

# **Chronology of the U.S. National Ambient Air Quality Standards**

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Supplemental Tables to A&WMA 2007 Critical Review

## **Will the Circle Be Unbroken: A History of the U.S. National Ambient Air Quality Standards**

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These tables summarize salient aspects of the chronology of the development and periodic revisions of the seven pollutants for which the U.S. Environmental Protection Agency has produced air quality criteria and national ambient air quality standards (NAAQS) since passage of the Clean Air Act Amendments of 1970. They are intended to provide reference and background to the main body of the 2007 Critical Review. They highlight when key steps in the criteria and NAAQS process occurred and highlight some of the key factors underlying the decisions.

**Table 1. Chronology of Particulate Matter (PM) National Ambient Air Quality Standards**

Year	Event	Comments
1969	First particulate matter criteria document (CD) <sup>1</sup> produced by Public Health Service [PHS] staff and consultants, 211 pages. Reviewed by the National Air Quality Criteria Advisory Committee (NAQCAC) and 17 Federal Agencies.	Health conclusions <sup>1</sup> based on 1950s and 60's epidemiology studies with both PM and SO <sub>2</sub> high. Key welfare effects were visibility, solar radiation, materials, and public concern. <sup>1</sup> Particle size, measurement issues were not highlighted in the quantitative conclusions sections.
1971	Proposal <sup>2</sup> , Promulgation <sup>3</sup> of first PM NAAQS for Total Suspended Particulate Matter (TSP) Primary: 260 µg/m <sup>3</sup> , 24 hr not to be exceeded more than once a year 75 µg/m <sup>3</sup> annual geometric mean Secondary: 150 µg/m <sup>3</sup> , 24 hr not to be exceeded more than once a year. All hi-vol measurements corrected to STP. <sup>3</sup>	Rationale not given. The 24 hr criteria <sup>1</sup> highlighted mortality, morbidity studies; <sup>4,5</sup> especially studies of London bronchitis <sup>6</sup> . Annual CD <sup>1</sup> conclusions focused on Buffalo TSP study <sup>7,8,9</sup> . Key welfare effect – maintain 5mi visibility at airports. <sup>1,10</sup> The Federal Reference method (FRM), the gravimetric filter based hi-volume air sampler, defined the indicator (TSP). <sup>3</sup> The upper particle size range was not well characterized.
1974	EPA published the Community Health Environmental Surveillance Study (CHESS) report <sup>11</sup> summarizing results from EPA's epidemiology research; Harvard Six-Cities Study <sup>12</sup> initiated by National Institute of Environmental Health Sciences (NIEHS).	The CHESS report suggested health effects at levels that met TSP and SO <sub>2</sub> NAAQS, possible concern over regional fine acid sulfates. <sup>13</sup> Critical reviews found problems with some analyses and data, which led later to a Congressional investigation of the program, <sup>14</sup> as well as legislation.
1976	NAQCAC recommended that all NAAQS be reviewed. <sup>15</sup> EPA established a schedule <sup>16</sup> making PM and sulfur oxides (SO <sub>x</sub> ) reviews the last to be done, with concurrent schedule for draft final CDs for PM (and for SO <sub>x</sub> and associated particles) of August 1979.	EPA dissolved the multi-stakeholder NAQCAC and began using <i>ad hoc</i> subcommittees of the newly established Science Advisory Board (SAB) for CD reviews. <sup>17</sup>
1977	NAS published a major study of PM effects and atmospheric sciences. <sup>18</sup> The 1977 CAA Amendments included new requirements for NAAQS reviews. <sup>19</sup>	The NRC/NAS <i>Airborne Particles</i> <sup>18</sup> report supported the level of protection of the 1971 standards, but called for revised criteria, consideration of size, other research results.
1978-79	The Environmental Research and Development & Demonstration Act (ERDDA) <sup>20</sup> required SAB review of new and revised CD, the NAAQS proposal notice, as well as the underlying science. ERDDA also proscribed use of CHESS studies in NAAQS reviews. The American Iron and Steel	EPA's Environmental Criteria Assessment Office (ECAO) began the criteria review by developing of early drafts chapters and inviting experts to review and comment at a workshop. AISI obtained a temporary restraining order stopping 'closed' expert workshops on the CD. <sup>21</sup> EPA opened

	<p>Institute (AISI) sued EPA. (<i>American Iron and Steel Institute et al, v. Douglas M. Costle, Administrator of the Environmental Protection Agency</i>. U.S. District Court for the Western District of Pennsylvania, Civil Action No. 78-92) over concerns over how well EPA was following ERDDA requirements in the PM review.</p> <p>EPA staff from Air Office and ORD worked to develop alternative indicators for NAAQS review, future research.</p>	<p>all subsequent CD workshops to the public. AISI deposed Agency staff and obtained personal files, notes, and initial drafts through discovery.<sup>17</sup></p> <p>EPA formally announced the review, with a combined CD for PM and SO<sub>x</sub>, in October, 1979 (44FR56731).</p> <p>EPA staff published<sup>22</sup> their definitions of inhalable and fine particle indicators based on dosimetry, bimodal distribution. PM<sub>15</sub>, PM<sub>2.5</sub> were monitored in an EPA PM research network.</p>
<b>1980-82</b>	<p>CASAC held 3 public review meetings on CD drafts (August 1980, July 1981, November 1981). EPA held 5 public workshops after August meeting. CASAC issued a ‘closure’ memorandum<sup>23</sup> and the 1400 page PM/SO<sub>x</sub> CD was completed in April 1982.<sup>24</sup> The initial draft of the Office of Air Quality Planning and Standards (OAQPS) Staff Paper (SP) for PM was reviewed at the July 1981 CASAC meeting, with a second draft reviewed at the November meeting. Following the CASAC closure memorandum,<sup>25</sup> EPA published the SP.<sup>26</sup></p> <p>Staff<sup>26</sup> and CASAC<sup>25</sup> recommended a “thoracic particle” indicator (later called PM<sub>10</sub>) for the primary standards, a fine particle indicator (PM<sub>2.5</sub>) to protect visibility, and retention of TSP for soiling and nuisance effects, with wide ranges of levels for all standards. An early draft of a Regulatory Impact Analysis (RIA) found that estimated benefits exceeded costs at lowest end of range.<sup>27</sup></p>	<p>Contrasting evaluations of available epidemiology by two groups of experts were sponsored by industry<sup>28</sup> and EPA<sup>29</sup>. The CD review focused on reinterpreting and reanalyzing studies of mortality in 14 London winters, London bronchitis and some US studies from the 1960s as well as the relationship of smoke, other measures to TSP, inhalable and fine particle mass.<sup>24</sup></p> <p>The basis for a size specific thoracic or inhalable particle indicator came largely from human particle dosimetry studies, supported by an integrated assessment of community and occupational studies controlled human and animal studies together with particle size and composition information.<sup>26</sup></p> <p>Early information from the EPA inhalable particle (IP) network provided data on relationships in the US.<sup>26</sup> Concerns about cross-sectional study methodology<sup>24,26</sup> limited use of a number of studies, including those<sup>7-9</sup> forming the basis of the original annual TSP standard. For most studies, it was difficult to separate PM from SO<sub>x</sub>.<sup>24</sup></p>
<b>1984</b>	<p>EPA formally proposed to replace TSP standards with PM<sub>10</sub>, using the wide ranges recommended by staff and CASAC to highlight scientific uncertainties and enhance discussion<sup>30</sup>. The 24-hr range was 150-250 µg/m<sup>3</sup>; the annual range was 50-65 µg/m<sup>3</sup> as PM<sub>10</sub>. The administrator (Ruckelshaus) expressed an inclination to use lower end of the ranges. EPA proposed revised TSP annual secondary standard of 70-90 µg/m<sup>3</sup>.</p>	<p>Action was delayed by a change in EPA administrators in 1983. The proposal relied heavily on the science in CD and the integrated summary and recommendations in SP, as well as CASAC recommendations on indicator, averaging time, form, and ranges of levels. EPA proposed to replace the original visibility based secondary standard (TSP) with a PM<sub>10</sub> standard; the administrator deferred action on staff recommendations for a secondary standard for PM<sub>2.5</sub>. The</p>

	EPA received 312 written public comments on the proposal in the first review period with 153 from industry. <sup>31</sup>	proposed annual TSP secondary standard was based on the SP assessment of soiling and nuisance effects.
<b>1986-87</b>	<p>Addenda to both the CD<sup>32</sup> and SP<sup>33</sup> were needed to update the new analyses and data since 1982 CD closed. Staff<sup>33</sup> and CASAC<sup>34</sup> recommendations were similar to 1982, but extended to lower levels. EPA reopened the public comment period receiving 20 comments, 17 from industry.<sup>31</sup></p> <p>EPA promulgated<sup>31</sup> final PM<sub>10</sub> standards in 1987.</p> <p><i>Primary:</i> 150 µg/m<sup>3</sup>, 24-hr, 1 expected exceedance/yr 50 µg/m<sup>3</sup> expected annual arithmetic mean.</p> <p>Both standards use a 3-yr attainment test.</p> <p><i>Secondary:</i> Same as primary.</p> <p>Action on a secondary PM<sub>2.5</sub> standard was formally deferred, as discussed in an Advanced Notice of Proposed Rulemaking.<sup>35</sup> EPA adopted CASAC recommendations for 1) more research and development of an acid aerosol issues paper<sup>33,31</sup> on health effects before further consideration of a sulfate or PM<sub>2.5</sub> primary standard, 2) a critical assessment document on the related issue of acid deposition (Table 6).</p>	<p>Further delays from another change in administrators. The final decision was made by Administrator Lee Thomas. New studies included reanalyses of London mortality/British Smoke data with more advanced techniques,<sup>36,37,38</sup> studies of acute lung function changes,<sup>39</sup> and initial episode<sup>40</sup> and long-term results<sup>41</sup> from Harvard Six Cities study. These supported consideration of lower levels of concern.<sup>33,34</sup> Still, no studies actually used PM<sub>10</sub> as a metric.</p> <p>A majority of commenters favored the PM<sub>10</sub> indicator and the proposed FRM, with some support by mining industry for PM<sub>6</sub> and by others for PM<sub>2.5</sub>. A majority of industry commenters favored the upper end of proposed ranges; others favored lower ends or below. Substantial industry comments on the adequacy of the epidemiology studies. Assessment of the IP network air quality data for multiple cities permitted more confidence in predicting non-attainment, comparison with TSP studies.<sup>33</sup></p>
<b>1988-91</b>	<p>AISI and AMC petitioned EPA to reconsider the PM decisions; EPA issued a notice denying them on all counts.<sup>42,43</sup> AISI, AMC, and NRDC sued the Agency for differing reasons.</p> <p>The D.C. Circuit Court of Appeals ruled against AISI and AMC in an opinion that affected multiple consolidated cases (<i>Natural Resources Defense Council, Inc. v. Administrator, U.S. EPA, Respondents; and Consolidated Cases 87-1441, 87-1442, 87-1443, 88-1913 and 89-1013</i>. 287 U.S. App. D.C. 286 [D.C. Cir. 1991]). The Supreme Court denied AISI's request to review the D.C. Circuit Court ruling. (<i>American Iron and Steel Institute, Petitioner v. United States EPA, et al.</i>, 498 U.S. 1082; 111 S. Ct. 952; 112 L. Ed. 2d 1040; [U.S. 1991], <i>Cert. den.</i>)</p>	<p>AISI argued that: 1) the recent vinyl chloride decision had implications for setting NAAQS; 2) the health effects of NAAQS induced unemployment should be considered; and 3) that EPA staff had presented management with a biased assessment.<sup>42</sup> AMC focused on more technical issues, including implementation.<sup>43</sup> In the process AISI called for a stay of litigation to consider possible problems with Harvard Six-City Study Data, but the stay was also denied by the D.C. Circuit.</p> <p>During this period, states with EPA assistance, completed installation and operation of an extensive national PM<sub>10</sub> network.</p>

