**SUPPLEMENTARY INFORMATION:**

**List of Subjects in 32 CFR Part 988**

Weather modification.

**Authority:** 10 U.S.C. 8013.

**PART 988—[REMOVED]**

Accordingly, 32 CFR, chapter VII, is amended by removing part 988.

**Patsy J. Conner,**

*Air Force Federal Register Liaison Officer.*

[FR Doc. 93-5293 Filed 3-8-93; 8:45 am]

BILLING CODE 3910-01-M

## ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Part 50**

**[AD-FDL-4601-6]**

## National Ambient Air Quality Standards for Ozone—Final Decision

**AGENCY:** U.S. Environmental Protection Agency (EPA).

**ACTION:** Final decision.

**SUMMARY:** In accordance with sections 108 and 109 of the Clean Air Act (Act), the EPA announced on August 10, 1992 its proposed decision under section 109(d)(1) that revisions of the national ambient air quality standards (NAAQS) for ozone ($O_3$) are not appropriate at this time. The level of the existing primary and secondary standards for $O_3$ is 0.12 parts per million (ppm). The standards are attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than 1, as determined by the Interpretation of the National Ambient Air Quality Standards for Ozone (appendix H). In the same notice, the EPA also announced its plans, in view of the large number of recent scientific papers and ongoing research on the health and welfare effects of $O_3$, to proceed as rapidly as possible with the next review of the air quality criteria and standards for $O_3$.

This document announces the EPA's final decision under section 109(d)(1) that revisions of the primary and secondary standards are not appropriate at this time. Since publication of the August 10 1992 notice, the EPA has initiated action to update the air quality criteria upon which this decision is based so that the recent information on health and welfare effects of $O_3$ can be considered as rapidly as possible in the next criteria and standards review.

**EFFECTIVE DATE:** This action is effective April 8, 1993.

**ADDRESSES:** A docket containing information relating to the EPA's review of the $O_3$ primary and secondary standards (Docket No. A-92-17) is available for public inspection in the Central Docket Section of the U.S. Environmental Protection Agency, South Conference Center, room 4, 401 M Street SW., Washington, DC. The docket may be inspected between 8 a.m. and 3 p.m. on weekdays, and a reasonable fee may be charged for copying. The information in the docket constitutes the complete basis for the decision announced in this notice. For the availability of related information, see **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Mr. John H. Haines, Air Quality Management Division (MD-12), U.S. Environmental Protection Agency, Research Triangle Park, NC, 27711, telephone (919) 541-5533.

**SUPPLEMENTARY INFORMATION:**

**Availability of Related Information**

Certain documents are available from: U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. Available documents include: the revised criteria document, Air Quality Criteria for Ozone and Other Photochemical Oxidants (five volumes, EPA-600/8-84-020aF-eF, August 1986; NTIS # PB-87142949, $168.00 paper copy), and the 1989 staff paper, Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information-OAQPS Staff Paper (EPA-450/2-92-001, June 1989; NTIS # PB-92-190446, $43.00 paper copy and $17.00 microfiche). (Add $3.00 handling charge per order.) The criteria document supplement, Summary of Selected New Information on Effects of Ozone and Other Photochemical Oxidants (EPA-600/8-88-105F) is available at no cost from the Center for Environmental Research Information (CERI), telephone (513) 569-7562. A limited number of copies of other documents generated in connection with this standard review can be obtained from: U.S. Environmental Protection Agency Library (MD-35), Research Triangle Park, NC, 27711, telephone (919) 541-2777. These and other related documents are also available in the EPA docket identified above.

The contents of this notice are listed in the following outline:



## I. Background

### *A. Legislative Requirements Affecting This Rule*

#### 1. Primary and Secondary Standards

Two sections of the Act govern the establishment and revision of NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify pollutants which "may reasonably be anticipated to endanger public health and welfare" and to issue air quality criteria for them. These air quality criteria are to accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of a pollutant in the ambient air.

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria and allowing an adequate margin of safety, is requisite to protect the public health." A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air." Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on

economic values and on personal comfort and well-being."

The U.S. Court of Appeals for the District of Columbia Circuit has held that the requirement for an adequate margin of safety for primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. [*Lead Industries Association* v. *EPA*, 647 F.2d 1130, 1154 (DC Cir. 1980), *cert. denied*, 101 S.Ct. 621 (1980); *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1177 (DC Cir. 1981), *cert. denied*, 102 S.Ct. 1737 (1982)]. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In selecting a margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. Given that the "margin of safety" requirement by definition only comes into play where no conclusive showing of adverse effects exists, such factors, which involve unknown or only partially quantified risks, have their inherent limits as guides to action. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association* v. *EPA*, *supra*, 647 F.2d at 1161–62.

Section 109(d)(1) of the Act requires that not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards and shall make such revisions in such criteria and standards as may be appropriate. Section 109(d)(2) (A) and (B) require that a scientific review committee be appointed and provide that the committee "shall complete a review of the criteria and the national primary and secondary ambient air quality standards and shall recommend to the Administrator any revisions of existing criteria and standards as may be appropriate."

The process by which the EPA has reviewed the existing air quality criteria and standards for $O_3$ under section 109(d) is described in a later section of this notice.

2. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under title I of the Act (42 U.S.C. 7410), States are to submit, for EPA approval, State implementation plans (SIP's) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with the EPA, also administer the prevention of significant deterioration program (42 U.S.C. 7470–7479) and the visibility protection program (42 U.S.C. 7491–7492) for these and other air pollutants. In addition, Federal programs provide for nationwide reductions in emissions of air pollutants through the Federal motor vehicle control program under title II of the Act (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, and aircraft emissions; the new source performance standards under section 111 (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 (42 U.S.C. 7412).

*B. Existing Standards for Ozone*

The principal focus of this standard review is on the health and welfare effects of $O_3$. Ozone produced in the ambient air is commonly referred to as tropospheric $O_3$. It is chemically identical to stratospheric $O_3$, which is concentrated miles above the earth's surface and provides a protective shield from excess ultraviolet radiation. In contrast, tropospheric $O_3$ produces harmful effects due to its oxidative properties and its proximity to humans, plants, and materials. Ozone is not emitted directly from mobile or stationary sources but, like other photochemical oxidants, commonly exists in the ambient air as an atmospheric transformation product. Ozone formation is the result of chemical reactions of volatile organic compounds (VOC's), nitrogen oxides ($NO_x$), and oxygen ($O_2$) in the presence of sunlight and generally at elevated temperatures.

Ozone is a highly reactive gas which at sufficient concentrations can produce a wide variety of harmful effects. At elevated concentrations, $O_3$ can adversely affect human health, vegetation, materials, economic values, and personal comfort and well-being. Hourly average ambient $O_3$ levels range from 0.03 ppm in the most remote rural areas to 0.30 ppm and higher in the most polluted urban areas. A detailed discussion of formation, concentrations, and effects of $O_3$ can be found in the 1986 Air Quality Criteria Document (U.S. EPA, 1986), the Criteria Document Supplement (U.S. EPA, 1992), and the Staff Paper (U.S. EPA, 1989).

On April 30, 1971, the EPA promulgated primary and secondary NAAQS for photochemical oxidants under section 109 of the Act (36 FR 8186). These were set at an hourly average of 0.08 ppm total photochemical oxidants not to be exceeded more than 1 hour per year. On April 20, 1977, the EPA announced (42 FR 20493) the first review and updating of the 1970 Air Quality Criteria Document for Photochemical Oxidants in accordance with section 109(d)(1) of the Act. In preparing the Air Quality Criteria Document, the EPA provided a number of opportunities for external review and comment. The EPA made two drafts of the document available for public comment, and these drafts were peer reviewed by the Subcommittee on Scientific Criteria for Photochemical Oxidants of the EPA Science Advisory Board. The EPA published the final revised Air Quality Criteria for Ozone and Other Photochemical Oxidants on June 22, 1978.

