ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[FRL 2345-6 Docket No. OAQPS 78-9]

Proposed Reaffirmation of the National Ambient Air Quality Standards for Nitrogen Dioxide

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: In accordance with sections 108 and 109 of the Clean Air Act, EPA has reviewed and revised the criteria upon which the existing primary and secondary nitrogen dioxide (NO_2) national ambient air quality standards (NAAQS) are based. The revised criteria document is being published simultaneously with this notice. The existing primary and secondary standards for (NO_2) are both currently set at 0.053 ppm (100 $\mu g/m^3$) as an annual arithmetic average. As a result of the review and revision of the health and welfare criteria, EPA proposes to retain the existing annual average standards. EPA is continuing to evaluate the evidence bearing on whether a separate short-term standard is requisite to protect public health. Consequently, EPA is not proposing to set a separate short-term standard at this time. Public comment is specifically requested on the question of the need for a separate short-term standard.

DATES: *Comments.* Written comments on this proposal must be submitted on or before May 23, 1984. *Public Hearing.* If anyone contacts EPA requesting to speak at a public hearing by March 23, 1984, a public hearing will be held on April 12, 1984 beginning at 10:00 a.m. Persons interested in attending the hearing should call Mr. Harvey Richmond at (919) 541-5655 to determine whether a hearing will occur.

Request to Speak at Hearing. Persons wishing to present oral testimony must contact EPA by March 23, 1984.

ADDRESSES: Submit comments (duplicate copies are preferred) to: Central Docket Section (A-130), Environmental Protection Agency, Attn: Docket No. OAQPS 78-9, 401 M Street, S.W., Washington, D.C. 20460. Docket No. OAQPS 78-9, Containing material relevant to this proposed decision, is located in the Central Docket Section of the U.S. Environmental Protection Agency, West Tower Lobby Gallery I, 401 M St., SW., Washington, D.C. The docket may be inspected between 8:00 a.m. and 4:00 p.m. on weekdays, and a reasonable fee may be charged for copying.

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing, it will be held at EPA's Environmental Research Auditorium, Research Triangle Park, North Carolina. Persons wishing to present oral testimony should notify Mr. Harvey Richmond, Ambient Standards Branch (MD-12), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5655.

Availability of Related Information

The revised Criteria Document, "Air Quality Criteria for Oxides of Nitrogen" (EPA-600/8-82-026F, December 1982; PB-83-16337, $53.50 paper copy), and the final revised OAQPS Staff Paper, "Review of the National Ambient Air Quality Standards for Nitrogen Oxides: Assessment of Scientific and Technical Information" (EPA-450/5-82-002, August 1982; PB 83-132829, $13.00 paper copy and $4.50 microfiche), are available from: U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161.

A limited number of copies of other documents generated in connection with this standard review, such as the Control Techniques Document, Regulatory Impact Analysis, and Environmental Impact Statement can be obtained from: U.S. Environmental Protection Agency Library (MD-35), Research Triangle Park, N.C. 27711, telephone (919) 541-2777 (FTS 629-2777).

FOR FURTHER INFORMATION CONTACT: Mr. Michael Jones, Strategies and Air Standard Division (MD-12), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone (919) 541-5531 (FTS 629-5531).

SUPPLEMENTARY INFORMATION:

Background

Legislative Requirements Affecting This Proposal

Two sections of the Clean Air 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 or welfare and to issue air quality criteria for such pollutants. Such air quality criteria are to reflect the latest scientific information useful in indicating the kind and extent of all identifiable effects on public health or welfare that may be expected from the presence of the pollutant in the ambient air.

Section 109(a) (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 for an adequate margin of safety, is requisite to protect the public health. The secondary standard, as defined in section 109(b)(2), must specify a level of air quality the attainment and maintenance of which in the judgement 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 are defined in section 302(h) (42 U.S.C. 7602(h)) and include effects on soils, water, crops, vegetation, man-made materials, animals, weather, visibility, hazards to transportation, economic values, personal comfort and well-being, and similar factors.