<p><b>1991-93</b> EPA, others produced new studies suggesting effects at levels below the new standards, prompting decision to begin an accelerated criteria and NAAQS review; the American Lung Association (ALA) brought a deadline suit.</p>	<p>Emerging time-series found acute associations of PM and mortality at lower levels;<sup>44-47</sup> Six Cities prospective cohort study finds long-term associations with fine particles.<sup>48</sup></p>
<p><b>1994-95</b> A Court order (American Lung Association v. Browner, CIV-93-643-TUC-ACM (D. Ariz., October 6, 1994) as later modified established deadlines for the review.<sup>49</sup> EPA announced the review in April 1994. The first “PM Colloquium” heard calls for reanalysis of published studies;<sup>50</sup> the Health Effects Institute (HEI) sponsored reanalyses of several epidemiology studies.<sup>51,52</sup> EPA held epidemiology workshops, developed an initial external draft of the CD for review at a CASAC meeting in August 1995; a second draft CD and initial drafts of the SP and staff PM risk assessment approach were reviewed by CASAC and the public at a meeting in December 1995.<sup>49</sup></p>	<p>The new PM network facilitated accelerated publication of PM<sub>10</sub>, other time-series studies of daily mortality in multiple locations and new hospital admissions time series.<sup>53</sup> Multiple groups reanalyzed Philadelphia mortality,<sup>45,52,54-56</sup> and attempted to replicate and validate original databases and analysis. Others significant publications included panel studies of susceptible populations,<sup>57,58</sup> a Utah intervention study,<sup>59</sup> the “ACS” prospective cohort study,<sup>60</sup> and many other new epidemiology studies. The CD assessed confounding by multiple pollutants, weather, modeling, exposure misclassification issues, weight of evidence from range of all studies using various PM indicators.<sup>53</sup></p>
<p><b>1996</b> EPA decided to conduct the proposed and final NAAQS rulemaking for PM on the same schedule as O<sub>3</sub>, with simultaneous proposal and promulgation notices. The PM CD<sup>53</sup> and the SP<sup>61</sup> were complete by June 1996. The staff recommended new annual and daily primary and secondary fine particle (PM<sub>2.5</sub>) standards, with wide ranges of levels. A CASAC consensus recommended new fine particle indicator, retaining PM<sub>10</sub>, with a wide variety of opinions on appropriate levels and averaging times, particularly for PM<sub>2.5</sub>.<sup>62</sup> Four CASAC PM panelists sent a letter urging adoption of strong PM<sub>2.5</sub> standards.<sup>63</sup></p> <p>EPA proposed<sup>49</sup> new PM<sub>2.5</sub> standards: 15 µg/m<sup>3</sup>, annual mean based on 3 yr average of monitors across an area; 50 µg/m<sup>3</sup>, 3 year average of the 98<sup>th</sup> percentile 24 hr value measured at each monitor. EPA proposed retention of PM<sub>10</sub> standards with revised 98 percentile form for 24-hr, expected annual mean. The proposed secondary standards were set</p>	<p>Several new key studies and reanalyses were accepted in time for CD, SP consideration, including reanalyses on confounding by co-pollutants/weather,<sup>64</sup> analysis of short-term fine and coarse particles and mortality in Six Cities,<sup>65</sup> a Toronto morbidity study<sup>66</sup>, and the 24-city children’s study.<sup>67</sup> The second PM symposium provided a check of upcoming work in progress for consistency with published studies.</p> <p>Many studies used the PM<sub>10</sub> indicator; a number used fine particle mass or components; few were done in areas dominated by coarse particles. EPA used only North American studies as the basis for selecting NAAQS levels. A two city risk assessment showed that multiple days at mid-level concentrations more important to cumulative risk than the sum of multiple peaks.<sup>49,61</sup> EPA based the proposed ‘controlling’ annual standard level mainly on the long-term averages in time-series studies reporting statistically significant associations with short-term concentrations,</p>

	equal to the respective primary standards, based on visibility (PM <sub>2.5</sub> ) and soiling and nuisance (PM <sub>10</sub> ).	buttressed by the Six Cities <sup>65</sup> , ACS <sup>60</sup> , 24 Cities long-term studies. <sup>67</sup>
<b>1997</b>	<p>EPA received an estimated 70,000 public written and verbal comments on the PM NAAQS proposal, with three simultaneous heavily attended public hearings held in conjunction with the O<sub>3</sub> NAAQS proposal.<sup>68</sup> Substantial debate in Congress (hearings in House and Senate), the executive branch, and in the media, concern over data availability for Harvard, ACS studies.</p> <p>EPA promulgated new standards for PM<sub>2.5</sub> in July.<sup>68</sup>  <i>Primary:</i> 15 µg/m<sup>3</sup>, annual mean, 3 yr average.  65 µg/m<sup>3</sup> 24-hr 98 percentile averaged over 3 yr.  <i>Secondary:</i> Same as primary.  EPA retained the 1987 PM<sub>10</sub> standard levels, but with revised statistical forms (24 hr to 99<sup>th</sup> percentile, annual expected mean). The final secondary PM<sub>10</sub> standards were the same as the primary.  A Presidential letter to the administrator directed a prompt 5 year review of criteria, standards<sup>69</sup>.</p>	<p>The administrator (Thomas) selected the annual standard as generally controlling for short-term and long-term PM<sub>2.5</sub> effects; the 24-hr level was a backstop against potential high risks on peak days. Some new reanalyses as well as a number of new studies completed after the CD closed were submitted in public comment. EPA conducted a detailed ‘provisional assessment’ of these studies, but concluded full consideration would not have changed the decision.<sup>68</sup> Discovery of a mislabeled figure in the ACS study led to revisions in quantitative estimates of long-term mortality in the staff risk assessment and the cost-benefit analyses. The PM RIA estimates found that the range of benefits substantially exceeded costs for standard options considered, assuming partial attainment.<sup>70</sup></p> <p>The Presidential letter focused on implementation, but noted the review would be complete before standards implemented.</p>
<b>1998-01</b>	<p>EPA began next PM review process. EPA, states developed national PM<sub>2.5</sub> monitoring network for mass and speciation.</p> <p>Multiple parties filed lawsuits and petitions on the PM NAAQS; DC Circuit vacated revised PM<sub>10</sub> standards, leaving older standards in place; remanded the PM<sub>2.5</sub> and O<sub>3</sub> standards to EPA due to lack of a ‘determinate criterion’ for non-threshold pollutants, raising a constitutional issue for the CAA (<i>American Trucking Associations v. EPA</i>, D.C. Cir. 1999). EPA/DOJ appealed this ruling to the Supreme Court, which unanimously upheld EPA’s position on the constitutional issue and on consideration of costs, an issue raised again by some petitioners (<i>Whitman v. American Trucking Associations</i>, 531 U.S. 457, 464, 475–76).</p>	<p>Congress charged the NRC to review and guide PM research program; panel produces 4 reports over 6 years with major impacts on EPA research and monitoring<sup>72,73,74,75</sup>.</p> <p>Despite detailed arguments against the new NAAQS by plaintiffs based on scientific issues such as confounding, exposure, and uncertainties, the DC Circuit Panel found ample evidence to justify new PM<sub>2.5</sub> standards and need to regulate coarse particles. They found, however, that EPA did not adequately justify use of PM<sub>10</sub> (including PM<sub>2.5</sub>) for coarse particles. The Supreme Court also reaffirmed DC Circuit, EPA position that costs cannot be considered in setting NAAQS.</p> <p>Increased funding and monitoring accelerated release of significant new epidemiological studies, reanalyses.</p>

	EPA produced three drafts of the PM CD and a preliminary draft SP, which were reviewed at CASAC meetings in 1999-2001. <sup>71</sup>	NMMMAPs multi-city studies addressed confounding issues. <sup>76</sup> HEI oversaw the reanalyses and extension of the Six-cities and ACS cohort studies, largely upholding original investigators. <sup>77</sup> Concentrated ambient particle studies, panel studies find additional links to effects on cardiovascular system. A number of new studies of exposures issues. <sup>78</sup>
<b>2002-04</b>	Just after the third external CD draft was released, the discovery of a software related issue prompted need for reanalyses of a number of time series studies; this resulted in substantial delay in the criteria review. <sup>79,80</sup> The final CD, which included the reanalyses results, was released in October 2004. <sup>81</sup> The CD includes only a few studies done after 2002, other than the reanalyses published in 2003.	HEI coordinated reanalyses of multiple studies to address the software issue, generally finding similar qualitative results, often smaller effects estimates as compared to the original publications. <sup>80</sup> Analyses raise new questions on time-series models, treatment of weather and other pollutants. Unprecedented numbers of new studies complicated integration; several new community studies included separate measures of fine (PM <sub>2.5</sub> ) and thoracic coarse (PM <sub>10-2.5</sub> ) PM.
<b>2005</b>	Completion of SP <sup>82</sup> and CASAC review. <sup>83,84</sup> Staff and CASAC recommended: 1) a range of more stringent PM <sub>2.5</sub> standards, emphasizing that the short-term standard was not protective 2) consideration of PM <sub>10-2.5</sub> indicator for coarse particles, with a focus on urban exposures either in the NAAQS or implementation; 3) shorter averaging time for PM <sub>2.5</sub> secondary standard, as well as a coarse secondary standard.	Staff and CASAC evaluated the combined protection of the suite of primary standards, using the staff 9-city quantitative risk assessment as well as 'evidence-based' assessment in guiding policy choices on standards. Both concluded that the data were sufficient to support coarse standard, but substantially weaker than for fine particles.
<b>2006</b>	EPA proposed revisions <sup>71</sup> to fine and coarse standards, including tighter 24-hr standard, a 'qualified' PM <sub>10-2.5</sub> standard (24-hr only) that would emphasize coarse PM from urban/industrial sources, prohibit regulation of agricultural sources. EPA received over 120,000 public comments on the PM proposal, and held three simultaneous public hearings. <sup>85</sup> CASAC reviewed the proposal and sent a letter <sup>86</sup> objecting to portions of the decision. EPA promulgated <sup>84</sup> a tighter (35 µg/m <sup>3</sup> ) 24-hr PM <sub>2.5</sub> standard, and retained the annual standard. Following substantial comment and deliberation, the administrator	This review garnered less Congressional interest than 1997. The public debate focused on the need for any revisions before 1997 standards were implemented, the strength and adequacy of the evidence and risk assessments, the recommendations to strengthen annual PM <sub>2.5</sub> standard and the need for and nature of any NAAQS for coarse particles. <sup>85</sup> The latter issue was of particular importance to agricultural interests. The final decision relied on an evidence-based assessment, not risk assessment; annual standard based on long-term studies, daily standard on multiple short-term studies. The administrator was not persuaded by CASAC arguments for tighter annual standard. Revocation of annual

departed from the main proposal and decided to retain the original 24-hr PM<sub>10</sub> standard for coarse particles and revoke the annual standard. The secondary standards for PM<sub>2.5</sub> and PM<sub>10</sub> were the same as the revised and retained primary standards.

coarse standard based on lack of evidence for coarse particle effects in long-term epidemiology studies. Air quality analyses found that the revised secondary standard provided visibility protection in the upper portion of the range of shorter-term standards recommended by CASAC.

**Table 2. Chronology of Sulfur Dioxide (SO<sub>2</sub>) National Ambient Air Quality Standards**

Year	Event	Comments
1967	First sulfur oxides (SO <sub>x</sub> ) criteria (PHS staff and consultants). <sup>87</sup>	These are the only criteria the PHS issued under the 1963 Clean Air Act. <sup>87</sup> The remaining early criteria used to support standards decisions were issued after passage of the 1967 or 1970 CAA amendments. On the basis of criticisms of the first document, the 1967 CAA called for reconsideration and revision of the SO <sub>x</sub> criteria, as well as formal consultations and reviews for future CAA criteria.
1969	Revised SO <sub>x</sub> CD <sup>88</sup> (PHS staff and consultants); 178 pages, reviewed by the NAQCAC and 17 Federal Agencies.	Health conclusions <sup>88</sup> based on 1950s and 60's epidemiology studies, with both SO <sub>2</sub> and PM high. SO <sub>2</sub> interactions with particles, acid sulfate effects were noted. Controlled human studies showed effects of 5 minute SO <sub>2</sub> exposures as low as 1 ppm, but not included in summary. Key welfare criteria based on injury to vegetation, materials damage, visibility.
1971	Proposal, <sup>2,89</sup> promulgation <sup>3</sup> of first NAAQS for SO <sub>x</sub> (measured as SO <sub>2</sub> ). Final NAAQS: <i>Primary:</i> 365 µg/m <sup>3</sup> (0.14 ppm), 24-hr not to be exceeded than once per year 80 µg/m <sup>3</sup> (0.03 ppm) annual mean <i>Secondary:</i> 60 µg/m <sup>3</sup> (0.02 ppm), annual mean 1300 µg/m <sup>3</sup> (0.5 ppm), 3-hr not to be exceeded than once per year	Rationale not given. 24 hr criteria focused on Dutch <sup>90,91</sup> (with lower PM) and British studies of mortality, <sup>4,5</sup> and morbidity. <sup>6</sup> Annual criteria highlight British schoolchildren studies <sup>92,93</sup> and British mortality study <sup>94</sup> – all with high PM. Key welfare criteria: <i>long-term</i> – vegetation damage downwind of Canadian smelter <sup>95</sup> ; <i>short term</i> (4-8 hr) vegetation damage. <sup>96</sup> The January proposal <sup>2</sup> included a 24-hr secondary standard. A supplemental proposal <sup>89</sup> in March added the 3-hr standard that was promulgated in April.