Based on the 1978 revised Air Quality Criteria Document (U.S. EPA, 1978) and taking into account the advice and recommendations of the Subcommittee, on June 22, 1978, the EPA proposed (43 FR 16962) revisions to the then-current primary and secondary NAAQS for photochemical oxidants. The proposed changes included raising the primary standard to 0.10 ppm, retaining the 0.08 ppm secondary standard, changing the chemical designation of the standards from photochemical oxidants to $O_3$, and changing to standards with a statistical form (i.e., expected exceedances) rather than a deterministic form (i.e., not to be exceeded more than $x$ number of times per year).

After taking into account public comments, the EPA announced its final decision on the proposed revisions to the 1971 standards (44 FR 8202, February 8, 1979). The final rulemaking revised the level of the primary standard from 0.08 ppm to 0.12 ppm, set the secondary standard identical to the primary standard, changed the chemical designation of the standards from photochemical oxidants to $O_3$, and revised the definition of the point at which the standard is attained to when

the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than one as determined by appendix H.

*C. Review of Air Quality Criteria and Standards for Ozone and Other Photochemical Oxidants; Development of the Staff Paper*

On March 17, 1982 (47 FR 11561), the EPA announced that it was undertaking plans to revise the existing 1978 Air Quality Criteria Document for Ozone and Other Photochemical Oxidants and on August 22, 1983, announced (48 FR 38009) that review of primary and secondary standards for $O_3$ had been initiated. A detailed summary of the review and revision process was presented in the August 10, 1992 proposal notice (57 FR 35542).

The EPA subsequently provided a number of opportunities for public review and comment, including making available two drafts of the revised criteria document (49 FR 29845; 51 FR 11339), prepared by the EPA's Environmental Criteria and Assessment Office (ECAO), and holding two public meetings of the Clean Air Scientific Advisory Committee (CASAC) (March 4–6, 1985 and April 21–22, 1986). The EPA placed transcripts of the CASAC meetings in the docket (ECAO–CD–81–1) for the 1986 Air Quality Criteria Document. The EPA considered the numerous and often extensive comments received from the public and the CASAC members in preparing the final document. On October 22, 1986, the CASAC sent the Administrator a "closure letter," outlining key issues and recommendations and indicating that it was satisfied with the final draft of the 1986 Air Quality Criteria Document. Following closure, a number of scientific articles were published or accepted for publication and appeared to be of sufficient importance concerning potential health and welfare effects of $O_3$ to warrant preparation of a supplement to the criteria document. In early 1988, the ECAO began preparation of the Supplement and made draft copies available to the CASAC and the public in November 1988.

After the CASAC meeting on March 4–6, 1985, the EPA's Office of Air Quality Planning and Standards (OAQPS) began work on the first draft of the Staff Paper (Review of the National Ambient Air Quality Standards for Ozone:

Assessment of Scientific and Technical Information—OAQPS Staff Paper). The CASAC reviewed first and second drafts of the Staff Paper at public meetings of the CASAC held on April 21–22, 1986 and December 14–15, 1987, and transcripts of these meetings have been placed in the docket. Numerous written and oral comments were received on the drafts from the CASAC, representatives of organizations, individual scientists, and other interested members of the public. The CASAC concluded that sufficient new information existed to recommend incorporation of relevant new information into a third draft of the Staff Paper. In early 1988, the EPA began working on a third draft of the Staff Paper and made available copies to the CASAC and the public in November 1988.

The CASAC held a public meeting on December 14–15, 1988 to review the draft Supplement and draft Staff Paper. Major issues included: The definition of adverse health effects of $O_3$, the significance of health studies suggesting that exercising individuals exposed for 6 to 8 hours to $O_3$ levels at or below 0.12 ppm may experience inflammation and transient decreases in pulmonary function, the possibility that chronic irreversible effects may result from long-term exposures to elevated levels of $O_3$, and the importance of analyses which indicate agricultural crop damage may be better defined by a cumulative seasonal average than by a 1-hour peak level of $O_3$. In its "closure letter" of May 1, 1989, (reprinted as appendix I of this notice) the CASAC indicated that the draft Supplement and draft Staff Paper "provide an adequate scientific basis for the EPA to retain or revise primary and secondary standards for ozone" (CASAC, 1989).

*D. Decision Docket*

On March 17, 1992, the EPA created a docket (Docket No. A–92–17) for this decision. The docket incorporated the standard review docket (Docket No. OAQPS A–83–04), created in 1983, and the separate docket established for criteria document revision (Docket No. ECAO–CD–81–1), created in 1981.

*E. Litigation*

On October 22, 1991, the American Lung Association and other plaintiffs filed suit under section 304 of the Act to compel the EPA to complete its review of the criteria and standards for $O_3$ under section 109(d)(1) of the Act [*American Lung Association* v. *Reilly*, No. 91–CV–4114 (JRB) (E.D.N.Y.)]. The U.S. District Court for the Eastern District of New York subsequently issued an order requiring the EPA to sign a **Federal Register** notice announcing its proposed decision on whether to revise the standards for $O_3$ by August 1, 1992 and to sign a **Federal Register** notice announcing its final decision by March 1, 1993.

**II. Summary of the 1992 Proposed Decision**

On August 10, 1992 (57 FR 35542), the EPA published its proposed decision under section 109(d)(1) that revisions to existing 1-hour primary and secondary standards are not appropriate at this time. (Consistent with the order in the American Lung Association case, the Administrator signed the proposed decision on August 1, 1992.) The notice explained in some detail (see 57 FR 35546) that the proposed decision would complete the EPA's review of information on health and welfare effects of $O_3$ assembled over a 7-year period and contained in the 1986 Air Quality Criteria Document and its Supplement. The review included an evaluation of key studies published through early 1989, the 1989 Staff Paper assessment of the most relevant information in these documents, and the advice and recommendations of the CASAC as presented both in the discussion of these documents at public meetings and in the CASAC's 1986 and 1989 "closure letters."

Under section 109(b) of the Act, primary and secondary NAAQS are to be based on the air quality criteria issued under section 108. Additionally, under section 109(d), the EPA must periodically conduct a "thorough review" of the criteria taking into account the advice and recommendations of the CASAC as the basis for periodic decisions on whether revisions of NAAQS are appropriate. When Congress enacted the latter requirement in 1977, it was well aware that implementation of the NAAQS can have profound economic and social, as well as environmental, consequences. Understandably, it required that the EPA's periodic decisions on whether to revise the NAAQS be based on scientific studies that had been rigorously assessed and incorporated into air quality criteria and whose implications for public health and welfare had been carefully considered by both the EPA and the CASAC. In view of this, the August 10, 1992 notice made clear that the Administrator did not take into account recent studies on the health and welfare effects of $O_3$ because these studies had not been assessed in the 1986 Air Quality Criteria Document nor its Supplement, nor had they undergone the rigorous review process (including CASAC review) required to incorporate them into a new criteria document.

Because of the scientific and technical complexity of such assessments, the EPA estimated that 2 to 3 years would

be necessary to rigorously assess the over 1,000 new studies and incorporate key information into a revised criteria document, to evaluate the significance of the key information for decision-making purposes, to develop staff recommendations for the Administrator, and to provide appropriate opportunities for the CASAC review and public comment. Given the importance of these new studies and concern about the health and welfare effects of $O_3$, the August 10, 1992 notice also outlined the EPA's plans to proceed as rapidly as possible with the next review of the criteria and standards for $O_3$.

