range of assumed thresholds is included. As a result, at the time of proposal the Administrator viewed the risk assessment as providing supporting evidence for the conclusion that there is a need to revise the current suite of $PM_{2.5}$ standards, but he judged that it did not provide an appropriate basis to determine what specific quantitative revisions are appropriate.

1. 24-Hour $PM_{2.5}$ Standard

Based on the approach discussed above, the Administrator relied upon evidence from the short-term exposure $PM_{2.5}$ studies as the principal basis for selecting the proposed level of the 24-hour standard. In considering these studies as a basis for the level of a 24-hour standard, and having provisionally selected a 98th percentile form for the standard, the Administrator agreed with the focus in the Staff Paper of looking at the 98th percentile values in these studies. In so doing, the Administrator recognized that these studies provide no evidence of clear effect thresholds or lowest-observed-effects levels. Thus, in focusing on 98th percentile values in these studies, the Administrator was seeking to establish a standard level that will require improvements in air quality generally in areas in which the distribution of daily short-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious health effects. Although future air quality improvement strategies in any particular area are not yet defined, most such strategies are likely to move a broad distribution of $PM_{2.5}$ air quality values in an area lower, resulting in reductions in risk associated with exposures to $PM_{2.5}$ levels across a wide range of concentrations.

Based on the information in the Staff Paper and in a supporting staff memorandum,[33] the Administrator observed an overall pattern of statistically significant associations reported in studies of short-term exposure to $PM_{2.5}$ across a wide range of 24-hour average 98th percentile values. More specifically, the Administrator observed a strong predominance of studies with 98th percentile values down to about 39 $\mu g/m^3$ (in Burnett and Goldberg, 2003) reporting statistically significant associations with mortality, hospital admissions, and respiratory symptoms. For example, within this range of air quality, statistically significant associations were reported for mortality in the combined Six Cities study (and three of four individual cities within that study[34]) (Klemm and Mason, 2003), the Canadian 8-City Study (Burnett and Goldberg, 2003), and in studies in Santa Clara County, CA

[33] As discussed in the Staff Paper (EPA, 2005, p. 5–30) and supporting staff memo (Ross and Langstaff, 2005), staff focused on U.S. and Canadian short-term exposure $PM_{2.5}$ studies that had been reanalyzed as appropriate to address statistical modeling issues and considered the extent to which the reported associations are robust to co-pollutant confounding and alternative modeling approaches and are based on relatively reliable air quality data. Additional air quality data used in this analysis were documented in another staff memo (Ross and Langstaff, 2006) that was placed in the docket during the public comment period.

[34] Of the four cities in this study that were within this range of air quality, statistically significant results were reported for Boston, St. Louis, and Knoxville, but not for Steubenville.

(Fairley, 2003) and Philadelphia (Lipfert, 2000); for hospital admissions and emergency department visits in Seattle (Sheppard *et al.*, 2003), Toronto (Burnett *et al.*, 1997; Thurston *et al.*, 1994), Detroit (Ito, 2003, for heart failure[35] and pneumonia, but not for other causes), and Montreal (Delfino *et al.*, 1998,[35] for some but not all age groups and years); and for respiratory symptoms in panel studies in a combined Six Cities study (Schwartz *et al.*, 1994, as reanalyzed in Schwartz and Neas, 2000) and in two Pennsylvania cities (Uniontown in Neas *et al.*, 1995; State College in Neas *et al.*, 1996).[37] Studies in this air quality range that reported positive but not statistically significant associations include mortality studies in Detroit (Ito, 2003), Pittsburgh (Chock *et al.*, 2000), Steubenville (Klemm and Mason, 2003), and Montreal (Goldberg and Burnett, 2003), and a study of lung function in Philadelphia[38] (Neas *et al.*, 1999).

Within the range of 24-hour average 98th percentile $PM_{2.5}$ concentrations of about 35 to 30 $\mu g/m^3$, the Administrator no longer observed this strong predominance of statistically significant results. Rather, within this range, one study reports statistically significant results (Mar *et al.*, 2003), other studies report mixed results in which some associations reported in the study are statistically significant and others are not (Delfino *et al.*, 1997; Peters *et al.*, 2000),[39] and other studies report associations that are not statistically significant (Ostro, 2003;[40] two individual cities within Klemm and Mason, 2003). Further, the Administrator concluded that the very limited number of studies in which the 98th percentile values are below this range (Stieb *et al.*, 2000; Peters *et al.*, 2001) do not provide a basis for reaching conclusions about associations at such levels. Thus, in the Administrator's view, this body of evidence provided confidence that statistically significant associations are occurring down close to this range, and it provided a clear basis for provisionally concluding that this range represents a range of reasonable values for a 24-hour standard level. The Administrator further noted that focusing on the range of 35 to 30 $\mu g/m^3$ is consistent with the interpretation of the evidence held by most CASAC Panel members as reflected in their recommendation to select a 24-hour $PM_{2.5}$ standard level within this range (Henderson, 2005a, p. 7). The Administrator recognized, however, the separate point that most CASAC Panel members favored the range of 35 to 30 $\mu g/m^3$ for the 24-hour $PM_{2.5}$ standard in concert with an annual standard set in the range of 14 to 13 $\mu g/m^3$ (*Id.*), as discussed in section II.F.2 below.