<p><b>1972-73</b></p>	<p>Kennecott sued EPA over the basis for the secondary SO<sub>2</sub> standards; the D.C. Circuit Court of Appeals remanded the annual standard back to EPA (<i>Kennecott Copper Corp. v. EPA</i>, 462 F.2d 846 [D.C. Cir. 1972]). EPA developed a revised Chapter 5 (Vegetation Effects) to the SO<sub>x</sub> CD,<sup>97</sup> reviewed by NAQCAC, Federal Agencies.</p> <p>EPA proposed<sup>98</sup> and promulgated<sup>99</sup> revocation of the disputed annual standard, but reaffirmed the 3-hr standard. EPA received 23 comments, 11 of 20 supported the action.</p>	<p>EPA's reassessment of the Canadian smelter study<sup>95</sup> found that because of repeated high SO<sub>2</sub> peaks, the observed effects could not be clearly related to long-term levels. No other effects could be shown at long-term levels below the level of the primary standard. Visible injury on plants at levels below 0.5 ppm for 1-hr peaks from newer studies was judged not to be adverse, so revised standards were not requisite.<sup>99</sup></p> <p>The Court decision called for a clear rationale and record. EPA adopted more formal internal procedures for NAAQS reviews, including White House Staff review, but completed the criteria and NAAQS review process in 18 months.<sup>17</sup></p>
<p><b>1974-78</b></p>	<p>David Rall (NIEHS) published review of health and other effects of sulfur oxides,<sup>100</sup> alone and in combination with PM. NAQCAC called for review of all criteria.<sup>15</sup> The NAS published major reviews on particles<sup>18</sup> and SO<sub>x</sub>.<sup>101</sup></p>	<p>The Rall and NAS Reviews generally supported the original standards, but suggested a need for a review of criteria and possible modifications. EPA originally planned for a CD for SO<sub>x</sub> and associated particles by August 1979.<sup>16</sup> Distinctions between approaches for SO<sub>2</sub> and acid sulfates became clearer.</p>
<p><b>1979-82</b></p>	<p>EPA announced the NAAQS review, with a combined revised CD for SO<sub>x</sub>/PM in October 1979. Consolidation Coal sued EPA for moving too slow on the SO<sub>2</sub> NAAQS review. The Court ruled that EPA had discretion over its schedule, but in 1981 ordered completion of the PM/SO<sub>x</sub> CD by January 15, 1982<sup>17</sup> (<i>Consolidation Coal Company v. Douglas M. Costle, Administrator of the Environmental Protection Agency</i>. U.S. Dis. Ct. for the S. District of Ohio).</p> <p>(See Table 1 for SO<sub>x</sub>/PM CD chronology). CASAC closed on the CD<sup>24</sup> in January and on the SO<sub>2</sub> SP<sup>102</sup> in August 1982.<sup>103</sup> Staff<sup>102</sup> and CASAC<sup>103</sup> recommended two primary NAAQS options: 1) add a new 1 to 3-hr primary SO<sub>2</sub> standard, retain a 24-hr with statistical form, convert the annual primary standard into a secondary NAAQS and 2) retain the existing suite of SO<sub>2</sub> standards, converting the short-term (3 hr) secondary standard into a primary standard.</p>	<p>Numerous delays in the process were related to the two lawsuits and length of the combined documents (see Table 1). The CD<sup>24</sup> epidemiology review focused on mortality in 14 London winters<sup>4,29,36</sup> London bronchitis from 1960s for both PM and SO<sub>x</sub>.<sup>94,104</sup> The CD reinterpreted the Dutch epidemiology studies,<sup>90,91</sup> with higher SO<sub>2</sub> effects levels. Long-term health epidemiology data found to be 'largely qualitative.'<sup>102</sup></p> <p>The clearest evidence for SO<sub>2</sub> effects at ambient levels shifted from epidemiology to controlled chamber studies of short-term peak exposures of asthmatics. The staff assessment of short-term air quality under 1971 and alternative standards was a major consideration. CASAC recommended moving consideration acid deposition effects on public welfare to a separate review.<sup>102,103</sup></p>

<b>1984</b>	The administrator decided not to revise the SO <sub>2</sub> NAAQS. EPA did not formally announce the decision.	Following extensive briefings, the administrator (Ruckelshaus) communicated the decision to Agency staff. <sup>105</sup>
<b>1986-87</b>	Addenda to criteria document <sup>32</sup> and staff paper <sup>106</sup> updated new analyses and data since 1982 CD closed. Staff and CASAC <sup>107</sup> recommendations were similar to 1982, with a range of 1-hr standard levels of 0.2 to 0.5 ppm), as well as reaffirming current standards as options. Secondary standards were not addressed in this supplemental review.	Sixteen new controlled studies of asthmatics with varying exercise levels reinforced the 1982 CD conclusions on short term exposures. New epidemiology studies found effects of SO <sub>2</sub> and PM at episode levels lower than those for 1982 CD and for long-term levels, which strengthened support for current primary standards. A staff exposure assessment examined the relative protection afforded by alternative 1-hr and current suite of standards. <sup>106</sup>
<b>1988</b>	EPA proposed <sup>105</sup> not to revise the SO <sub>2</sub> NAAQS, but sought comment on a 1 hr alternative of 0.4 ppm. EPA proposed to clarify ‘averaging’ convention as sequential ‘blocks’ and not overlapping ‘running average’ periods and restate standards in ppm, not µg/m <sup>3</sup> . EPA also proposed to revise the ‘Significant Harm’ and episode levels under section 303 of the CAA and add 1-hr averaging time.  EPA extended the comment period twice and issued a supplemental notice clarifying the averaging convention. EPA received extensive written comments from 80 groups/individuals that generally supported the current standards, sharply divided on need for 1 hr standard. <sup>108,109</sup>	The proposal placed substantial weight on exposure analysis, which found that with 1980’s air quality, a limited number of asthmatics (100,000) nationwide would experience an exposure of concern (0.5 ppm at exercise), and fewer than 1% would experience more than one. Residual exposures not a ‘significant public health problem’ requiring a NAAQS.  The decision not to revise secondary SO <sub>2</sub> standards recognized acidic deposition, but concluded it was premature to consider NAAQS for this complex, multi-pollutant problem. Proposed 1-hr significant harm/episode levels under Section 303 of the CAA were intended to address large point sources that could produce very high peaks.
<b>1989-93</b>	EPA delayed final action on the 1988 proposal. In 1992, EDF and ALA sued EPA to complete actions on secondary and primary standards.  EPA took final action <sup>108</sup> on the SO <sub>2</sub> secondary standards in 1993, deciding revisions were not appropriate at that time, and deferred action on proposed minor technical changes. EPA began work on new supplements to the CD and SP addenda on the issue of short-term effects of SO <sub>2</sub> on asthmatics. Initial drafts were reviewed by CASAC. <sup>109</sup>	Action on all NAAQS reviews was slowed during the development of CAA amendments <sup>110</sup> in 1989 and 1990.  The major preamble discussion of secondary NAAQS was on acid deposition. The decision not to add a new or revised secondary SO <sub>x</sub> standard relied in part on the acid rain provisions of the 1990 CAA (Title IV), which included a legislative requirement to examine the need for an acid deposition standard.

<b>1994</b>	<p>CASAC provided a single closure letter<sup>111</sup> on the CD addendum<sup>112</sup> and SP supplement.<sup>113</sup> Staff recommended keeping the current standards and 3 options: 1) adding a new 5 minute standard, 2) establishing a new program under Section 303 of the Act 3) augmenting implementation of current NAAQS by focusing on sources likely to produce peaks. CASAC advised against option 1.</p> <p>EPA re-proposed<sup>109</sup> the decision not to revise the SO<sub>2</sub> primary standards, having considered the revised CD, SP, and CASAC recommendations. The minor technical changes proposed in 1988 were re-proposed. The proposal solicited comments on the 3 staff alternatives.</p>	<p>A number of new controlled human, survey, and air quality related studies since the 1986 addendum added information on the distribution of responses of asthmatics of different degrees of severity, the extent of medication use among mild to moderate asthmatics, the protective effect or lack thereof for common asthma medications, and exposure related issues.<sup>112,113</sup> SO<sub>2</sub> exposures of concern were 5 minute at 0.6 to 1 ppm.</p> <p>Re-proposal was needed because of the 6 year delay and the updated CD and SP addenda. CASAC noted that SO<sub>2</sub> emissions and levels were lower than in the previous review (1986) and were declining further with the 1990 amendments, making peak exposures rarer.</p>
<b>1995-96</b>	<p>EPA received 105 written comments on the re-proposal.<sup>114</sup> Most supported the existing standards, but opinion was divided on need for a short-term primary standard.</p> <p>EPA promulgated<sup>114</sup> a final decision stating that revisions to the SO<sub>2</sub> NAAS were not appropriate at that time, aside from the minor technical changes. Administrator Browner determined that the residual health risk posed by short-term peaks should be addressed at the state level, and committed to ‘propose shortly’ revisions to concern and intervention levels and associated guidance to assist states in addressing short-term peaks.</p> <p>ALA sued EPA on the decision not to add a peak standard,</p>	<p>The rationale again focused on the significance of the asthmatic response to various levels, the likelihood of such responses at various levels, and the probability and total numbers of asthmatics that may experience exposures of concern given current and projected emissions and air quality. While the data showed that peaks &gt;0.6 ppm could occur around particular point sources, such peaks were not ubiquitous from a national perspective and the risk of exposures that could cause significant effects varies significantly with site-specific factors.</p> <p>The administrator concluded that neither a revised NAAQS (option 1) nor a national Sec. 303 program (option 2) were appropriate to address such residual risks.</p>
<b>1997</b>	<p>EPA proposed<sup>115</sup> an intervention level program (ILP) as indicated in the 1996 Final decision.</p>	<p>The proposed approach would establish a 5 minute SO<sub>2</sub> level of concern of 0.6 ppm and an endangerment level at 2 ppm. The program would require states to have authority to take necessary actions to prevent exposures of concern, considering a number of factors.</p>

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**1998-01** The D.C. Circuit found EPA had not provided an adequate explanation for the decision not to revise the primary SO<sub>2</sub> NAAQS and remanded the case to permit EPA to more fully explain its decision not to set a short-term standard (*American Lung Association v. Browner*, No. 96-1251 [D.C. Cir.]).

ALA agreed to extend the time for EPA to respond to the SO<sub>2</sub> remand<sup>116</sup> to await resolution of the issues raised in *American Trucking Association v. EPA* (see Tables 1,4) then pending in the Supreme Court.

EPA published supplemental information on 5 minute SO<sub>2</sub> values and a status report on actions on the ILP.<sup>116</sup>

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**2005-07** The Center for Biological Diversity sued EPA to complete a review of the SO<sub>2</sub> (and NO<sub>2</sub>) criteria and standards by mid to late 2009. (*Center for Biological Diversity et al. v. Stephen L. Johnson.*, No. 05-1814 [D.C. Cir.]). EPA began a review<sup>117</sup> of the SO<sub>x</sub> criteria in two parts; a combined NO<sub>x</sub>/SO<sub>x</sub> “Integrated Science Assessment” (ISA) document focusing on effects on public welfare<sup>118</sup> and a separate ISA document focusing on the health effects of SO<sub>2</sub>.

The final schedule will depend on court action and related discussions. EPA is applying the newly announced NAAQS process<sup>119</sup> to this review, substituting the ISA for the CD, backed up by a reference document.<sup>118</sup> The SP will be replaced with a “Policy Assessment,” currently planned to be issued in the form of an Advance Notice of Proposed Rulemaking (ANPR) published in the Federal Register.