*A. The Primary Standard*

In reaching his August 10, 1992 proposed decision that revisions of the existing $O_3$ primary standard were not appropriate, the Administrator considered the health effects information assessed in the 1986 Air Quality Criteria Document, the Supplement that updated that information, the 1989 Staff Paper, and the advice and recommendations of the CASAC in its 1989 "closure letter." Based on his review of this information, the Administrator concurred with the staff and the CASAC conclusions that the preliminary information on effects of prolonged exposures to $O_3$ was not sufficient to support the establishment of a new 6- to 8-hour standard to protect against prolonged exposures, or a seasonal or other long-term standard to protect against chronic effects. In reaching this proposed determination, the EPA recognized that a number of new studies, particularly on 6- to 8-hour exposures to $O_3$, had been published in the scientific literature since early 1989. Mindful of this, as well as research in progress on the chronic effects of $O_3$, the EPA made clear in the proposal that it intended to proceed with the next periodic review of the air quality criteria as rapidly as possible. The notice added that when this new information had been incorporated into the air quality criteria, a more informed decision could be made as to whether adding a new 6- to 8-hour standard and/or a seasonal or other long-term standard would be appropriate.

The EPA also carefully considered the health effects information on 1- to 3-hour exposures to $O_3$ contained in the air quality criteria. Based on these assessments and taking into account the advice and recommendations of the CASAC in its 1989 "closure letter," the Administrator in August 1992 reached the proposed determination that revisions of the existing 1-hour primary standard were not appropriate to provide increased protection against 1- to 3-hour exposures to $O_3$. The standard level is below the levels where controlled human 1- to 3-hour exposure studies found substantial changes in pulmonary function and symptoms. In reaching this conclusion, the Administrator was mindful that the mean group response observed in the controlled human studies up to 0.15 ppm $O_3$ would at most be characterized as mild, and that most of the responders within this population of normal healthy individuals reportedly experienced only mild to moderate responses under very heavy exercise (U.S. EPA, 1989, pp. VII–53 to VII–56). Although there was a difference of opinion among the EPA's scientific advisors as to the significance of decrements in lung function in the range of 10 to 20 percent when accompanied by symptoms (CASAC, 1989), it was the Administrator's judgment that the lesser effects associated with exposure to $O_3$ in the range of 0.12 ppm to 0.15 ppm observed in the controlled human studies did not constitute adverse effects for purposes of section 109 of the Act.

The EPA also considered other sensitive population groups whose response to $O_3$ had not been fully characterized. Although some epidemiology studies considered in the 1986 Air Quality Criteria Document and its Supplement suggested that exposure to $O_3$ at ambient concentrations may result in the aggravation of asthma and preexisting respiratory disease, the Administrator concurred with the staff's view that the direct use of these studies was limited by uncertainties about individual exposure levels and the role of other pollutants. In addition, although individuals with preexisting lung disease are not more responsive to $O_3$ than healthy persons in controlled human exposure studies, the same small change in pulmonary function may have more impact on people whose lung function is already compromised. While certain others (field/epidemiology studies) suggested that these sensitive groups may be at somewhat greater risk at levels of 0.12 ppm $O_3$ and higher, compared to normal healthy individuals in controlled human exposure studies, the Administrator concluded these studies did not provide a sufficient basis for lowering the existing standard. The Administrator also considered and concurred with the staff recommendations that $O_3$ should remain as the surrogate for controlling ambient concentrations of photochemical oxidants and that the existing form of the standard should not be revised.

*B. The Secondary Standard*

In reaching the proposed decision that revision of the existing 1-hour $O_3$ secondary NAAQS was not appropriate, the EPA carefully considered the welfare effects information assessed in the 1986 Air Quality Criteria Document and its Supplement, the 1989 Staff Paper assessment, and the advice and recommendations of the CASAC in its 1989 "closure letter." A principal reason for the proposed decision was the Administrator's judgment that there was insufficient information in the air quality criteria to specify a new form, averaging period, and level of a secondary standard that would be more protective of forest tree species as well as agricultural crops. The notice added that when information had become available from research currently under way on key aspects of $O_3$ exposure dynamics that are important for assessing the effects of $O_3$ on forest tree species and had been incorporated into the air quality criteria during the next review, a more informed judgment could be made as to whether revision of the secondary standard is appropriate.

The EPA also carefully considered the available information on the effects of $O_3$ on agricultural crops alone. Although the National Crop Loss Assessment Network (NCLAN) studies have provided extensive data on the effects of $O_3$ on crops, the appropriateness of the seasonal mean exposure indicator used in these studies had been subject to much criticism during the development of revised air quality criteria. Because of this and other shortcomings of this exposure index that are discussed more fully in the August 10, 1992 proposal notice, the EPA concluded that the use of the 7-hour seasonal mean derived from NCLAN data for standard-setting purposes would be inappropriate. The CASAC also recognized this and recommended that retrospective analyses be undertaken in order to identify a more appropriate exposure index that would offer protection from both repeated $O_3$ peaks of concern and long-term $O_3$ exposures. While these analyses had identified several indicators that showed promise, the Administrator concurred with the staff's view that it would be premature to base a change in the form and averaging time of the secondary standard on the preliminary results presented in the Supplement to the 1986 Air Quality Criteria Document and the Staff Paper.

The Administrator also considered tightening the current secondary standard as an interim measure. He noted that, throughout the review of the air quality criteria and staff assessment,

no consensus had been reached on an appropriate range of alternative 1-hour standards. The staff had great difficulty throughout the review in developing and justifying alternative levels below that of the current standard due to the lack of data (U.S. EPA, 1989, p. XI–13). In the end, while the staff relied on the preliminary results of the Lee *et al.* (1988) study to conclude that the upper-end of the proposed range (0.12 ppm) offered little protection for vegetation (U.S. EPA, 1989, pp. XI–16 to XI–18), the staff also determined that the study was too preliminary to serve as a basis for recommending changes in the form and averaging time of the standard. Even if the results of the Lee *et al.* (1988) study provided a sufficient basis for revising the standard downward from 0.12 ppm to 0.10 ppm, as some had suggested, it was the Administrator's judgment that such a change would provide only marginal improvement because a 1-hour averaging period was not the most appropriate exposure indicator for the full range of exposures, as discussed in the August 10, 1992 proposal, and would be seriously reconsidered during the next standard review. In the interim, it would have imposed a disproportionate and largely meaningless burden on States to review and make appropriate revisions in applicable SIP's.

Given the above information, it was the Administrator's judgment that the most prudent course of action was to retain the current secondary standard until a more informed decision could be made during the next standard review.

## III. Summary of Public Comments on the Proposed Decision

A limited number of comments were received on the August 10, 1992 proposed decision. Of 27 written submissions, 10 were provided by individual industrial companies or industry associations, eight by Federal and State government agencies and other entities, seven by environmental and public interest groups, one by the CASAC Chairman, and one by an interested individual. In addition, three persons presented testimony at the September 1, 1992 public hearing. Of the three presentations, one individual was highly critical of the EPA's proposed decision and presented basically the same arguments as those made in the written comments submitted by his organization; the second maintained that newly published studies supported the need for a revised standard; and the third individual supported the proposed decision and his testimony closely paralleled his organization's written comments. The public hearing transcript and a more detailed summary of the comments received and the EPA's responses have been placed in Docket No. A–92–17.

Of the 27 comments received, 11 concurred in general with the Administrator's proposed decision that revision of the primary and secondary standards is inappropriate at this time. Some of these commenters also maintained that any new studies published after closure on the air quality criteria should undergo rigorous evaluation, be reviewed by the CASAC and the public, and be incorporated into a revised criteria document before being considered for standard setting.

In contrast, 14 comments disagreed with the proposed decision that revision of the primary and secondary standards is inappropriate at this time. With respect to the primary standard, most of these commenters maintained that a new 6- to 8-hour standard should be established to protect against health effects associated with multihour or prolonged exposures to $O_3$. In support of their position, these commenters, for the most part, relied on recent studies that have not undergone the rigorous review in a criteria document, including the CASAC and public review, necessary before incorporation into the air quality criteria. Apparently in recognition of this, these commenters typically were critical of the EPA for not updating the criteria document before announcing its proposed decision, and some also maintained that the Act does not preclude the EPA and the CASAC from considering information not in the criteria document in setting standards. Several of these commenters also expressed the view that CASAC review was not required before such studies could be used. Many of the same commenters maintained that the recent studies should, at a minimum, be considered in determining whether the existing 1-hour standard provides an adequate margin of safety.