At proposal, in considering what level would be appropriate for a 24-hour standard, the Administrator was mindful that this choice requires judgment based on an interpretation of the evidence that neither overstates nor understates the strength and limitations of the evidence, or the appropriate inferences to be drawn from the evidence. In the absence of evidence of any clear effects thresholds, EPA may select a specific standard level from within a range of reasonable values. In making this judgment, the Administrator noted that the general uncertainties related to the shape of the concentration-response functions and to the selection of appropriate statistical models affect the likelihood that observed associations are causal down to the lowest concentrations in the studies. Further, and more specifically, the variation in results found in the short-term exposure studies in which the 98th percentile values were below 35 $\mu g/m^3$ indicated an increase in uncertainty as to whether likely causal associations extend down below this level (71 FR 2649).

In considering the extent to which the quantitative risk assessment should inform EPA's selection of a 24-hour $PM_{2.5}$ standard, the Administrator recognized that risk estimates based on simulating the attainment of standards set at lower levels within this range will inevitably suggest some additional reductions in risk at each lower standard level considered. However, these quantitative risk estimates largely depend upon assumptions made about the lowest level at which reported associations will likely persist and remain causal in nature. Thus, the Administrator was hesitant to use such risk estimates as a basis for proposing a specific standard level, particularly one below 35 $\mu g/m^3$, and instead preferred to base the decision on level directly on the evidence in the studies themselves (71 FR 2649).

Taking the above considerations into account, the Administrator proposed to set the level of the primary 24-hour $PM_{2.5}$ standard at 35 $\mu g/m^3$.[41] In the Administrator's judgment at that time, based on the currently available evidence, a standard set at this level would protect public health with an adequate margin of safety from serious health effects, including premature mortality and hospital admissions for cardiorespiratory causes that are likely causally associated with short-term exposure to $PM_{2.5}$. This judgment appropriately considered the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognized that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

At the time of proposal, the Administrator recognized that sharply divergent views on the appropriate level of this standard had been presented to EPA as part of the NAAQS review process, and solicited comment on a wide range of standard levels and alternative approaches to characterizing and addressing scientific uncertainties. One such alternative view focused very strongly on the uncertainties inherent in the epidemiologic and toxicologic studies and the quantitative risk assessment as the basis for concluding that no change to the current 24-hour $PM_{2.5}$ standard of 65 $\mu g/m^3$ was warranted. In sharp contrast, others viewed the epidemiologic evidence and other health studies as strong and robust, and generally placed much weight on the results of the quantitative risk assessment as a basis for concluding that a much stronger policy response is warranted, generally consistent with a standard level at or below 25 $\mu g/m^3$. As discussed below, the same sharply divergent views were generally repeated in comments on the proposal by the two distinct groups of commenters identified in section II.B.2 above.

In considering comments received on the proposal, the Administrator first notes that CASAC provided additional recommendations concerning the

[36] The proposal incorrectly listed this as an association with ischemic heart disease.

[37] The proposal incorrectly included Delfino *et al.*, 1997 here as well as correctly including it in the next lower air quality range.

[38] Of the studies within this group that evaluated multi-pollutant associations, as discussed above in section II.A.3, the results reported in Fairley (2003), Sheppard (2003), and Ito (2003) were generally robust to inclusion of gaseous co-pollutants.

[39] The proposal incorrectly identified this as a statistically significant association.

[39] For example, Delfino *et al.* (1997) report statistically significant associations between $PM_{2.5}$ and respiratory emergency department visits for elderly people (>64 years old), but not children (<2 years old), in one part of the study period (summer 1993) but not the other (summer 1992). Peters *et al.* (2000) report new findings of associations between fine particles and cardiac arrhythmia, but the Criteria Document observes that the strongest associations were reported for a small subset of the study population that had experienced 10 or more defibrillator discharges (EPA, 2004a, p. 8–104).

[40] The proposal incorrectly identified this as a statistically significant association.

[41] As noted above, the proposed form of the 24-hour standard was the same as the current standard.