**Table 3. Chronology of Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS)**

Year	Event	Comments
1970	First CO CD <sup>120</sup> (PHS staff and consultants) reviewed by NAQCAC and 17 Federal Agencies.	Health conclusions relate effects to blood carboxyhemoglobin (COHb) levels; focus on studies of relationship of ambient CO to blood COHb; equilibrium blood level of COHb was reached in 8-12 hrs of exposure. <sup>120</sup> Controlled human data suggested central nervous system (CNS) effects at equilibrium 2 to 5 % COHb and above, some evidence that shorter term peak exposures could produce effects at high levels. No welfare effects at ambient levels.
1971	Proposal, <sup>2</sup> promulgation <sup>3</sup> of first NAAQS for CO <i>Primary:</i> 10 mg/m <sup>3</sup> (9 ppm) 8-hr not to be exceeded more than once per year 40 mg/m <sup>3</sup> (35 ppm) 1-hr, not to be exceeded more than once per year <i>Secondary:</i> same as primary	Commenters raised serious questions on lowest COHb levels that cause a CNS effect <sup>3</sup> , which was impairment of the ability to discriminate time intervals. <sup>121</sup> EPA concluded that the evidence for this effect was uncertain, but not refuted. Accordingly, EPA kept 2% COHb as the protective target, but raised 1-hr level from that proposed (15) to 40 mg/m <sup>3</sup> , which was more in line with original study in CD. <sup>3</sup>
1976	NAQCAC recommended revisions of all criteria, NAAQS <sup>15</sup>	EPA scheduled CO as the third of NAAQS pollutants to be reviewed with a projected final CD draft by 8/78. <sup>16</sup>
1978	EPA announced start of review of CO CD <sup>122</sup>	First external review draft of CD made available for review.
1979	CASAC and public review of 2 drafts of CD, final CD. <sup>123</sup> CASAC issues 'closure' memorandum. <sup>124</sup> First draft OAQPS SP <sup>125</sup> identified factors for possible revisions, including sensitive populations, critical COHb effects levels, statistical form. The draft SP was 'favorably reviewed' by CASAC. <sup>122</sup>	CO was the first NAAQS review by CASAC, with the first integrated OAQPS SP(draft); the SP did not recommend ranges of levels. The key CNS study <sup>120</sup> cited as basis of 1971 standard could not be replicated. New controlled human studies found additional CNS, cardiovascular system, exercise effects across range of COHb levels. <sup>123,125</sup>
1980	EPA proposed <sup>122</sup> to retain level of 8-hr CO NAAQS, lower the level of 1-hr NAAQS from 35 to 25 ppm, change the form of standards to no more than 1 expected exceedance/yr (3 yr test), adopt a 'daily interpretation (only 1 exceedance counts per day). EPA proposed to revoke the CO secondary standards.	Nine key controlled human studies identified done by two groups (Aronow, <sup>126</sup> Anderson <sup>127</sup> ), key adverse effect identified as decreased time to onset of angina; lowest mean effects levels at 2.7 to 3% COHb, individual down to 2.4%. Coburn (CFK) model used to assess range of COHb in sensitive groups from exposures at alternative standards. <sup>128</sup> Proposed

	EPA held two public meetings on the proposal. CASAC met to review it. EPA received 30 written comments on aspects of proposed levels. Seven of 11 favored proposed or more stringent 8-hr; 12 of 18 favored the proposed (25 ppm) or original (35 ppm) 1-hr standard. <sup>129</sup>	standards would prevent 99% of population from exceeding 2.1% COHb. Changes to form made to increase stability, with a rationale similar to that used earlier for O <sub>3</sub> (See Table 4). The White House Regulatory Assessment and Review Group (RARG) suggested, as for the O <sub>3</sub> NAAQS, that standard levels should be based on cost/effectiveness analysis. <sup>129</sup>
<b>1981-82</b>	In 1982, EPA announced an additional public comment period to address key issues including new studies, a possible move to a multiple exceedance form of the NAAQS, and the adequacy of CFK model sensitivity and exposure analysis (47FR26407). CASAC provided written advice on these issues. <sup>130</sup> EPA received 13 comments on stringency of the 8-hr standard, with 35 of 45 against a relaxation. <sup>129</sup>	Aronow published a new study <sup>131</sup> suggesting an angina effect at 2% COHb, which if correct, would call the margin of safety for the proposed CO NAAQS into question.  Staff revised the CFK sensitivity analyses and used the National Exposure Model (NEM) to respond to public comments, and improve range of COHb estimates for alternative standards.
<b>1983-84</b>	In 1983, on learning about questions regarding adequacy of drug studies done by Aronow, EPA convened an expert committee led by Dr. Steven Horvath to examine records from his most recent work on CO. This panel concluded EPA should not rely on Aronow's data for the NAAQS. <sup>132</sup> EPA developed an addendum to the CO CD <sup>133</sup> and an SP Reassessment, <sup>134</sup> both reviewed by CASAC and the public.  CASAC concurred with the staff recommendations on ranges for standards, and to keep the level of protection provided by the original standards. <sup>135</sup> After revisions and the CASAC letter, EPA issued final documents, solicited further public comment (49FR31923), and received 7 comments on the levels with mixed opinions. <sup>129</sup>	Aronow responded in writing <sup>136</sup> , but EPA characterized his letter as "disputing, but not effectively refuting, the major points raised by the 'Horvath Committee' report."  The SP Reassessment <sup>134</sup> reinterpreted effects studies in the CD and the CD addendum excluding work of Aronow, focusing on multiple studies with lowest effects levels between 2.3 and 7 % COHb, including aggravation of angina (2.9- 4.5 %) and decreased work time to exhaustion (2.3-4.3%).
<b>1985</b>	EPA promulgated final decision <sup>129</sup> not to revise the primary CO standards and to revoke the secondary standards. EPA did change the 'preferred' measurement unit of the CO NAAQS from mg/m <sup>3</sup> to ppm, but retained both systems. The ppm measure precludes the need for corrections to account for pressure and temperature.	Exposure analyses showed the original standards would keep over 99% of the sensitive population below 2.1% COHb. <sup>129</sup> The final preamble noted that EPA and HEI were conducting follow-up clinical studies of onset to angina, concluded it was prudent to keep current standards and consider new data in next review.

<p><b>1987-93</b> EPA began work on revised CD; the first draft was reviewed by CASAC and public in 1991. CASAC sent a closure letter<sup>137</sup> and EPA completed the CD.<sup>138</sup> The first draft SP was reviewed by CASAC and the public in March 1992. Subsequent minor revisions to the SP were reviewed by CASAC, who then sent a closure letter.<sup>139</sup></p> <p>CASAC agreed with the final SP<sup>140</sup> conclusion that retention of the original standards was supported by present scientific data. EPA opened a decision docket on the NAAQS in 1993.</p>	<p>The CD and SP focused on the results of several of the new controlled human studies that were anticipated in the 1985 CO decision and published between 1987-9. Five key studies, particularly those by a multi-center group,<sup>141,142,143</sup> provided substantial new evidence on effects in angina patients. The SP<sup>140</sup> judged increased angina effects in range of 2.9 to 5.9% COHb to be potentially adverse. Small electrocardiogram (ECG) changes were seen at 2 to 2.9%. A revised exposure analysis found &lt;0.1% of the non-smoking population would have COHb&gt;2.1% at the 8-hr standard, &lt;1% at the 1-hr standard. The analysis also found COHb levels would be higher for individuals with high indoor exposures from gas stoves, passive smoking, but did not attempt to account for non-ambient exposures.</p>
<p><b>1994</b> EPA issued a ‘direct final’ decision<sup>144</sup> not to revise the CO standards. EPA did not issue a proposed decision or take public comments beyond those on the CD and SP.</p>	<p>The administrator accepted recommendations of staff and CASAC. Under the original CO NAAQS, very few individuals would experience COHb levels of 2.1% or greater, which is below levels of concern for angina (2.9-3%); the significance of ECG effects at 2% appeared ‘trivial,’ and the small decrease in maximal exercise performance of concern “mainly for competing athletes.”<sup>144</sup></p> <p>In contrast to the approach used earlier for Pb (see Table 7), EPA concluded that the potential for higher CO exposures from indoor sources plus outdoor “cannot be effectively mitigated” by the NAAQS.<sup>144</sup></p>
<p><b>1998-00</b> EPA developed first draft of CD, reviewed by CASAC and public (6/99); CASAC reviewed a revised draft (11/99) and sent a closure letter.<sup>145</sup> Final CD<sup>146</sup> issued.</p>	<p>New evidence from time series studies suggested that CO is associated with mortality and hospital admissions at ambient levels, but difficult to separate from PM, other pollutants. EPA held action on the CO SP pending review of multi-pollutant time-series studies in PM CD and standards review.</p>

**Table 4. Chronology of O<sub>3</sub> and Photochemical Oxidant National Ambient Air Quality Standards**

Year	Event	Comments
1970	Photochemical oxidant CD <sup>147</sup> (PHS staff and consultants) 211 pages, reviewed by the National Air Quality Criteria Advisory Committee (NAQCAC) and 17 Federal Agencies.	The CD health conclusions focused on oxidants as measured in epidemiology studies (mostly Los Angeles area), O <sub>3</sub> effects in controlled human studies. Key welfare effects: damage to vegetation and materials, public concern. Measurement issues, role of other oxidants (notably peroxyacyl nitrate – PAN) noted.
1971	Proposal, <sup>2</sup> promulgation <sup>3</sup> of photochemical oxidant NAAQS, measured as O <sub>3</sub> by NO <sub>2</sub> /SO <sub>2</sub> corrected KI method  <i>Primary:</i> 160 µg/m <sup>3</sup> (0.08 ppm), maximum hourly level not to be exceeded more than once per year <i>Secondary:</i> same as primary.	The proposed level was 125 µg/m <sup>3</sup> (0.06 ppm), based on a study that reported a reduction in athletic performance. <sup>148</sup> Commenters raised serious questions about the validity of the data, and the principal study cited for the final level found increased asthma attack frequency when hourly average levels reached 125 µg/m <sup>3</sup> (0.10 ppm). <sup>149</sup> The final standard included a margin of safety “below the most likely threshold level suggested” by this study. <sup>3</sup> No rationale given for secondary. The CD reported vegetation damage at 100 µg/m <sup>3</sup> (0.05 ppm) for 4 hrs.
1976	NAQCAC recommended that all criteria and NAAQS be reviewed. <sup>15</sup> EPA’s Criteria and Special Studies Office (CSSO) began work on a revised CD with an international conference. Subsequently, the American Petroleum Institute (API) and the City of Houston petitioned EPA to revise the criteria and standards, as well as control strategy guidelines. <sup>17</sup>	EPA scheduled photochemical oxidants as the first criteria to be reviewed with a projected final CD draft by 8/77. <sup>16</sup> Reanalyses of oxidant measurements in the key study <sup>149</sup> cited for the 1971 standard level found effects at 0.25 ppm, more than double the 1970 CD estimate. EPA convened a subcommittee of the SAB to review the revised CD. <sup>17</sup> Because O <sub>3</sub> was to be used as the ‘chemical measurement’ (i.e. indicator) for the standard, the revised CD was titled “Ozone and Other Photochemical Oxidants.”
1977	OAQPS staff developed a decision analytic approach for a risk assessment <sup>150,151</sup> intended to inform the standard review. Staff solicited advice on the risk assessment and on the adversity of health effects from a panel of six health experts convened by Dr. Carl Shy at two meetings. <sup>152</sup>	The “Shy Panel” found adverse effects of O <sub>3</sub> and other oxidants at levels of 0.15 to 0.25 ppm, supported the risk assessment method for O <sub>3</sub> , and saw ‘no compelling reason’ to change the 0.08 ppm level of the standard. <sup>153</sup> Following the second meeting, staff proceeded to develop a draft risk



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Pursuant to a consent agreement with API, the EPA was originally required to complete the revised CD by the end of 1977, but the D.C. Circuit Court granted extensions.<sup>17</sup>

assessment using the new methodology. Ultimately staff encoded the subjective judgments of nine health experts to estimate probabilistic exposure-response relationships for four different health effects.<sup>150</sup>

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**1978** The SAB subcommittee and the public reviewed and commented on two successive drafts of the CD; the SAB provided final formal comments.<sup>17</sup> EPA completed the O<sub>3</sub>/Photochemical Oxidants CD.<sup>154</sup> EPA made the draft risk assessment and several draft ‘staff papers’ that made recommendations about the NAAQS publicly available. EPA held a public meeting in January to review the draft risk assessment and staff papers.<sup>152</sup>

In June 1978, EPA proposed<sup>155</sup> to revise the 1-hr primary standard to be indicated by O<sub>3</sub> at a level of 0.10 ppm, with a statistical form. The proposed level of the secondary O<sub>3</sub> standard was kept at 0.08 ppm.