Another commenter in this group argued that the preliminary studies on prolonged exposures that were considered by the EPA strongly suggest and, in the judgment of the commenter, provide a sufficient basis for a new 6- to 8-hour standard. This commenter recognized, however, that newer studies (published after early 1989) that support these preliminary findings are not part of the air quality criteria that serve as the basis for the proposed decision. In view of this, the commenter urged the EPA not to wait the 2 to 3 years needed to fully evaluate these new studies, update the criteria document and staff paper and submit them to the CASAC and public review, but instead to develop an alternative primary standard more expeditiously.

Several commenters questioned the adequacy of the existing 1-hour primary standard, particularly with respect to protection it affords the elderly and children, and recommended that the standard be revised downward. One commenter noted that his State's advisory committee, with responsibilities similar to those of the CASAC, had recommended a more stringent 1-hour standard based on many of the same studies, including the preliminary studies on prolonged exposure, considered in this review.

Of the 14 comments that did not support the proposed decision, only four provided specific comments on the secondary standard. Of these four comments, two were highly critical of the EPA for not considering recently published information in reaching the proposed decision. As in the case of the primary standard, these commenters maintained that the EPA was not precluded from considering newly published peer-reviewed studies when reaching a decision on whether revisions to the secondary standard are appropriate. One of these commenters cited a number of newly published studies, as well as some in press, to support the position that the existing 1-hour secondary standard should be revised downward to a maximum of 0.10 ppm or be augmented by a new exposure index expressed as a cumulative seasonal standard of 14.2 ppm-hours. The same commenter was also critical of the EPA for not accepting staff and CASAC recommendations for revising the existing 1-hour standard.

A third commenter also urged the EPA to consider lowering the existing 1-hour secondary standard as an interim measure until such time as a new and more appropriate exposure index could be developed that would be protective of crops and forest tree species, and ultimately forest ecosystems. In support of this position, the commenter cited a series of newly published studies and some that are still in press or manuscript form on effects of $O_3$ on forest tree species. The fourth comment on the secondary standard expressed the view that a lower 1-hour primary standard would also substantially reduce the impact of $O_3$ on agricultural crops.

The final two comments on the August 10, 1992 proposal did not take an explicit position on the merits of the proposed decision. In the first of these, the commenter, a past Chairman of the CASAC, submitted a manuscript that

critically reviewed health effects information on $O_3$, with particular emphasis on studies published after the CASAC completed its review of the air quality criteria that served as the basis for the August 10, 1992 proposal, as well as other $O_3$ health effects information that is just emerging. Based on this review, the author concluded that the CASAC, after having the opportunity to review this new information, would be unlikely to reach the same conclusions as it did in 1989.

The second of these comments is an August 31, 1992 letter from the then-Chairman of the CASAC to the Administrator. In his letter (reprinted as appendix II of this notice) the Chairman noted with interest the EPA's plans not to revise the $O_3$ standards and to initiate a new assessment of the health and environmental effects of $O_3$. He added that the purpose of his letter was to express the Committee's willingness to assist the EPA in carrying out this new assessment in an expeditious manner. The Chairman also noted that a carefully planned strategy for preparation of the criteria document and staff paper would be essential in view of the magnitude and complexity of the task, particularly with respect to the review, integration, and interpretation of old and new scientific information.

## IV. Rationale for Final Decision

### *A. The Primary Standard*

The August 10, 1992 proposal discussed in some detail the underlying health effects information and the rationale for the EPA's proposed determination under section 109(d)(1) that revisions to the existing primary standard were not appropriate. After taking into account the public comments and for the reasons discussed below, the EPA again concludes, based on the rationale presented in the August 10, 1992 proposal notice, that revisions to the existing primary standard are not appropriate at this time.

For the most part, the commenters that objected to the proposed decision on the primary standard did not dispute the EPA's assessment of the health effects information that served as the basis for the proposed decision, nor did they maintain that the EPA erred in concluding that this information did not provide a sufficient basis for establishing a new 6- to 8-hour primary standard. Instead, they argued that the EPA improperly excluded from consideration studies that were published in the peer-reviewed literature after early 1989 and that as a result the proposed decision was based on "stale" data. In their view, the EPA should have updated the criteria document prior to reaching the proposed decision. Absent that, some maintained that the Act does not preclude the use of peer-reviewed studies in standard setting even though they have not been incorporated into the air quality criteria.

As discussed more fully in the proposal notice (57 FR 35546, 35554), the EPA was fully aware of the new studies on the health effects of $O_3$ and acknowledged that they had not been taken into account. Based on applicable statutory requirements and the volume of material requiring careful evaluation, the EPA estimated that it would take 2 to 3 years to incorporate these new health studies, as well as new studies on welfare effects, into a revised criteria document; to evaluate the significance of key information for decision-making purposes; to develop staff recommendations for the Administrator; and to provide for CASAC review and public comment. Given various legal constraints and the fact that the EPA had already missed both the 1985 and 1990 deadlines for completion of review cycles under section 109(d), the Administrator concluded that the best course of action was to complete the current review based on the existing air quality criteria and at the same time to proceed as rapidly as possible with the next review of the criteria and standards for $O_3$.

Having considered the comments on this issue, the EPA adheres to that conclusion. A number of commenters noted the complexity of the issues that the EPA would have to address when updating the air quality criteria document and staff paper, including the large volume of new material that would have to be evaluated, incorporated into the revised documents, and submitted for CASAC review and public comment (e.g., Docket No. IV–D–20). The CASAC also recognized that the preparation of a revised criteria document and staff paper would not be an easy undertaking. In his August 31, 1992 letter to the Administrator, the Chairman of the CASAC noted that "a carefully planned strategy for preparation of the criteria document and staff position is essential in view of the magnitude and complexity of the task." He added that "the review, integration and interpretation of the old and new information will be a substantial undertaking. In addition, it will be imperative that the next staff position paper carefully consider alternative forms of the ozone standard, both in terms of averaging times, such as daily (6–24 hour), as well as frequency of occurrence, and seasonal standards, in addition to the traditional one-hour standard. This too, will require substantial preparation effort and, I suspect, ample time for debate" (McClellan, 1992).

The EPA has considered the view urged by some commenters that health and welfare effects studies published in the peer-reviewed literature after early 1989 should be considered even though not incorporated into the air quality criteria. The language of section 109(b)(1) and 109(b)(2) makes clear that primary and secondary standards are to be based on scientific information assessed in air quality criteria issued under section 108 of the Act. Furthermore, under section 109(d), which was added to section 109 in 1977, the EPA must periodically conduct "a thorough review" of the air quality criteria taking into account the advice and recommendations of the scientific review committee known as the CASAC. Taking these provisions together, it is clear that the Act contemplates that the EPA base its NAAQS decisions on scientific studies that have been reviewed by the CASAC and incorporated into air quality criteria.[1]

The EPA's interpretation not only is the most straightforward reading of the statutory scheme, but it makes good sense in the context of this decision. As discussed in the August 10, 1992 proposal notice (57 FR 35546), implementation of the NAAQS can have profound economic and social as well as environmental consequences, and it is understandable that Congress would require them to be based on scientific studies that had been rigorously assessed not only by the EPA but also by an independent advisory committee (i.e., CASAC). Under the statute, the process for performing this assessment is preparation or revision of a criteria document [see *Lead Industries Association* v. *EPA*, 647 F.2d 1130, 1136–37 (DC Cir. 1980), *cert. denied*, 101 S. Ct. 621 (1980)]. During that process, a large number of studies, though published in peer-reviewed journals, are typically judged unsuitable for use in standard setting. In other

[1] Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies that have been assessed in air quality criteria [see, e.g. 36 FR 8186 (April 30, 1971) (the EPA based promulgation of original NAAQS for six pollutants on scientific studies discussed in the air quality criteria and limited consideration of comments to those concerning validity of scientific basis); 38 FR 25678, 25679–80 (September 14, 1973) (the EPA revised air quality criteria for sulfur oxides to provide basis for reevaluation of secondary NAAQS)]. This longstanding interpretation has been strengthened by the addition of the 1977 amendment that provides for CASAC review of air quality criteria.

words, publication in a peer-reviewed journal does not in itself establish the validity or usefulness of a given study. As Administrator Reilly noted, "it would be premature to draw conclusions on either the scientific merit or the ultimate implications of particular studies prior to a rigorous and comprehensive assessment * * * by the EPA and CASAC" (57 FR 35546).