As indicated above, the Act requires not only that primary standards be based on the section 108 criteria, but also that they provide an adequate margin of safety. This requirement was intended to address uncertainties associated with inconclusive scientific and technical information available at the time as well as to provide a reasonable degree of protection against hazards that research has not yet identified.(*1*),(*2*) These uncertainties in the available information and about unidentified human health effects are both components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in providing an adequate margin of safety, the Administrator is regulating not only to prevent pollution levels that have been demonstrated to be harmful, but also so as to prevent pollutant levels for which the risk of harm, even if not precisely identified as to nature or degree, are considered unacceptable. In weighting such risks for margin of safety purposes, EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment.(*1*)

As indicated above, section 109(b) specifies that NAAQS are to be based on the scientific criteria issued under section 108. Several recent judicial decisions make clear that the economic and technological feasibility of attaining NAAQS are not to be considered in setting them, although such factors may be considered to a degree in the development of state plans to implement the standards.(*1*),(*2*)

Section 109(d) of the Act (42 U.S.C. 7409(d)) requires periodic review and, if appropriate, revision of existing criteria and standards. If, in the Administrator's judgment, the Agency's review and revision of criteria make appropriate the proposal of new or revised standards, such standards are to be revised and promulgated in accordance with section 109(b). Alternatively, the Administrator may find that revision of the standards is not appropriate and conclude the review by reaffirming them. The process by which EPA has reviewed the original criteria and standards for nitorgen oxide under section 109(d) is described in a later section of this notice. In addition, section 109(c) specifically requires the Administrator to promulgate a primary standard for NO_2 with an averaging time of not more than 3 hours unless he or she finds no significant evidence that such a short-term standard is required to protect public health.

States are primarily responsible for assuring attainment and maintenance of ambient air quality standards. Under section 10 of the Act (42 U.S.C. 7410), States are to submit to EPA for approval State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants included. Other federal programs provide for nationwide reductions in emissions of these and other air pollutants through the federal motor vehicle control program, which involves controls for automobile, truck, bus, motorcycle, and aircraft emission under Title II of the act (42 U.S.C. 7501 to 7534), and through the development of new source performance standards for various categories of stationary sources under section 111 (42 U.S.C. 7411).

Nitrogen Oxides and Existing Standards for NO_2

A variety of nitrogen oxide (NO_x) compounds and their transformation products occur naturally and as a result of human activities. Nitric oxide (NO), nitrogen dioxide (NO_2), gaseous nitric acid (HNO_3), in addition to nitrite and nitrate aerosals, have all been found in the ambient air. The formation of nitrosamines in the atmosphere by reaction of NO_x with amines has been suggested, but not yet convincingly demonstrated.

Despite considerable scientific research on the potential health and welfare effects of NO_x compounds, there exists little evidence linking specific health or welfare effects to near ambient concentrations of most of these substances. The one significant exception is NO_2. Therefore, EPA has focused its review primarily on the health and welfare effects that have been reported to be associated with exposure to NO_2.

NO_2 is an air pollutant generated by the oxidation of NO and is emitted from a variety of mobile and stationary sources. At elevated concentrations, NO_2 can adversely affect human health, vegetation, materials, and visibility. Nitrogen oxide compounds may also contribute to increased rates of acidic deposition. Typical long-term ambient concentrations of NO_2 range from 0.001 ppm in isolated rural areas to a maximum annual concentration of approximately 0.08 ppm in one of the nation's most populated urban areas. The mean annual NO_2 concentration for 186 urbanized areas during 1977–1979 was 0.029 ppm. Over 95 percent of these urbanized areas had annual average NO_2 concentrations below the current 0.053 ppm standard during this same period. During 1977–1979, peak 1-hour average NO_2 concentrations ranged from 0.06 to 0.5 ppm in urbanized areas. In most of these areas, 1-hour average concentrations seldom exceeded 0.30 ppm.

On April 30, 1971, EPA promulgated NAQS for NO_2 under section 109 of the Clean Air Act (36 FR 8186). Identical primary and secondary standards for NO_2 were set at 0.053 ppm (100 $\mu g/m^3$), averaged over one year. The scientific and medical bases for these standards are contained in the document, "Air Quality Criteria for Nitrogen Oxides," published by EPA in January 1971 (AP-84). The primary standard set in 1971 was based largely on a group of epidemiology studies (*3*),(*4*),(*5*) conducted in Chattanooga which reported respiratory effects in children exposed to low-level NO_2 concentrations over a long-term period. Reevaluation of the Chattanooga studies based on more recent information (especially regarding the accuracy of the air quality monitoring method for NO_2 used in the studies) indicates that these studies provide only limited evidence for an association between health effects and ambient exposures to NO_2. These data and other new information, discussed later in this notice, confirm the need for maintaining NO_2 ambient standards.