EPA held 4 public meetings and received 168 written comments, 132 of which opposed the proposal as too strict or too lax.<sup>155</sup> President Carter’s new RARG submitted comments critical of EPA’s interpretation of the evidence and analysis, suggesting consideration of marginal costs per person-hr of O<sub>3</sub> effects avoided.<sup>156</sup>

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**1979** EPA promulgated<sup>160</sup> final revisions to the standards expressed as O<sub>3</sub> with a new Federal Reference Method (FRM):

*Primary:* 0.12 ppm, daily maximum 1-hr with no more than 1 expected exceedance per year;

*Secondary:* same as primary.

In the final notice,<sup>160</sup> EPA responded to the API and Houston petitions, including some technical issues related to implementation. In part, EPA deleted “Appendix J” as

The SAB panel did not require a full rewrite of the CD because of the court ordered deadline, but did ask to see revisions to the summary and conclusions. Several members still had problems, but EPA proceeded to publication.<sup>17</sup> The draft staff papers recommended the NAAQS should: 1) be designated as O<sub>3</sub>, 2) with no separate standard for PAN or other oxidants; 3) be expressed in a statistical form, rather than deterministic; 4) retain the 1-hr averaging time; and 5) be selected from a range of levels of 0.08 and 0.15 ppm.

The FR notice noted three clinical studies<sup>157,158,159</sup> that found reduction in pulmonary function and/or symptoms as having the lowest effect level in humans in the range of 0.15 to 0.3 ppm with evidence for lower effects levels in animals.<sup>155</sup> Results of the draft risk assessment<sup>150</sup> were presented in the proposal as preliminary. The proposal observed there would be no detectable effects on crops where the original 1-hr NAAQS (0.08 ppm) is met. EPA extended the public comment period to accommodate the RARG review.<sup>17</sup>

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The FR preamble detailed organizational commenters’ positions on level by name. Key technical issues included whether effects at lower levels were adverse, the proper interpretation of key studies, particularly controlled human studies, the margin of safety given no clear safe level, exposure, and welfare effects. Procedural issues included the use of the Shy panel to provide advice, the use of the preliminary risk assessment, the lack of a clear approval of the CD by the SAB and failure to submit the proposal for SAB review (required by ERDDA).<sup>20</sup>

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	implementation guidance for hydrocarbon control, allowing states to use any of four analytical techniques for developing strategies, including the Empirical Kinetics Modeling Approach (EKMA) and changes to the FRM from KI to the chemiluminescence (UV photometry) method.	The rationale specified the likely lowest adverse effects levels based on the studies and on the advice and judgment of experts. EPA judged this range of levels to be 0.15 to 0.3 ppm, and argued margin of safety considerations suggested a still lower level of 0.12 for the standard. The final rationale for revising the secondary NAAQS noted the relationship of crop foliar injury with O <sub>3</sub> at lower levels, but found the implications for crop yield to be too uncertain. Relying on field studies of crop growth and yield, EPA concluded that no significant decreases in crop yield would be expected where revised primary standard is met.
<b>1980</b>	The DC Circuit upheld the revised standards against legal, technical, and procedural challenges ( <i>American Petroleum Institute vs. EPA</i> , 665 F.2d 1176 [D.C. Circuit Court, 1981], <i>cert. den.</i> 455 U.S. 1034 [1982].)	As in the earlier Pb case (see Table 7), the Court rejected arguments that costs and feasibility should be considered in setting NAAQS. They rejected the API argument the final O <sub>3</sub> NAAQS was too far below an effects level of 0.25 ppm and the NRDC argument that it failed to protect against reasonably predicted risks below 0.12 ppm.
<b>1982-83</b>	EPA announced the start of review of the O <sub>3</sub> criteria and standards. <sup>17</sup> EPA held public workshops on working draft chapters on welfare effects and health effects.	Following the debate over the 1979 revised standards, a substantial amount of new research was conducted focused on controlled human exposures, effects on vegetation, and longer exposure.
<b>1984-87</b>	The first external review drafts of the CD were reviewed by CASAC and the public, in three public meetings. CASAC sent a closure letter on the CD <sup>161</sup> and EPA released 5 volume final CD. <sup>162</sup> The first draft SP was reviewed by CASAC and the public (4/86). CASAC recommended OAQPS staff consider new studies on prolonged O <sub>3</sub> exposures and alternative indicators of impacts on crops in the subsequent draft. The second draft SP was reviewed at a public CASAC meeting in December 1987. CASAC found enough significant new information to recommend that EPA develop a supplement to the 1986 CD <sup>161</sup> and a 3 <sup>rd</sup> draft of the SP.	Information on 1-3 hr controlled human exposures was greatly expanded, <sup>163-165</sup> and found small functional changes or symptoms with heavy exercise at 0.12 to 0.15 ppm. The wide variability of responses across subjects and studies suggested 5-20% of otherwise healthy subjects were particularly responsive. Enhanced effects from 'prolonged' (6-8 hr) exposures began to appear in 1985 in summer camp panel studies of children <sup>166</sup> with some <sup>167</sup> published too late for inclusion in the 1986 CD. New epidemiological studies <sup>168-171</sup> found increased asthma attacks, hospital admissions, but were dismissed in the CD as too uncertain for definitive conclusions. EPA

	researchers presented summaries of newly published and emerging information on prolonged exposures and crop effects indicators at the December CASAC meeting.
<p><b>1988-89</b> The draft CD supplement<sup>172</sup> and 3<sup>rd</sup> SP were reviewed by CASAC and the public in 12/88. CASAC issued one closure letter on both.<sup>173</sup> The final SP<sup>174</sup> recommended ranges of 1-hr primary and secondary standards that included the 1979 standards level as an upper bound. CASAC reached no consensus on the range, providing individual opinions across both staff ranges. CASAC recommended the possible need for a 6-8 hr standard should be considered in the next review, when then emerging studies were published.<sup>173</sup> CASAC recommended a cumulative seasonal form for the secondary standard, but also consideration of a 0.1 ppm 1-hr standard.</p>	<p>New studies continued to appear, including an EPA study<sup>175</sup> suggesting exercising subjects exposed at or below 0.12 ppm for 6-8 hrs may experienced inflammation as well as transient functional changes. Published and other analyses<sup>176,177</sup> suggested O<sub>3</sub> damage to crops may be better defined by alternative weighted seasonal exposure measures than by the 1-hr peak measure of the NAAQS.</p>
<p><b>1990-93</b> In 1991, a Court ordered EPA to propose a decision on whether to revise the standards by 8/1/92 and make a final decision by 3/1/93 (<i>American Lung Association v. Reilly</i>, No.91-cv-4114. {JRB}[E.D.N.Y.]).</p> <p>EPA proposed<sup>178</sup> Administrator Reilly's decision that revisions to the O<sub>3</sub> standards 'are not appropriate at this time.' The proposal outlined EPA's plans to proceed as rapidly as possible with the next review of the criteria and standards to incorporate the new science. EPA received 27 written submissions and held a public meeting, but only 3 individuals testified. EPA promulgated the decision<sup>179</sup> by Administrator Browner not to revise the standard for the same reasons. EPA announced it had already begun to update the O<sub>3</sub> criteria.</p>	<p>As expected, the increase in publication of relevant new studies on O<sub>3</sub> effects continued. By the time of proposal, EPA estimated over 1000 new studies would need to be assessed.</p> <p>Given its reading of the Act, EPA based the proposed and final decisions on the scientific information contained in the 1986 CD and the 1988 supplement and not on the new studies, estimating it would take 2-3 years to fully assess and integrate the new information for decision making. The final notice stressed that EPA had long taken the view that NAAQS must be based on scientific studies that have been assessed in air quality criteria.</p>
<p><b>1994-95</b> After several workshops in 1993, EPA released a draft of the fourth O<sub>3</sub>/photochemical oxidants CD, which was reviewed by CASAC and the public at a meeting in 1994. Subsequent</p>	<p>New studies continued to find effects at levels below the 1979 standard, with an increased importance of 6-8 hr exposures. Key studies found lung function decrements, respiratory</p>

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drafts of the CD and separate health/primary and welfare/secondary portions of the O<sub>3</sub> SP were reviewed by CASAC and the public in two 1995 meetings. Staff developed a 9 city quantitative exposure analysis and health risk assessment and a quantitative assessment of damage to crops and tree seedlings. CASAC issued closure letters on the CD,<sup>180</sup> which was completed<sup>181</sup> and on the health/primary standards portions of the SP.<sup>182a</sup> The revised welfare/secondary standard portions of the SP were reviewed by CASAC and the public at a separate meeting, and CASAC subsequently issued a closure letter on it.<sup>182b</sup>

The final SP<sup>183</sup> recommended replacing the 1-hr primary standard with an 8 hr standard selected from a range of 0.07 to 0.09 ppm, with a concentration-based form. CASAC was unanimous in recommending revisions to the averaging time and form, and indicated the staff recommended range was appropriate for consideration, although no individual members recommended 0.07 ppm. CASAC felt the risk assessment should play a central role in selecting a level, which they viewed as a policy judgment.<sup>182a</sup> Staff and CASAC concluded that the 1979 O<sub>3</sub> standard was not adequate to protect welfare, recommended consideration of a seasonal secondary standard using 'SUMO6' form in the range of 25 to 38 ppm-hrs or a secondary 8-hr standard set equal to the revised primary standard.<sup>182b,183</sup>

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**1996** EPA decided to conduct the proposed and final NAAQS rulemaking for O<sub>3</sub> on the same schedule as PM (see Table 1), citing a number of overlapping aspects significant for air quality management.

EPA proposed<sup>187</sup> to replace the 1-hr O<sub>3</sub> standard with an 8-hr standard of 0.08 or 0.09 ppm, solicited comments on an alternative level of 0.07 ppm and the alternative of not

symptoms, increased sensitivity to irritants, and indicators of pulmonary inflammation increasing across a range of 0.08, 0.1, and 0.12 pm for 6 to 8 hr exposures with subjects engaged in intermittent exercise.<sup>175,184,185</sup> Observations supported in field and animals studies. Numerous epidemiology studies found increased hospital admissions, emergency room visits for respiratory causes attributed primarily to O<sub>3</sub>. The risk assessment focused on fraction of children outdoors who would experience functional or symptomatic effects of concern and asthma hospital admissions<sup>186</sup> for various standard alternatives of averaging time, levels and form.

New welfare studies added effects on forest tree species and dynamics of exposure to the substantial data on crop effects.<sup>183</sup> The staff assessed crop and seedling loss for alternative primary and secondary standard forms, levels and averaging times using 1990 air quality data and models to extrapolate to nationwide exposures, adapting effects studies results to predict losses. Analysis found that 1990 air quality would produce significant losses in large portions of California and the Eastern US. The staff favored a SUMO6 form, which is the sum of all hourly O<sub>3</sub> concentrations  $\geq 0.06$  ppm over a given time period (e.g. 3-month growing season) and diurnal window (e.g. 12 daylight hours).