For these reasons, the EPA concludes that it may not consider studies not incorporated into air quality criteria and reviewed by the CASAC when setting or revising NAAQS.[2] Given the extraordinary importance of the NAAQS for $O_3$, the EPA further concludes that consideration of such studies in this instance would be inappropriate even if permitted under section 109.

At times, the EPA has found it appropriate to supplement a criteria document before completing its review of the corresponding NAAQS. For example, the EPA in 1986 prepared addenda to the criteria document for particulate matter and sulfur oxides so that newly published studies could be incorporated and, thus, serve as part of the basis for determining whether revisions to the air quality standards were appropriate. Similarly, the EPA prepared the $O_3$ Supplement that is part of the basis for today's decision so that newly published studies could be properly considered. The EPA's discretion to delay completion of its periodic reviews under section 109(d) for such purposes is not unlimited, however, and at some point the process of incorporating new studies must end so that decisions can be made. The Chairman of the CASAC emphasized this in his August 31, 1992 letter when he noted "it is crucial that at a particular point in time, that is understood by all parties, the knowledge base on ozone be summarized and used for regulatory purposes" (McClellan, 1992).

The EPA also considered the comments that specifically address the protection afforded by the existing 1-hour standard against 1- to 3-hour exposures to $O_3$. Several commenters maintained that the EPA erred in reaching its proposed decision because potentially sensitive population groups such as children, the elderly, and women had not been properly considered. While age has been suggested as a factor which could modify responsiveness to $O_3$ exposure, controlled-exposure studies conducted on human subjects do not show children or the elderly to have greater changes in lung function than other subjects. In one study by McDonnell et al. (1985), changes in lung spirometry in children were similar to those found in adults exposed under similar conditions, except that no significant increases in symptoms were found in children (U.S. EPA, 1986, p. 12–35). With regard to the elderly, subjects 50 years of age or older were found by Bedi et al. (1988) and Bedi and Horvath (1987) to have smaller changes in lung function than younger subjects when exposed to similar $O_3$ levels, thus leading to the suggestion that a possible drop-off in responsiveness to $O_3$-induced pulmonary function changes occurs sometime in middle age (U.S. EPA, 1992, p. 3–61). As for gender differences, there were no significant differences in pulmonary function [forced expiratory volume ($FEV_1$) and forced vital capacity (FVC)] between men and women exposed to $O_3$ (Drechsler-Parks et al., 1987; Reisenauer et al., 1988), although the data suggest women may be somewhat more responsive to $O_3$ than men because women had slightly lower mean exercise rates during the studies (U.S. EPA, 1992, p. 3–61). For these reasons, the EPA concludes that the characterization of the sensitive populations most affected by short-term exposure to $O_3$ presented in the August 10, 1992 proposal notice (57 FR 35549) is in accordance with the air quality criteria.

Several commenters questioned the adequacy of the margin of safety provided by the existing 1-hour standard. In general, these commenters argued that the standard should be tightened to provide increased protection against effects of prolonged (6- to 8-hour) exposures. One commenter also referred to short-term exposures; he noted that his State's advisory committee, with responsibilities similar to those of the CASAC, had identified a lowest observed effects level of 0.12 ppm for exposures of 1 to 2 hours based on its assessment of McDonnell et al. (1983) and Gong et al. (1986). This commenter added that after considering an additional study indicating that multihour exposures at 0.12 ppm and below produced decrements in lung function (Lioy et al., 1985), as well as mounting evidence of cumulative effects from chronic exposure to $O_3$, his State agency had adopted a 1-hour $O_3$ standard of 0.09 ppm in 1987, citing the need to provide an adequate margin of safety to "prevent substantial risk of harm to human health as a result of short-term exposures and to provide protection against probable effects of long-term exposures." This commenter added that evidence for a more protective margin of safety is more compelling now because of multihour studies (Spektor *et al.*, 1988a,b) and controlled human exposure studies (Folinsbee et al., 1989; Horstman et al., 1989) reporting decrements in pulmonary function at 0.12 ppm and lower as well as multihour studies reporting biochemical indicators of inflammation (Koren et al., 1988a,b). This commenter concluded by noting that adoption of a 1-hour standard more stringent than the current one would provide a greater degree of protection against multihour exposures.

With respect to short-term exposures, the EPA also considered McDonnell *et al.* (1983) and Gong *et al.* (1986) in conjunction with other studies discussed in the air quality criteria and reached a quite different conclusion as to the significance of effects reported at 0.12 ppm $O_3$. As discussed in the proposal notice (57 FR 35547, 35548), controlled-exposure studies of human subjects (McDonnell et al. 1983; Gong et al. 1986) reported small but statistically significant, transient declines in pulmonary function (e.g., reductions in lung volume and air flow), which in some cases were accompanied by symptoms (e.g., cough, chest pain, throat irritation, shortness of breath) during exposure to $O_3$ in the range of 0.12 to 0.15 ppm. These effects, however, were reported only when subjects were engaged in very heavy exercise ($V_e$=68–89 liters per minute). Without heavy exercise, even the most sensitive subjects did not experience statistically-significant decrements in lung function ($FEV_{1.0}$) at low-level $O_3$ exposures (around 0.12 ppm after 1 to 3 hours). As discussed in the staff paper, the magnitude of effects which can be measured at these exposure levels, even with heavy exercise, is not generally considered to be adverse to health (U.S. EPA, 1989, pp. VII–53 to VII–56).

As discussed in the proposal notice, another key point that emerged during the review of these and other studies

[2] This conclusion does not vitiate the role of public comment in the standard-setting process, as several commenters have suggested. Broadly speaking, the EPA believes Congress intended the Administrator to consider comments that address such issues as the scientific merit, the implications, and the proper use of studies discussed in criteria documents, just as the Administrator might consider staff opinions or recommendations on such matters in a staff paper or other analytical document. By contrast, the EPA does not believe Congress intended to allow interested parties to add new studies to the basis for decision, circumventing the rigorous scrutiny they would otherwise undergo, by the simple expedient of attaching them to public comments. Of course, if new studies that appear to be important are brought to the EPA's attention in public comments or otherwise, it may be appropriate to supplement a criteria document as discussed below.

was the high degree of variability in responsiveness between individuals exposed to similar $O_3$ levels. This was evident from the number of studies (Gibbons and Adams, 1984; Linn et al., 1986; Avol et al., 1984; Schelegle and Adams, 1986) that found no statistically-significant response at exposures (0.12 to 0.15 ppm $O_3$) and exercise levels ($V_e$ = 55 to 86 liters per minute) similar to those in McDonnell et al. (1983) and Gong *et al.* (1986). In two of these studies (Avol et al., 1984; Linn et al., 1986), statistically-significant changes in $FEV_1$ began to appear at 0.16 ppm $O_3$.

Recognizing that between 5 and 20 percent of otherwise healthy individuals may be more responsive to $O_3$ during exercise and, therefore, might be at higher risk, the EPA also examined the intersubject variability reported by McDonnell *et al.* (1983) and Kulle *et al.* (1985). For these studies, the effects experienced by even the most sensitive individuals exposed to 0.12–0.15 ppm $O_3$ for 1 to 3 hours ranged from −9 to −16 percent decline in $FEV_{1.0}$ with few, if any, symptoms. These effects have been characterized as only mild to moderate (U.S. EPA, 1989, pp. VII–53 to VII–56).