Development of Revised Air Quality Criteria for NO_x and Summary of Findings

As required by the Clean Air Act Amendments of 1977, EPA has been reviewing the need for revised NO_2 standards since September 1977. In addition to reviewing the existing annual NO_2 standard, the Administrator is required to promulgate a short-term (1 to 3 hours) NO_2 primary standard unless he or she finds that there is no significant evidence that such a standard is required to protect public health. During the summer of 1978, EPA however, expanded the review to include both short- and long-term exposures and standards. This change was made because of the difficulty in attributing reported effects to a particular exposure duration and because of the uncertainty regarding the relative importance of short- and long-term exposures.

On December 12, 1978 (43 FR 58117), EPA announced that it was in the process of reviewing and updating the 1971 document, "Air Quality Criteria for Nitrogen Oxides," in accordance with section 109(d)(1) of the Clean Air Act, as amended. In developing the revised criteria document, EPA has provided a number of opportunities for review and comment by organizations and individuals outside the Agency. Three drafts of the revised NO_x criteria document have been made available for external review. EPA has received and considered numerous comments on each of these drafts. The Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board has held two public meetings (January 30, 1979 and November 13–14, 1980) to review successive drafts of the document, "Air Quality Criteria for Oxides of Nitrogen" (Criteria Document). These meetings were open to the public and were attended by many individuals and organization representatives who provided critical reviews and new information for consideration. The CASAC's June 19, 1981, closure letter (*6*) to the Administrator stated that the revised Criteria Document presented a balanced and comprehensive critical review of the pertinent literature on human health effects and that the document accurately reflected the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare from NO_x in the ambient air.

From the extensive review of scientific information presented in the Criteria Document, findings in several key areas have particular relevance for consideration in decision making regarding primary and secondary NAAQS for NO_x compounds.

1. Of all the oxides of nitrogen which occur in the atmosphere, NO_2 is the compound of most concern to human health at or near ambient levels.

2. During the period 1975–1980, ambient air NO_2 monitoring data in the United States indicate that peak 1-hour NO_2 concentrations rarely exceeded 0.4 to 0.5 ppm. During that same period, annual average concentrations exceeding 0.05 ppm were found only in a relatively few scattered locations, including population centers such as Chicago and Southern California.

3. At concentrations of 5.0 ppm or above, exposure to NO_2 for as little as 15 minutes both increases airway resistance in healthy human adults and impairs the normal transport of gases between the blood and the lungs.

4. In healthy adults, concentrations of 2.5 ppm NO_2 for 2 hours have been reported to increase airway resistance significantly without altering arterialized oxygen pressure. Single exposures for 3 minutes to NO_2 at concentrations of 1.6 ppm are also likely to increase airway resistance in healthy adults and individuals with chronic bronchitis but are not likely to interfere with the transport of gases between blood and lungs.

5. Single exposures to NO_2 for periods ranging from 3 minutes to 2 hours at concentrations of 1.0 ppm or below have not been shown to affect respiratory function in healthy individuals or in those with bronchitis.

6. Whether asthmatic subjects are more sensitive than healthy adults in experiencing NO_2-induced pulmonary function changes remains to be resolved. One controlled human exposure study suggests that some asthmatics may experience chest discomfort, dyspnea, headache, and/or slight nasal discharge following 2-hr exposures to 0.5 ppm NO_2, but the study did not provide convincing evidence of pulmonary function changes in asthmatics at that NO_2 concentration.

7. Certain animal studies demonstrate various mechanisms of action which may also be the mechanisms by which potential health effects are induced in humans at relatively low NO_2 exposure levels. At higher (generally greater than ambient) NO_2 exposure levels and after long-term exposure, more serious changes such as emphysematous effects have been found n several animal species. Long-term exposures also cause other structural alterations of the lungs as well as biochemical and physiological changes in the lungs and increased susceptibility to respiratory infection in animals.

8. Ongoing studies of the effects of indoor air pollution suggest that, in some instances, an increased incidence of respiratory illness in young children may be associated with the use of gas stoves and possibly with NO_2 produced by these appliances. Caution must be applied, however, in using these findings for standard-setting purposes until (a) they are confirmed by further analyses of data subsequently gathered in the ongoing studies; (b) the significance of potential confounding factors is more clearly understood; and (c) clearer exposure/effect relationships are defined through more intensive NO_2 monitoring in homes using gas stoves.

9. No definitive estimates can yet be provided for peak 1–2 hours, 24 hour, weekly, or annual average NO_2 exposure levels that may be associated with any increased respiratory illness in young children residing in homes using gas stoves, although some basis exists for suggesting that repeated exposures to peak levels are most likely to be involved.