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The proposal highlighted the risk assessment for children (9-city) and for NYC hospital admissions. Analysis found declining risks in terms of % children with three effects categories of concern with more stringent options, but no obvious break point. On an absolute basis, the difference between 8-hr standard level options represented hundreds of thousands of times children that could experience effects of concern. The assessment found the 0.09 ppm option was

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	<p>revising the 1-hr standard. The proposed revised 8-hr form would reflect a 3 year average of a range of specified high values (1<sup>st</sup> to 5<sup>th</sup> annual daily 8-hr maximum).</p> <p>EPA proposed two alternatives for secondary standards: 1) set identical to primary or 2) a new seasonal standard (SUM06) at a level of 25 ppm-hrs.</p>	<p>roughly equivalent to protection afforded by the 1979 1-hr standard. The difference in risk of NYC hospital admissions between alternatives was small in percentage terms.</p> <p>The proposal provided a summary rationale for 3 alternative levels stressing alternative views on the significance of the effects<sup>182a,188</sup> and risk reduction and how to address uncertainties in policy.</p> <p>Welfare options relied on risk/economic assessment, extent and amount of estimated regional crop and seedling effects.</p>
<b>1997</b>	<p>EPA held three simultaneous well attended public meetings on the O<sub>3</sub> and PM proposals. Over 50,000 written and verbal comments on the O<sub>3</sub> proposal. A broad majority supported an 8-hr standard more stringent than 0.09 ppm; a number of commenters submitted detailed rationales for recommended no revisions or 8-hr standards ‘equivalent’ to current 1-hr standard.<sup>189</sup></p> <p>EPA promulgated a final decision<sup>189</sup> to replace the 1-hr standard with an 8-hr standard of 0.08 ppm, based on the 3 year average of the annual 4<sup>th</sup> highest daily maximum 8-hr average at each monitor in an area. The final secondary standard was set equal in all respects to the primary standard.</p>	<p>The final decisions on level and form of the primary NAAQS focused on the implications of risk the assessment for options, significance of effects, potential for more serious, but uncertain chronic effects. The administrator’s task was to “reduce risk sufficiently to protect public health... since a zero-risk standard is neither possible nor required by the Act.” The secondary NAAQS decision focused on the smaller increment of welfare benefits/protection between the primary standard chosen and the proposed SUM06 alternative.</p> <p>EPA also adopted an interim implementation approach continuing the 1990 amendment approach (Subpart 2) until the 1-hr standard was met.</p>
<b>1998 -01</b>	<p>Multiple parties filed lawsuits and petitions for review of the O<sub>3</sub> NAAQS based on a variety of legal, policy, and technical arguments. A divided DC Circuit panel remanded the O<sub>3</sub>, PM<sub>2.5</sub> and PM<sub>10</sub> standards to EPA due to lack of a “determinate criterion” for non-threshold pollutants, raising a constitutional issue (<i>American Trucking Association vs. EPA</i>, D.C. Circuit Court, 1999). The Court also remanded the O<sub>3</sub> standard on the basis that EPA had not considered the alleged beneficial effect of ground level O<sub>3</sub> against ultraviolet (UV-b) radiation. EPA petitioned the Supreme Court on the constitutional issue and two others. In the</p>	<p>The D.C. Circuit panel again upheld EPA position that costs cannot be considered in setting NAAQS. The full Circuit Court declined to review the panel ruling with regard to the potential beneficial effects of O<sub>3</sub> in shielding against UV-b effects, and EPA did not appeal this issue to the Supreme Court. This resulted in the need to review the evidence on O<sub>3</sub>/UV-b and to consider the implications for the O<sub>3</sub> NAAQS.</p> <p>EPA had explored the ‘shielding’ effect of ground level O<sub>3</sub> in developing the benefits analysis portion of the RIA<sup>190</sup> for the</p>

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process, other ATA plaintiffs brought up additional issues, including the issue of costs.

The Supreme Court unanimously upheld EPA's position on the constitutional issue and on consideration of costs (*Whitman v. American Trucking Associations*, 531 U.S. 457, 464, 475–76) and remanded the case back to the DC Circuit, which later found that the O<sub>3</sub> (and PM) standards were “neither arbitrary nor capricious” and rejected the remaining petitions for review (*American Trucking Associations vs. EPA*, 283 F.3d 355, 369–372, D.C. Circuit Court, 2002).

EPA proposed<sup>190</sup> a response to the remand on the issue of ground level O<sub>3</sub> shielding UV-b, provisionally concluding that the relevant information was too uncertain to warrant any relaxation in the level of protection previously determined necessary to protect public health. Further, considering the evidence that was available, any changes in UV-b exposures of concern between alternative standards would likely be very small. EPA reached these conclusions for both the primary and secondary standards, and proposed to conclude it was not appropriate to revise either standard. EPA received 10 written public comments on the proposal.

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**2002** EPA promulgated<sup>192</sup> a final response to the remand, reaffirming the 1997 8-hr O<sub>3</sub> primary and secondary standards. EPA committed to include issues related to indirect potentially beneficial effects of ground-level O<sub>3</sub> in the ongoing review of the criteria and standards. This final action occurred 10 years after EPA initiated the O<sub>3</sub> review, including 5 years related to post-promulgation litigation.

Development of the fifth O<sub>3</sub>/photochemical oxidant criteria began in 2002. EPA reached a negotiated settlement agreement with several environmental groups (*American*

PM/O<sub>3</sub> NAAQS review, ultimately concluding that the information was too uncertain to produce reliable quantitative estimates. Further, given that total ground-level O<sub>3</sub> represents only about 5% of total column O<sub>3</sub>, any protective benefits of a 0.01 ppm change in the 4<sup>th</sup> maximum value in the standard (0.09-0.08 ppm) would necessarily be small.

The 1996 O<sub>3</sub> CD contained some information on O<sub>3</sub> UV attenuation, and referenced a number of more comprehensive treatments of UV-b effects. Because this was a response to a remand from the 1997 review, EPA decided it was neither necessary nor appropriate to delay the process by developing an addendum to the 1996 CD. Instead, EPA evaluated authoritative references on UV-b effects and shielding, as well as other material available in the rulemaking docket, some of which was developed for the RIA.<sup>191</sup> The 26 page proposal<sup>190</sup> contains a substantial discussion setting forth EPA's integrated assessment of the relevant multidisciplinary science, in order to provide a coherent basis for the decision. It also presents a summary of information on the direct health effects of O<sub>3</sub> from the 1996-97 notices. EPA provided the proposal to the CASAC.

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Some commenters objected to the process, suggesting that EPA should have reopened the CD to evaluate the information; EPA reiterated its position in its remand response, noted deficiencies in the documents relied on by commenters, and the fact that the next O<sub>3</sub> criteria review, which could fully develop relevant information, was already underway

On April 30, 2004, EPA announced its decision to make the 1-hr O<sub>3</sub> NAAQS no longer applicable to areas one year after the effective date of the designation of those areas for the 8-hr

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*Lung Association v. Whitman* [No. 1:03CV00778, D.D.C. 2003]); EPA was required to complete review of the O<sub>3</sub> CD by 2006. Under the most recent extension, EPA expects to propose decisions on the O<sub>3</sub> NAAQS by June, 2007 and to issue final decisions no later than March, 2008.

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**2005-07** Following workshops, the first external review draft of the CD was released and reviewed by CASAC and the public in May 2005. The revised second external draft was reviewed at a public CASAC meeting in August 2005. Subsequently, CASAC sent a letter to the administrator on the CD,<sup>193</sup> and EPA released the final O<sub>3</sub> CD.<sup>194</sup> CASAC provided additional advice on the final integrative chapter of the CD regarding time-series studies and welfare effects to be considered in developing the SP.<sup>195</sup>

EPA released the first draft SP, focused on health effects, and drafts of the human exposure analysis and risk assessment; all were reviewed by CASAC and the public in December 2005. A revised draft final SP with conclusions and recommendations, together with an extensive array of exposure and risk analyses results, was reviewed at an August 2006 CASAC meeting. CASAC sent a letter<sup>196</sup> to the administrator with comments and recommendations for tightening the primary and secondary standards, and requested to review the final SP conclusions. After revision, the final O<sub>3</sub> SP<sup>196</sup> was released in January 2007. The staff recommended that the 1997 8-hr standard be strengthened, with the level selected from a range of 0.060 to a maximum below 0.080 ppm, and that the secondary standard should be revised to a 12-hr seasonal “W126” form with a level picked from a range of 7 to 21 ppm-hrs.

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NAAQS (69 FR 23966). For most areas, the date that the 1-hr NAAQS no longer applied was June 15, 2005.

A number of new single and multicity epidemiological studies and meta-analyses had been published since the 1996 CD. More controlled human studies had been conducted for prolonged exposures. Many of the newer studies suggested that varying effects on morbidity, mortality, lung-function, symptoms, and inflammation could occur at levels at or below the 1997 standards.

The 2<sup>nd</sup> draft SP recommended consideration of 8-hr standards that included the current standard (0.08) down to 0.06 ppm. CASAC responded that the scientific information would no longer support retaining the current O<sub>3</sub> standards for health or welfare, and that both needed to be strengthened.<sup>196</sup> They further recommended that monitoring had advanced to the point where the standard should be expressed as in two significant digits, recommending a range of primary standards from a maximum of 0.070 down to 0.060 ppm.

Following their review of the final SP, CASAC reiterated their position on the primary and secondary standards in a letter commenting on the final SP recommendations.<sup>198</sup>

**Table 5. Chronology of Hydrocarbon (HC) National Ambient Air Quality Standards**

Year	Event	Comments
<b>1970</b>	HC CD <sup>199</sup> (PHS staff and consultants), reviewed by National Air Quality Criteria Advisory Committee (NAQAC) and 17 Federal Agencies.	Individual compounds may have effects but no adverse effects as a class; major is concern as oxidant former. Based on air quality analyses in the CD (Chapter 5) for several U.S. cities, the CD concluded that a non-methane HC concentration of 200 µg/m <sup>3</sup> at 6-9am or peak days might produce 1-hr oxidant concentration of up to 200 µg/m <sup>3</sup> 2-4 hrs later on 1 % of days.
<b>1971</b>	Proposal <sup>2</sup> , promulgation <sup>3</sup> of HC NAAQS, Final: <i>Primary:</i> 160 µg/m <sup>3</sup> (0.08 ppm), 3-hr average, 6-9 am not to be exceeded than once per year <i>Secondary:</i> same as primary. FRM subtracted methane, with the result expressed as a methane equivalent. The Notice states the HC NAAQS is intended as a 'guide' for oxidant implementation plans.	The 'sole purpose' the HC standard was to control photochemical oxidants. The proposed level of 125 µg/m <sup>3</sup> , was identical to level of the proposed oxidant standard, apparently based on the CD conclusions. The change in HC level in the final notice was based on the corresponding change to the final oxidant standard in response to public comment (see Table 4).
<b>1976</b>	NAQCAC recommended that all criteria, NAAQS be reviewed. <sup>15</sup>	EPA's response <sup>16</sup> to NAQCAC provided no schedule for the HC criteria review, but the Agency targeted 1980. <sup>17</sup>
<b>1977-79</b>	As part of their oxidants action, the city of Houston petitioned EPA to revoke the HC standard. <sup>155,200</sup>	EPA response was to adjust implementation guidance to provide that HC controls sufficient to attain the O <sub>3</sub> standard were adequate for attaining the HC standard. <sup>160,200</sup>
<b>1979-80</b>	EPA decided not to develop a revised HC CD, given the basis for the standard and recent developments in photochemistry. <sup>17</sup> EPA produced a draft paper reviewing the 1970 document and more recent scientific data together with an identification of key issues. The draft was reviewed by CASAC and the public in March 1980.  CASAC found the paper satisfactory and agreed with the major conclusions and recommendations, <sup>201</sup> which included: 1) HCs (and other volatile organic compounds) are a major precursor to O <sub>3</sub> /oxidants; 2) More recent science does not	The review paper relied in part on extensive discussions on HC/O <sub>3</sub> chemistry in the 1979 O <sub>3</sub> and other photochemical oxidants CD and on 1976 NAS reports on O <sub>3</sub> /oxidants and vapor phase organic pollutants. The paper focused on HC, and generally excluded discussion of other volatile organic compounds, such as aldehydes, that also contribute to O <sub>3</sub> formation and can be directly toxic.



	support the concept of a nationally uniform ambient HC level as a guide to meeting the O <sub>3</sub> standard everywhere; 3) as a class, HCs do not cause adverse health or welfare effects at ambient levels. EPA published the final review paper <sup>202</sup> in August 1980.	
<b>1981</b>	<p>EPA proposed<sup>200</sup> to revoke the HC standards to eliminate unnecessary regulations pertaining to air quality.</p> <p>The proposal pointed out that elimination of the HC standards would not preclude regulation of volatile organic compounds (HC or other organics) in state implementation plans for O<sub>3</sub>.</p> <p>EPA received 15 comments on the proposal, all of which supported the proposed revocation. EPA also submitted the proposal to CASAC for review.</p>	<p>The notice, signed by Acting Administrator (and OAQPS Director) Walter Barber, relied extensively on the review paper and CASAC conclusions. The proposal noted that individual HC's and other volatile organics that might have health or welfare effects were either already listed as a hazardous pollutant (e.g. benzene), or were under review by EPA or by the NAS for EPA (e.g. aldehydes, trichloroethylene, acrylonitrile) for possible listing and regulation under sections 112 or 111. It also noted that ethylene, which had resulted in damage to ornamental plants, did not "appear to be a problem nationwide."<sup>200,</sup></p>
<b>1983</b>	EPA promulgated <sup>203</sup> the final decision to revoke the HC standards in January.	<p>The one page preamble was the shortest since the 1971 standards actions. It was signed by acting Administrator John Hernandez in late December.</p>