The EPA's assessment of these and other controlled-exposure studies of human subjects led Administrator Reilly to conclude, taking into account the differences of opinion among CASAC members on this point, that the lesser effects associated with 1- to 3-hour exposures to $O_3$ in the range of 0.12 to 0.15 ppm did not constitute adverse effects for purposes of section 109 of the Act. The EPA adheres to that judgment.

With respect to prolonged exposures, the EPA also evaluated Lioy *et al.* (1985) as part of its assessment of the emerging research in this area. Lioy *et al.* (1985) conducted a summer camp field study of children engaged in outdoor activities for periods of several days to weeks, during which they were exposed to ambient $O_3$ for several hours per day. This study reported that statistically-significant, short-term pulmonary function decrements, compared to initial baseline values, could be measured even when the $O_3$ NAAQS were not exceeded. The effects increased with exposure to increasing levels of $O_3$. The pulmonary function decrements reported, however, could be attributed in part to factors such as other pollutants or heat. Moreover, the health significance of pulmonary function decrements of the duration and magnitude reported in this study is unclear (U.S. EPA, 1989, pp. VII–53 to VII–56).

Based on the its assessment of McDonnell *et al.* (1983), Gong *et al.* (1986), and Lioy *et al.* (1985), the EPA does not agree that these three studies warrant revision of the 1-hour $O_3$ NAAQS, either to provide greater protection against short-term (1- to 3-hour) effects or to provide a margin of safety against the effects of multihour exposures. As noted above, the EPA adheres to Administrator Reilly's judgment that effects associated with 1- to 3-hour exposures in the range of 0.12 ppm to 0.15 ppm do not constitute adverse effects. The EPA also believes that tightening the 1-hour standard to provide "surrogate" protection against multihour exposures would be inappropriate for reasons discussed below. Under section 116 of the Act, of course, the States are free to establish ambient air quality standards that are more stringent than the NAAQS. Because decisions on such questions as whether detectable responses to air pollution are significant enough to be regarded as adverse health effects, whether a given margin of safety is adequate, or whether it is appropriate to use a short-term standard to provide surrogate protection against the effects of multihour exposures are inescapably judgmental (see, e.g., *Lead Industries Association* v. *EPA*, *supra*, 647 F.2d at 1144, 1160, 1161–62), different decision-makers may well come to different conclusions.

The preliminary information on multihour exposures cited by this commenter and others was considered by the CASAC in its assessment of the adequacy of the existing 1-hour standard (CASAC Transcript, 1988). The CASAC was divided on whether it would be appropriate to set a lower 1-hour standard as a surrogate to protect against multihour exposures. In any event, the CASAC could not reach a consensus on an appropriate range for such a standard. The CASAC noted in its "closure letter" that "this lack of consensus is reflective of major deficiencies in our knowledge base regarding health and welfare effects of long-term exposure (beyond a few hours) to ozone. The data base is very large and adequate for knowledgeable individuals to reach agreement on the effects of acute exposure to ozone in the range appropriate for setting a 1-hour standard. However, there is not an adequate data base on the effects of multiple hour or seasonal exposures to ozone * * *." (CASAC, 1989).

Administrator Reilly was very aware of the views of the CASAC on these points. Taking those views into account, he determined that the appropriateness of revising the existing 1-hour primary standard should be judged in terms of the large body of information on acute (1- to 3-hour) exposures to $O_3$, and that the preliminary information on multihour or prolonged exposures should be evaluated in terms of whether it provided a sufficient basis for setting a new multihour standard. This was the approach adopted in the proposal notice, and the EPA continues to believe it is the proper one. Tightening the 1-hour standard to a degree appropriate for surrogate protection against prolonged or multihour exposures would require many if not all of the same determinations that would be needed to establish a multihour standard. At a minimum, only after an appropriate multihour averaging period and concentration level of concern had been established, would it be possible to compute, based on $O_3$ air quality relationships, a 1-hour value that would generally (but not always) provide the same approximate level of protection. Given the preliminary nature of the information available, making such determinations now would be premature. As discussed above, the CASAC in essence undertook such an assessment in its deliberations and could not reach a consensus due to the lack of an adequate data base.

Based on its review of the record, the EPA concludes that there is insufficient information on prolonged or multihour exposures to provide a reasoned basis for lowering the existing 1-hour primary standard to serve as a surrogate for a longer-term standard. Even if there were sufficient information available, the adoption of a tighter 1-hour standard as a surrogate for a longer-term standard would be a poor policy choice. When establishing a new or revised standard, the averaging time selected should match to the extent practicable the exposure period associated with the health effects of concern. While 1-hour peak $O_3$ levels correlate well with longer-term $O_3$ levels in many areas of the country, the variability of air quality relationships means that the adoption of a 1-hour standard as a surrogate would not assure uniform protection for the entire country. As a result, some areas would have to over-control to meet the lower 1-hour value while others, even though they attained the lower 1-hour standard, would not necessarily receive the desired level of protection against prolonged or multihour exposures. For these reasons, the EPA concludes that the more reasoned approach is to proceed as rapidly as possible with the next review of the air quality criteria so that recently published studies can be appropriately considered. Being aware

of many of these new studies, the EPA believes they will provide important new information so that a more informed decision can be made with respect to the need for and specification of a new standard to address the public health concerns associated with prolonged or multihour exposures to $O_3$.

In the proposal notice, the Agency estimated that it would take 2 to 3 years to update the air quality criteria for ozone and develop staff recommendations for the Administrator, following the relatively complex process outlined in Section III of the notice. As previously noted, a number of commenters, including the immediate past Chairman of the CASAC, have stressed the magnitude and complexity of the task. Others have argued that the newer studies raise serious concerns about the adequacy of the existing standards. The Agency continues to believe that a rigorous assessment of the new studies is necessary to assure a sound decision. Because of the extraordinary importance of this public health issue, however, the Administrator intends to move the process ahead as quickly as possible and, if appropriate, to propose revisions of the standards at the earliest possible date. To that end, the Administrator has directed the Agency staff to examine all possible ways of accelerating the process consistent with assuring a sound decision.

*B. The Secondary Standard*

The rationale for the proposed determination under section 109(d)(1) that revisions to the existing secondary standard are not appropriate at this time was presented in some detail in the August 10, 1992 proposal (57 FR 35550). Based on this information, Administrator Reilly concluded that the most prudent course of action was to retain the current standard until a more informed decision could be made during the next standard review. After taking into account the public comments on the secondary standard and for the reasons discussed below, the EPA again concludes, based on the rationale presented in the August 10, 1992 proposal notice, that revisions to the existing secondary standard are not appropriate at this time. As discussed in the summary of public comments above, only four commenters opposed the proposed decision on the secondary standard. Several of these commenters argued that the EPA should have considered studies published in the peer-reviewed literature after completion of the air quality criteria and staff paper that served as the basis for the proposed decision. As in the case of the primary standard, and for the same reasons, the EPA concludes that secondary NAAQS must and should be based on information contained in the air quality criteria. Again, the EPA believes the proper course of action is to proceed as rapidly as possible with the next review of the air quality criteria so that the more recent studies can be fully evaluated. In this regard, the EPA notes the number of new studies, some of which are still in press, cited by one of the commenters (see Docket Number IV–D–27) on the effects of $O_3$ on forests. As discussed in the August 10, 1992 proposal, this is precisely the type of information that, once it has been incorporated into the air quality criteria, will assist the EPA in reaching a more informed decision on a new form, averaging period, and level of a secondary standard that would be more protective of forest tree species and agricultural crops. As in the case of the primary standard, once the review process is completed, the EPA will reach a determination as to whether revisions are appropriate and announce its proposed decision as quickly as possible thereafter.