**Table 6. Chronology of Nitrogen dioxide (NO<sub>2</sub>) National Ambient Air Quality Standards (NAAQS)**

Year	Event	Comments
1971	First NO <sub>x</sub> CD <sup>204</sup> (written by PHS staff and consultants) pages, reviewed by National Air Quality Criteria Advisory Committee (NAQCAC) and 17 Federal Agencies, but released as an EPA document at the time of the first NAAQS proposal <sup>2</sup> . NO <sub>x</sub> was the first pollutant listed under Section 108 and this was first CD issued after passage of the 1970 Clean Air Act amendments.	Major health criteria in summary from 6-month epidemiology study <sup>205a,b</sup> of 4 areas in Chattanooga finding increased incidence of acute respiratory disease in family groups (117-205 µg/m <sup>3</sup> NO <sub>2</sub> ), bronchitis in school children (118-156 µg/m <sup>3</sup> NO <sub>2</sub> ) in combination with nitrate particles and other pollutants. The estimated maximum 24-hr value associated with 118 µg/m <sup>3</sup> (0.063 ppm) was as low as 284 µg/m <sup>3</sup> (0.15 ppm). The CD associated corrosion of electrical components observed in two cities with average nitrate levels around 3 µg/m <sup>3</sup> and NO <sub>2</sub> levels of 124 to 158 µg/m <sup>3</sup> . <sup>204</sup>
	Proposal <sup>2</sup> , promulgation <sup>3</sup> of first NAAQS for NO <sub>2</sub> . Final <i>Primary</i> : 100 µg/m <sup>3</sup> (0.05 ppm) annual arithmetic mean <i>Secondary</i> : same as primary	No rationale given. A 24-hr standard (250 µg/m <sup>3</sup> ), presumably related to the peak estimate from the studies above, was proposed but not adopted, presumably because no effects had been directly associated with these levels.
1976	NAQCAC recommended revisions of all criteria, NAAQS <sup>15</sup>	EPA scheduled NO <sub>x</sub> second of NAAQS pollutants to be reviewed, with a final draft CD by 2/78. <sup>16</sup>
1977-78	The Clean Air Act Amendments of 1977 required EPA to issue criteria on the short-term effects of NO <sub>2</sub> six months after passage and promulgation of a short-term (1-3 hr) primary standard within 1 yr, unless the administrator found no significant evidence that such a standard was needed. <sup>206</sup> EPA began work on a NO <sub>2</sub> short-term health effects document. An external review draft was reviewed by an SAB subcommittee, which noted the case for a short-term standard was weak. <sup>17</sup> EPA held a public hearing on the standard in summer of 1978, and decided to defer any decision on the issue. <sup>17</sup> The short-term document was folded into to the ongoing full review of the NO <sub>x</sub> CD at all averaging times. <sup>17</sup>	Congress was aware of a 1974 NAS panel report that recommended a short-term NO <sub>2</sub> standard <sup>207</sup> as well as the results of two recent controlled human studies <sup>208,209</sup> that reported effects in asthmatics and bronchitics exposed to short-term peak NO <sub>2</sub> concentrations of 0.1 ppm or less.  Besides beginning immediate work on a short-term NO <sub>2</sub> health effects document immediately after passage of the provision, EPA researchers also began discussing approaches plans to replicate aspects of these particular studies in their chamber facilities.

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**1979 -83** CASAC and the public reviewed successive drafts of the revised CD at two meetings in 1979-80. CASAC sent a closure letter<sup>210</sup> and EPA issued the final CD<sup>211</sup> (8/82). Two successive drafts of the SP were reviewed at three public meetings of CASAC in 1980-81; CASAC issued a closure letter<sup>212</sup> and the SP was completed<sup>213</sup> in August 1982.

CASAC<sup>212</sup> generally agreed with staff conclusions and recommendations, concluding that 1) no single study provides a basis for the NAAQS decision, but the accumulation of evidence indicated the need for a NO<sub>2</sub> standard; 2) an annual standard could protect against both short- and long-term exposures of concern; 3) EPA should maintain an annual primary NO<sub>2</sub> standard at the lower end of the range of 0.05- 0.08 ppm; and 4) an annual secondary standard in this range would protect against direct effects of NO<sub>2</sub> on the environment, excluding the contribution of NO<sub>x</sub> to acid deposition, which should be considered in a broader critical assessment document.

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**1984** EPA proposed<sup>217</sup> to retain the existing annual primary and secondary standards (0.053 ppm), but solicited public comment on the need for a separate short-term primary standard. The majority of commenters who addressed the issue (15 of 20) supported the decision on the annual standard; 12 of 20 commenting opposed a new short term standard.<sup>218</sup> Some commenters expressed concerns that EPA had not assessed the most recent scientific evidence as represented by several new studies published after the CD was completed. EPA developed an assessment of the newer studies in a

Controlled human studies of peak and repeated peak exposures and indoor studies of homes with gas stoves, and animal toxicology provided the major basis for assessing potential health effects of NO<sub>x</sub>.<sup>213</sup> Most controlled studies found responses only at high levels (> 1ppm). The two studies<sup>208,209</sup> that had sparked concern over effects of peak exposures ultimately were judged by the CD and CASAC not to provide reliable quantitative results, and the significance of the observed effects (increased responses to a bronchoconstricting agent) were judged to be uncertain. EPA researchers<sup>214</sup> and others<sup>215</sup> were initially unable to reproduce the results of these studies, but their results were published only after the CD and SP had been completed.

Staff<sup>213</sup> analyzed peak short-term NO<sub>2</sub> levels expected with alternative long-term standards. The CD evaluation highlighted limitations in the 1970 Chattanooga epidemiology study,<sup>205a,b</sup> including unreliability of the monitoring method and the difficulty in distinguishing NO<sub>2</sub> from other pollutant effects. Both this study and a Japanese epidemiology study<sup>216</sup> were judged to provide mainly qualitative evidence. Welfare effects criteria highlighted acid deposition, symptomatic effects in humans, vegetation effects, visibility impairment and materials damage.

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Several additional potentially relevant controlled human and indoor epidemiology (gas stove homes) studies were released in 1982-84, but most were available only as abstracts. In contrast to earlier NAAQS preambles, and consistent with CASAC and staff recommendations, the proposal focused on a combination of results from multiple disciplines in support of the decision to retain the standard. In addition to the mixed results from attempts to replicate the two short-term controlled studies<sup>208,209</sup> noted above, the preamble highlighted one other study<sup>220</sup> that reported symptomatic effects at lower peak levels (0.5 ppm), characterizing the mild and reversible responses in

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	<p>review paper and submitted it and the proposal for review by CASAC at a public meeting (50FR25538). CASAC recommended<sup>219</sup> that the Agency reaffirm the annual NO<sub>2</sub> standard and defer a decision on a short-term standard while pursuing an aggressive research program.</p>	<p>asthmatics as “subtle effects that are of uncertain significance to health.”<sup>217</sup> EPA further discussed the possibility that these effects (slight headache, nasal discharge, dizziness, chest tightness and labored breathing during exercise) might be considered as effects on ‘personal comfort’ of relevance to setting the secondary standard.</p>
<b>1985</b>	<p>EPA promulgated a final decision<sup>218</sup> to retain the existing annual primary and secondary NO<sub>2</sub> standards at 0.053 ppm and deferred a decision on the need for a short-term standard pending additional research. In so doing, EPA committed to carrying out a “focused research program” on the short-term health effects of NO<sub>2</sub>.</p> <p>In setting aside consideration of the contribution of NO<sub>x</sub> to acidic deposition for purposes of the secondary standard, EPA relied on earlier CASAC advice<sup>103</sup> and to prepare a separate, comprehensive document on acidic deposition. The document<sup>221</sup> was released later in 1985.</p>	<p>Due to the extended time since completion of the 1982 CD<sup>211</sup> and the increase in relevant publications stimulated by the review, EPA’s final NO<sub>2</sub> decision relied heavily on the assessment of the mixed results from post CD studies (FR) and analysis done after the proposal. Staff updated the air quality analyses of peak NO<sub>2</sub> levels associated with attainment of the current standard in response to public comments.<sup>222</sup> The final decision on the annual standard echoed the proposal rationale, which relied on the weight of the updated evidence, and the air quality analysis that suggested few areas would experience short-term peaks above 0.2 ppm if all met the 1971 NO<sub>2</sub> standards.</p>
<b>1987-93</b>	<p>EPA announced plans to revise the 1982 NO<sub>x</sub> CD in 1987 (52FR27580). After early reviews at a workshop in 1990, the first external review draft (11/91) was reviewed by CASAC and the public at an August 1993 meeting; CASAC followed with their closure letter<sup>223</sup> and EPA released the final CD.<sup>224</sup></p> <p>In July 1993, the Oregon Natural Resources Council had sued EPA to complete the review of the CD and NAAQS.</p>	<p>Relevant new studies continued to be published, with a number of new indoor “gas stove” epidemiology studies, and controlled human studies of asthmatics to peak NO<sub>2</sub>, with and without the use of bronchoconstricting agents.</p> <p>This is one of the few cases in which CASAC was essentially satisfied with the first external draft of a CD.</p>
<b>1994-95</b>	<p>The first external review draft of the NO<sub>x</sub> SP was reviewed by CASAC and the public in late 1994. Shortly thereafter, the US District Court of Oregon ordered EPA to promulgate a final decision on the NAAQS by October 1, 1996 (<i>Oregon Natural Resources Council v. Carol M. Browner</i>, No. 91-6529-HO [D.Or.]). The revised final draft SP<sup>225</sup> was reviewed by CASAC and the public in June 1995; CASAC sent their closure letter.<sup>226</sup></p>	<p>An EPA meta-analysis of nine published epidemiology studies found significant relative risk of increased respiratory symptoms in children (age 5-12) in homes with gas stoves,<sup>229</sup> which was attributed to higher repeated peaks in such homes; these studies – taken singly or collectively- could not establish whether the effects were related to peak or more prolonged exposures.<sup>225</sup> Controlled human studies continued to find mixed results,<sup>225</sup> with some evidence of increased airway</p>

	<p>Staff<sup>225</sup> and CASAC<sup>226</sup> recommendations on the NO<sub>2</sub> NAAQS were similar to those in 1984: 1) retain an annual standard at or above the current level, recognizing that the current standard would prevent 1-hr NO<sub>2</sub> peaks of 0.2 ppm or greater 2) there is insufficient evidence to set secondary NAAQS to protect ecosystems against nitrogen deposition related acidification and eutrophication.</p> <p>EPA proposed<sup>227</sup> not to revise either the primary or secondary standards.</p> <p>EPA received only 8 written comments on the proposal.<sup>228</sup> All five of those addressing the primary standard agreed with the proposed decision not to revise the annual primary or secondary standards. The other three commenters believed a revised secondary standard was needed to address NO<sub>x</sub> deposition effects (acidification and/or eutrophication).</p>	<p>sensitivity, functional changes, and symptoms in asthmatics at peaks as low as 0.2 to 0.5 ppm,<sup>230</sup> but not at higher levels.<sup>231-234</sup></p> <p>The proposal<sup>227</sup> relied heavily on the staff and CASAC assessment of the science and recommendations. The notice presented an extensive discussion of the effects of nitrogen deposition on aquatic and terrestrial ecosystems; the case against addressing acidification and eutrophication with a national NO<sub>x</sub> standard relied in part on a recent SAB subcommittee review<sup>235</sup> of EPA's report to Congress on the feasibility of a national acid deposition standard.<sup>236</sup> The SAB panel concluded there was not an adequate basis for establishing such a standard. The NO<sub>2</sub> proposal<sup>227</sup> noted regional variability in the need for programs to address NO<sub>x</sub> deposition, supporting regional approaches to address the most sensitive areas subject to high deposition, such as the Chesapeake Bay, but also that a uniform secondary standard could be either too strict or too lenient for many areas.</p>
<b>1996</b>	EPA promulgated a final decision <sup>228</sup> not to revise either the primary or secondary NO <sub>2</sub> standards, leaving both set at a level of 0.53 ppm, annual average.	<p>The five page final notice contained a terse rationale for retaining the primary standard based on the proposal, with the majority of the discussion devoted to the secondary standard decision. The notice noted that integrated regional programs might be more suited to addressing NO<sub>x</sub> deposition effects and also stressed that emerging regional initiatives (e.g. the Ozone Transport Assessment Group) and national mobile standards to meet the O<sub>3</sub> NAAQS would have the beneficial effect of reducing NO<sub>x</sub> and associated deposition effects.</p>
<b>2005 -07</b>	<p>A deadline suit called for EPA to complete a review of the NO<sub>2</sub> (and SO<sub>2</sub>) criteria and standards by mid to late 2009 (<i>Center for Biological Diversity v. Stephen L. Johnson</i>. Civ. No. 05-1814 (JGP), D.C.C.A). EPA split the NO<sub>x</sub> review into two parts; a combined NO<sub>x</sub>/SO<sub>x</sub> "Integrated Science Assessment" (ISA) on welfare effects and a separate (ISA) document focused on the health effects of NO<sub>2</sub>.<sup>118</sup></p>	<p>The final schedule will depend on court action and related discussions. EPA is applying the newly announced NAAQS process<sup>119</sup> to this review, substituting the ISA for the CD, backed up by a reference document.</p>

**Table 7. Chronology of Lead (Pb) National Ambient Air Quality Standards**

Year	Event	Comments
<b>1971-75</b>	<p>EPA proposed to phase down the Pb content of gasoline in 1972,<sup>237</sup> but delayed action on a final rule. NRDC brought suit and the DC Circuit Court ruled that, given its health conclusions, EPA “had no choice” but to regulate Pb in gasoline (<i>Natural Resources Defense Council v. EPA</i>, NR No. 72-2233 [D.C. Cir. 1973]). EPA issued a final rule in two months later.<sup>238</sup> Subsequent litigation (<i>Ethyl Corporation v. Environmental Protection Agency</i>, 541 F.2d 1 [D.C. Cir. 1976]) modified and delayed implementation until 1976.<sup>239</sup></p> <p>In 1975, NRDC and others sued EPA to list Pb under Section 108 of the CAA and to develop criteria and standards.<sup>17</sup></p>	<p>In 1971, EPA decided against the original PHS plan to develop Pb criteria and NAAQS, given the dominance of mobile sources and the need to reduce Pb in gasoline to enable use of catalytic converters.<sup>156</sup> An EPA document developed to support the Pb phase down (<i>EPA's Position on the Health Implications of Airborne Lead</i>), suggested that ambient Pb levels greater than 2 µg/m<sup>3</sup> might be of health concern.<sup>239</sup> The Court decision accelerated the final lead phase-down promulgation date, which had been stalled in the executive branch.<sup>156</sup></p> <p>In the 1975 NAAQS case, EPA argued that it should have the discretion to determine the appropriate regulatory approach for various pollutants.</p>
<b>1976-77</b>	<p>The court ruled for NRDC (<i>Natural Resources Defense Council et al. v. Train</i>, 545 F.2d 320 [2<sup>nd</sup> Cir. 1976]). EPA listed Pb under S. 108 of the CAA and initiated work on criteria and standards.<sup>17,240</sup> EPA made three successive drafts of the Pb CD available for public review, receiving 60-80 written comments on each draft. Each draft was reviewed at a public meeting of a special subcommittee of the new EPA Science Advisory Board (SAB); the final CD<sup>241</sup> was issued at the same time as the proposed NAAQS. OAQPS staff developed analyses and alternative approaches for aspects of the proposal; staff also analyzed the economic impacts of controlling Pb from a variety of stationary sources to meet the NAAQS, considering the reductions from the Pb phase-down.</p> <p>EPA proposed<sup>240</sup> to set a standard for airborne Pb of 1.5 µg/m<sup>3</sup>, monthly average. The proposed secondary standard was equal to the primary standard.</p>	<p>Pb was the first CD not reviewed by NCAQAC, which was disbanded in 1976. The first draft of the document, prepared by the Criteria and Special Studies Office of EPA’s health laboratory, was heavily criticized by the SAB subcommittee for omitting and mischaracterizing the available information and for suggesting a standard level of 5 µg/m<sup>3</sup>. At SAB’s suggestion, EPA brought in outside experts to work on subsequent drafts. The final CD<sup>240</sup> found a range of effects of Pb at varying exposures, with the most useful index of exposure being blood level, in µg/deciliter. Exposure to Pb came from multiple sources, including ingestion as well as inhalation. The relationship between air Pb and blood level and the relative contribution of air were critical.</p> <p>The proposal identified a ‘pivotal adverse health effect’ for Pb, elevation of erythrocyte protoporphyrin (EP), which the CD found occurred in women and children at 15-20 µg/dl of</p>

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EPA proposed rules for state implementation plans for the new Pb standards in the same Federal Register.<sup>242</sup>

Pb.<sup>241</sup> EP elevation indicates an impairment of cell function. EPA set a target population geometric mean of 15 µg/dl blood Pb as a safe level for total Pb in children, noting this would keep 99.5% of children below the then Center for Disease Control (CDC) Pb guideline of 30 µg/dl. EPA determined an allowable blood Pb level for children from air sources (3µg/dl) by subtracting an assumed baseline non-air contribution (12 µg/dl) from the population target. Using an air/blood Pb ratio of 1:2, EPA calculated the ambient air Pb target of 1.5 µg/m<sup>3</sup>.

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**1978** EPA received 95 written and oral comments on the proposed standard or the proposed implementation requirements.<sup>243</sup> The final rule listed commenting organizations and individuals, noting that all 25 comments opposing the proposal as too stringent came from affected industries, 4 comments (including NRDC) favored a more stringent standard, and 17 comments supported the proposal.

The preamble included a special section summarizing the comments from other Federal Agencies. CDC, PHS, the Consumer Product Safety Commission, the Food and Drug Administration, the Occupational Safety and Health Administration, and the Department of Transportation all generally supported the analyses and the targets. The Departments of Interior and Commerce expressed concerns about the potential impacts on industry.

EPA promulgated<sup>243</sup> the final Pb NAAQS, set at the proposed level of 1.5 µg/m<sup>3</sup>, but, in response to comments, extended the averaging time from one month to a calendar quarter.

Commenters did not challenge the basic approach or the attribution of 12µg/dl to non-air sources for the purposes of the NAAQS. A number of commenters did question elevation of EP as the lowest level adverse effect, the use of 15 µg/dl target, the air/blood relationships, the form of the standard, and other factors.

In the final preamble,<sup>243</sup> EPA shifted the target of the standard from maintaining a population mean of 15 µg/dl keeping individual children below a maximum blood level of 30 µg/dl, the level of the CDC guideline. EPA noted that this would provide some margin of safety below the threshold for a decline in hemoglobin (40 µg/dl) and risk of nervous system effects (50 µg/dl). EPA determined the standard should ensure that 99.5% of children would be below 30 µg/dl blood Pb. EPA used a value from a range of distribution parameters to determine that the resultant population average blood level consistent with this goal was 15 µg/dl, and determined the standard level as in the proposal.

Some industry commenters noted that the monthly maximum form of the standard would require longer term average Pb levels as low as 0.41 µg/m<sup>3</sup> to keep the maximum month below 1.5 µg/m<sup>3</sup> and others noted problems with the

		conventional PM sampling frequency (1 in 6 days) for determining monthly averages. EPA concluded that a quarterly average would provide a more robust target without compromising the intended protection.
<b>1979-80</b>	A consortium of lead industries brought suit against the standards on scientific, policy, and procedural grounds. The D.C. Circuit Court issued a landmark decision upholding EPA's opinion that economic and technical feasibility cannot be considered in the NAAQS decision. ( <i>Lead Industries Assoc., Inc. vs. EPA</i> , 647 F. 2d 1130,1154 [D.C. Cir. 1980] <i>cert. den.</i> 101 S. Ct. 621 [1980]). Further, the Court found EPA's approach to selecting the standard, including the use of a number of conservative assumptions, was appropriate.	The Pb listing, criteria, and standards development was the first major NAAQS action since the 1971 standards, opening both Pb specific and wider issues, including consideration of costs and the approach to margin of safety. EPA and DOJ had maintained in the rulemaking and response to the suit that the law precluded EPA from considering costs in setting the NAAQS.
<b>1984-86</b>	EPA began the first review of the Pb criteria and NAAQS. EPA developed two external review drafts of the CD that were reviewed by CASAC at public meetings. The final 1986 CD <sup>244</sup> was published with an addendum <sup>245</sup> that addressed information that emerged after the cutoff date for the main CD.	As a result of the continuing regulations requiring Pb phase down in gasoline, Pb emissions dropped precipitously between 1978 and 1986. <sup>246</sup> Urban air Pb levels also dropped dramatically, <sup>246</sup> as did measurements of blood Pb levels in urban children. <sup>247</sup> Based on increasing evidence of effects at lower levels, CDC lowered their blood lead guideline for children to 25 µg/dl. <sup>248</sup> Additional effects of particular concern included developmental effects in children (e.g. reduced IQ) and effects on the cardiovascular system (e.g. blood pressure).
<b>1989-90</b>	EPA developed a draft supplement to the 1986 CD/Addendum to address significant new health studies. EPA staff developed an exposure assessment <sup>249</sup> and a draft of the first Pb SP, based on the 1986 CDA and the draft CD supplement. <sup>244,245</sup> The drafts of the supplement and SP were reviewed by CASAC and the public at a 1990 meeting. CASAC sent a single closure letter for both <sup>250</sup> and EPA released the final versions. <sup>251,252</sup>	Additional studies continued to be published showing effects at still lower blood Pb levels, necessitating the supplement to the CD. In 1992, CDC further lowered its guideline to 10 µg/dl. <sup>253</sup> The 1990 Clean Air Act Amendments listed Pb compounds as a hazardous air pollutant class, and subject to source-specific Section 112 "MACT" standards. Noting the major air Pb exposures occurred near a limited number of large point sources, EPA decided not to revise the Pb NAAQS following this review, but did not publish this decision in the Federal Register. In 1991, the agency



	The staff recommended consideration of a revised primary standard in the range of 0.5 to 1.5 µg/m <sup>3</sup> , second highest monthly average in 3-years.	developed a broad <i>Strategy for Reducing Lead Exposure</i> , <sup>254</sup> focused on reducing Pb exposure from a variety of non-air sources that posed more extensive public health risks, as well as other actions to reduce air emissions.
<b>1995-99</b>	EPA used the new authorities under Title III of the 1990 amendments to require technology-based standards on two major stationary source categories of Pb.	EPA promulgated section 112(d) standards for secondary Pb smelters on June 23, 1995 (60 Fed. Reg. 3587) and revised them on June 13, 1997 (62 Fed. Reg. 32209), followed by promulgation of section 112(d) standards for primary Pb smelters on June 4, 1999 (64 Fed. Reg. 30194).
<b>2004-06</b>	The Missouri Coalition for the Environment sued EPA to review the Pb standards in 2004. <sup>255</sup> The US District Court in Missouri ordered EPA to complete a review of the Pb NAAQS by September, 2008 ( <i>Missouri Coalition for the Environment v. EPA</i> , Civil Action No. 4:04-CV-00660 (ERW) [E.D. Mo. Sept. 14, 2005]). EPA released the first external review draft of the CD, which was reviewed at a public CASAC meeting in March 2006. A revised second draft was reviewed at a public CASAC meeting in June 2006. Revisions of summary and integration chapters were further reviewed at a CASAC telephone meeting in August. CASAC followed with a letter <sup>256</sup> generally indicating satisfaction with the draft, including comments and the final CD <sup>257</sup> was completed on time.  The first drafts of the SP <sup>258</sup> and exposure analysis were released in December 2006.	The current schedule <sup>255</sup> calls for a final CD by 10/06, a final SP by 11/07, and a proposal by 5/08. The CD incorporated a number of newer studies that have continued to appear since 1989, strengthening the evidence that significant effects occur at lower blood Pb levels for many endpoints.  The draft SP did not contain recommendations, but did state that a component of this review would be to examine the question of whether, in light of the current nature of air Pb sources and exposure and the inclusion of Pb compounds and regulation of several source categories under Section 112, Pb should remain listed under Section 108.
<b>2007</b>	The draft SP and exposure analysis were reviewed at a CASAC meeting in February 2007. CASAC recommended against the option of revoking the Pb NAAQS. <sup>259</sup>	

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