Two commenters also argued that the EPA should give further consideration to the staff's and the CASAC's recommendations on tightening the existing 1-hour secondary standard. As discussed in the August 10, 1992 proposal, Administrator Reilly was aware that both the staff and the CASAC had great difficulty throughout their review of the air quality criteria and standards for $O_3$ in determining an appropriate range for a 1-hour secondary standard (U.S. EPA, 1989, p. XI–15). In the end, the staff had to rely on the preliminary results of the Lee *et al.* (1988) study to develop and specify a range of alternative levels below that of the current standard. Even after considering the staff's new assessment based on the Lee study, the CASAC could not reach a consensus (CASAC, 1989). As noted in the proposal notice, the staff found this study too preliminary to serve as the basis for recommending changes in the form and averaging time of the standard. Given the preliminary status of data that provided the basis for staff recommendations and the CASAC's clearly expressed view that a 1-hour averaging period was not the most appropriate exposure indicator, Administrator Reilly was initially inclined not to consider any revisions because of the absence of sufficient information to specify a new form, averaging time, and level for the secondary standard.

Being mindful of the opinion expressed by the CASAC in its "closure letter" Administrator Reilly did, however, consider lowering the 1-hour standard as an interim measure. As discussed in the August 10, 1992 proposal, even if the results of the Lee *et al.* (1988) study provided a sufficient basis for revising the standard downward from 0.12 to 0.10 ppm, as an interim measure, it was Administrator Reilly's judgment that such a change would provide only marginal improvement because a 1-hour averaging period is not the most appropriate exposure indicator for the full range of exposures that affect crops and forest tree species and will have to be reconsidered during the next review. Administrator Reilly also concluded that, in the interim, such a change would have imposed a disproportionate and largely meaningless burden on States to review and make appropriate revisions in applicable SIP's. Having considered the public comments on the issue, the EPA adheres to these judgments.

*C. Final Decision*

For the reasons discussed above and in the August 10, 1992 proposal notice (57 FR 35542), it is the Administrator's judgment under section 109(d)(1) that revisions to the existing primary and secondary NAAQS are not appropriate at this time. Because a large body of new information on the health and welfare effects of $O_3$ has been published in the scientific literature since completion of the air quality criteria upon which this decision is based, the EPA has already initiated action to update the air quality criteria (57 FR 38832, August 27, 1992). As discussed above, the EPA will proceed with the next review of the criteria and standards for $O_3$ and announce its proposed decision on revisions of the standards as rapidly as possible.

**V. Regulatory Impacts**

*A. Regulatory Impact Analysis*

Under Executive Order 12291, the EPA must judge whether an action is a "major" regulation for which a Regulatory Impact Analysis (RIA) is required. For reasons set forth in the proposal notice, the EPA has judged that today's decision on the primary and secondary NAAQS is not a major action. The EPA, therefore, has deemed unnecessary the preparation of either a final RIA or a final Environmental Impact Statement.

*B. Impact on Small Entities*

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., the EPA must prepare initial and final regulatory flexibility analyses assessing the impact of certain rules on small entities. For reasons set forth in the proposal notice, the EPA has determined that the impact assessment requirements of the RFA are inapplicable to this final decision.

**VI. Other Reviews**

This decision was submitted to the Office of Management and Budget (OMB) for review. Written comments from the OMB and the EPA written responses to these comments are available for public inspection at the EPA's Central Docket Section (Docket No. A–92–17), South Conference Center, room 4, Waterside Mall, 401 M Street SW., Washington, DC.

Dated: March 1, 1993.

**Carol M. Browner,**

*Administrator.*

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**Appendix I**

May 1, 1989

The Honorable William K. Reilly,
*Administrator, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460*

Dear Mr. Reilly: I am pleased to transmit via this letter the advice of the Clean Air Scientific Advisory Committee (CASAC) concerning the National Ambient Air Quality Standards for Ozone. CASAC has reviewed and offered comments directly to EPA staff on the EPA criteria document "Air Quality Criteria for Ozone and Other Photochemical Oxidants (1986)," the draft "Criteria Document Supplement (1988)," and the Office of Air Quality Planning and Standards staff position paper "Review of the National Ambient Air Quality Standards for Ozone Assessment of Scientific and Technical Information (1988)" and related support documents.

CASAC previously reached closure on the 1986 Criteria Document. At a meeting held on December 14–15, 1988, CASAC came to closure on the "Criteria Document Supplement (1988)" and the 1988 Staff Position Paper and concluded that they provide an adequate scientific basis for EPA to retain or revise primary and secondary standards for ozone. While reaching closure at this time, the Committee did note an emerging data base on the acute health effects resulting from 6-plus hours of ozone exposure, providing evidence of the possible need for a standard with a 6–8 hour averaging time. However, it was the Committee's view that it would be some time before enough of this developing information would be published in scientific journals to receive full peer review and, thus, be suitable for inclusion in a criteria document. CASAC concluded such information can better be considered in the next review of the ozone standards.

CASAC did not reach a consensus opinion on endorsement of the staff position paper recommendation that "the range of 1-hour average ozone levels of concern for standard setting purposes is 0.08–0.12 ppm for a primary standard." The opinion of the CASAC Ozone Review Committee was divided with regard to the upper range of the standard with eight individuals favoring a range with an upper value of 0.12 ppm, three individuals favored an upper bound in the range of 0.10–0.12 ppm, four individuals favored an upper bound value no higher than 0.10 ppm, and one individual abstained from offering an opinion. Several individuals who supported an upper value of 0.12 ppm as well as all of the other individuals who favored a lower value for the upper end of the range expressed the view that at 0.12 ppm there was little or no margin of safety. As you are aware, the margin of safety is intended to provide protection against adverse effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement. Finally, several members of the subcommittee favored development of a standard with a more statistically robust upper bound on the annual distribution of ozone concentrations rather than reliance on the current expected exceedance form of the standard. While the Committee offers no further advice on what form the Agency should consider, we would caution you against any form which alters the degree of health protection afforded by the current standard.

CASAC had substantial discussion of the issue of what are or are not adverse health effects. This discussion was aided by the presentation of this issue in the staff position paper. Within CASAC there was diversity of opinion; some members felt that healthy individuals experience adverse effects when ozone exposure induced any of the responses categorized as moderate (i.e., >10% decrement in $FEV_1$ or mild to moderate respiratory symptoms) in the staff position paper, while a few members believed that adverse effects would not be experienced until ozone induced more severe effects (i.e., >20% decrement in $FEV_1$ and moderate to severe respiratory symptoms). The view of some individuals on this matter was influenced by recognition that resolution of the adverse health effect issue represents a blending of scientific and policy judgments and, thus, we feel it appropriate to inform you of the range of our views on this matter.

Of particular concern to CASAC is the potential for effects arising from exposures to ozone with daily peak concentrations at or near 0.12 ppm for periods of 6–8 hours and with co-exposure to other pollutants. This concern is due to air quality analyses which have shown that even in areas which do not repeatedly exceed the ozone standard, ozone concentrations can remain close to 0.12 ppm for several hours per day for extended periods of time in summer. There was concern based on recent controlled human exposure, epidemiology and toxicology studies, that such prolonged exposures could result in increased respiratory impairment. Further, for people exposed to these ozone concentrations over a lifetime, the possibility that chronic irreversible effects may result is of concern, although such changes have not been demonstrated.

The Committee noted that the Criteria Document Supplement failed to cite and discuss a group of "ecological" epidemiological studies of the effects of ozone on various measures of human health such as hospitalizations for respiratory illnesses or exacerbation of chronic respiratory problems. Although these studies have obvious limitations in establishing cause and effect relationships, they have certain strengths which can aid in regulatory decision-making. Studies of this type should be discussed and evaluated in future criteria documents as a complementary source of information.

While reaching closure on the staff position paper recommending a 1-hour standard, CASAC urged that the Agency provide increased support for research that will prove an improved scientific basis for evaluating the need for standards with multi-hour or seasonal averaging times. Clearly, the obvious, research on this critical environmental health issue must be supported now in order for results to be available for consideration in the next 5-year review cycle. CASAC has enumerated these research needs in some detail in a September 1987 submission to the Agency. The Committee feels these research recommendations are still valid and should be incorporated as expeditiously as possible into the Agency research program.

CASAC did not reach a consensus opinion on endorsement of the staff position paper recommendation of "a 1-hour averaging time standard in the range of 0.06–0.12 ppm" for a secondary standard. The CASAC Ozone Welfare Effects Subcommittee that considered this matter reached a divided opinion; two favored a range with an upper value of 0.12 ppm, three favored an upper value of less than 0.12 ppm, and five favored an upper value of 0.10 ppm. The Committee noted that the form of the standard was of critical importance in protecting against ozone effects on vegetation. The Committee was of the opinion that a cumulative seasonal standard would be more appropriate than a 1-hour standard and felt that such a standard could be developed. CASAC favored issuance of a cumulative seasonal standard form assuming its development would not further delay the standard setting process. If this form of standard cannot be developed in time for the current review, the Committee is of the opinion that you should give serious consideration to setting a 1-hour secondary standard with a maximum of 0.10 ppm. The Committee took note of the lack of information on the effects of ozone on forest ecosystems and urged support for research to remedy this deficiency.

In closing, I would like to briefly comment on CASAC's failure to reach a consensus as to the appropriate range for setting the ozone standards. This lack of consensus is reflective of major deficiencies in our knowledge regarding health and welfare effects of long-term exposure (beyond a few hours) to ozone. The data base is very large and adequate for knowledgeable individuals to reach agreement on the effects of acute exposure to ozone in the range appropriate for setting a 1-hour standard. However, there is not an adequate data base on the effects of multiple hour or seasonal exposures to ozone, especially as regards whether such exposures may produce chronic health effects. This is especially troubling since such long-term exposures to ozone occur in many parts of the United States and involve many millions of people and thousands of acres of crop and forest lands. As a result, there continues to be concern for the public health and welfare threat which may be posed by chronic exposure to ozone. It is critical that the data base on health and welfare effects related to multiple hour, seasonal and lifetime exposures of ozone be increased through an accelerated and expanded research effort. This must be done so that future considerations of ozone standards will derive from a stronger scientific base.

CASAC recognizes that your statutory responsibility to set standards requires public health policy judgments in addition to determinations of a strictly scientific nature. While the Committee is willing to further advise you on the ozone standards, we see no need, in view of the already extensive comments provided, to review the proposed ozone standards prior to their publication in the **Federal Register**. In this instance, the public comment period will provide

sufficient opportunity for the Committee to provide any additional comments or review that may be necessary.

CASAC would appreciate being kept informed of progress on establishing revised or new ozone standards and plans for research on ozone effects. Please do not hesitate to contact me if CASAC can be of further assistance on this matter.

Sincerely,

Roger O. McClellan, D.V.M.

*Chairman, Clean Air Scientific Advisory Committee.*

**Appendix II**

August 31, 1992

Hon. William K. Reilly,
*Administrator, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460*

Dear Mr. Reilly: The members of the Clean Air Scientific Advisory Committee (CASAC) have noted with interest the announcement that the Agency is not revising the national air quality standard for ground-level ozone at this time and is initiating a new assessment of the health and environmental effects of ozone. The purpose of this letter is to indicate the willingness of the CASAC to assist the Agency in carrying out a review of the new assessment in an expeditious manner. To facilitate CASAC involvement, it would be useful for the Committee to be briefed at an early date on the Agency's plans for development of the new criteria document on the health and environmental effects of ozone and the subsequent development of a staff position paper on the ozone standard(s).

A briefing for CASAC would provide the opportunity for both CASAC and other interested persons to comment on the Agency's plan for carrying out the important task of preparing new documents. With this as background, CASAC can plan its associated review of the criteria document and staff position paper in a timely manner. The briefing would also provide an opportunity for the Agency and other scientists to describe the state of research now in progress on ozone that will potentially be completed and subjected to peer-review in time for its inclusion in a new assessment. This is especially important since research on ozone is, and should be, ongoing because of the importance of ozone as a pollutant. Nonetheless, it is crucial that at a particular point in time, that is understood by all parties, the knowledge base on ozone be summarized and used for regulatory purposes. A side benefit of the summarization process is that it can also serve to identify information needs which in turn provides input for establishing the research agenda for the future.

The CASAC members are of the opinion that a carefully planned strategy for preparation of the criteria document and staff position paper is essential in view of the magnitude and complexity of the task. As you and your staff are aware, substantial new information has been published since the last criteria document and supplement and staff position paper were prepared. Other studies which may yield significant new information include the National Toxicology Program chronic bioassay with rodents exposed to ozone and new human exposure assessment models are nearing completion. The review, integration and interpretation of the old and new information will be a substantial undertaking. In addition, it will be imperative that the next staff position paper carefully consider alternative forms of the ozone standard, both in terms of averaging time, such as daily (6–24 hour), as well as frequency of occurrence, and seasonal standards, in addition to the traditional one hour standard. This, too, will require substantial preparation effort and, I suspect, ample time for debate.

The CASAC is anxious to assist in these important activities and looks forward to hearing from you as to when the Agency will be ready to brief CASAC on the proposed plans for preparation and review of the ozone criteria document and staff paper.

Sincerely,

Roger O. McClellan, D.V.M.,

*Chairman, Clean Air Scientific Advisory Committee.*

[FR Doc. 93–5266 Filed 3–8–93; 8:45 am]

BILLING CODE 8560–50–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### 45 CFR Part 1303

**RIN: 0970–AB00**

### Head Start Program; Technical Correction

**AGENCY:** Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF).

**ACTION:** Technical correction to final rule.

**SUMMARY:** This document contains a technical correction that adds the Office of Management and Budget approval number for information collection requirements in the Head Start final rule on appeals, published December 14, 1992 (57 FR 59260).

**DATES:** This correction is effective March 9, 1993.

**FOR FURTHER INFORMATION CONTACT:** Joseph A. Mottolo, Acting Commissioner, Administration on Children, Youth and Families, P.O. Box 1182, Washington, DC 20013, (202) 205–8347.

**SUPPLEMENTARY INFORMATION:**

#### Background

The Administration on Children, Youth and Families published a final rule on December 14, 1992 (57 FR 59260) which revises and clarifies for Head Start grantees and delegate agencies the requirements concerning appeals by grantees from termination and denial of refunding actions. The final rule also includes provisions on appeals by current or prospective delegate agencies of grantee's rejections of, or failures to act on, applications, or grantee's terminations of grants or contracts.

#### Need for Correction

As published, §§ 1303.10 through 1303.23 contained information collection requirements for which an OMB approval number was required. OMB approved and assigned a number to those sections on January 22, 1993, which this correction will show in a section added at the end of the rule, specifically for the OMB number.

#### Correction of Publication

Accordingly, the publication of the Head Start Program final rule on appeals (57 FR 59260) is corrected as follows: On page 59271, at the end of § 1303.23, add:

**§ 1303.24 OMB control number.**

The collection of information requirements in sections 1303.10 through 1303.23 of this part were approved on January 22, 1993, by the Office of Management and Budget and assigned OMB control number 0980–0242.

**Neil J. Stillman,**

*Deputy Assistant Secretary for Information Resources Management.*

[FR Doc. 93–5301 Filed 3–8–93; 8:45 am]

BILLING CODE 4130–01–M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 0 and 1

**[DA 92–1115]**

### Reorganization of the Field Operations and Private Radio Bureaus

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This amendment changes the Commission's Rules To incorporate the reorganization between the Private Radio Bureau and the Field Operations Bureau. The reorganization was necessary in order to promote a more efficient and effective organizational structure.

**EFFECTIVE DATE:** October 1, 1992.

**FOR FURTHER INFORMATION CONTACT:** Tom Sullivan, Office of Managing Director, (202) 632–0923.