10. Data from human and animal studies are comparable in some ways. Estimates of repeated, short-term peak concentrations of NO_2 possibly associated with increased respiratory illness in homes with gas stoves are only slightly below the lowest (0.5 to 1.0 ppm) repeated exposure concentrations found to increase susceptibility to respiratory infections in animal infectivity studies.

11. At elevated concentrations, NO_2 has been associated with visibility impairment, adverse effects on vegetation, and materials damage. NO_x compounds also may contribute to increased rates of acidic deposition.

Review of Primary NO_2 Standards

In the fall of 1980, the Office of Air Quality Planning and Standards (OAQPS) prepared a paper, "Review of the National Ambient Air Quality Standards for Nitrogen Dioxide: Assessment of scientific and Technical Information (OAQPS Staff Paper),"(7) based on the Criteria Document, which evaluated the available scientific and technical information most relevant to the review of the NO_2 NAAQS. The OAQPS Staff Paper also presented recommendations on alternative approaches to revising the standards. Two successive versions of the OAQPS Staff Paper were reviewed at three CASAC meetings (November 13–14, 1980; February 6, 1981; and November 18, 1981). Based on this review, CASAC concluded that the OAQPS Staff Paper provided the kind and amount of technical guidance needed to make any appropriate revisions to the primary and secondary standards. The CASAC's July 6, 1982, closure letter(8) to the Administrator stated that the revised OAQPS Staff Paper was a balanced and thorough interpretation of the scientific evidence pertaining to NO_2.

The current primary NAAQS for NO_2 is 0.053 ppm (100 $\mu g/m^3$), averaged over one year. As indicated above, the Act requires review of the existing criteria and standards for NO_2 and other pollutants every five years. In addition section 109(c) specifically requires the Administrator to promulgate a primary standard for NO_2 with an averaging time of not more than 3 hours unless he or she finds no significant evidence that such a short-term standard is required to protect public health. Thus, during the current standard review for NO_2, EPA is required to determine whether to initiate rulemaking (1) to revise the current NO_2 standards and/or (2) to establish a new short-term standard for NO_2. For the reasons detailed below, EPA has concluded that the current 0.053 ppm annual average standards adequately protect against adverse health and welfare effects associated with long-term exposures and provide some measure of protection against possible short-term health and welfare effects. EPA is continuing to evaluate the evidence bearing on whether a separate shour-term standard is requisite to protect public health. Consequently, EPA is not proposing to set a separate short-term standard at this time.

As indicated above, section 109(b)(1) of the clean Air act requires EPA to set primary standards, based on the air quality criteria and allowing an adequate margin of safety, which in the Administrator's judgment are requisite to protect the public health. The legislative history of the Act makes clear the Congressional intent to protect sensitive persons who in the normal course of daily activity are exposed to the ambient environment. Air quality standards are to be established with reference to protecting the health of a representative, statistically related, sample of persons comprising the sensitive group rather than a single person in such a group.

EPA's objective, therefore, is to determine whether new or revised primary standards are required, based on the existing scientific evidence, assessment of the uncertainties in this evidence, and a reasonable provision for scientific and medical knowledge yet to be acquired, so as to protect sensitive population groups with an adequate margin of safety. None of the evidence presented in the Criteria Document shows a clear threshold of adverse health effects for NO_2. Rather, there is a continuum, ranging from NO_2 levels at which health effects are undisputed, through levels at which many, but not all scientists generally agree that health effects have been convincingly shown, down to levels at which the indications of health effects are less certain and more difficult to identify. This does not necessarily mean that there is no threshold, other than zero, for NO_2 related health effects; it simply means no precise threshold can be identified with certainty based on existing medical evidence. Thus, the standard-setting decision does not involve appending an exact margin of safety to a known threshold effect level. Rather, it involves a public health policy judgment that must take into account both the known continuum of effects and any gaps and uncertainties in the existing scientific evidence.

In reviewing the need for any new or revised primary NO_2 standards, EPA must make assessments and judgments in the following areas:

1. Identification of reported effect levels and associated averaging times that medical research has linked to health effects insensitive persons.
2. Characterization of scientific uncertainties with regard to the health effects evidence and judgments concerning which effects are important to consider in reviewing or setting primary standards.
3. Description of the most sensitive population groups and estimates of the size of those groups.
4. Consideration of NO_2 standard levels and averaging times that provided an adequate margin of safety based on NO_2 levels and exposure periods that may affect sensitive population groups, taking into account the various uncertainties.

Assessment of Health Effects Evidence

The OAQPS Staff Paper, which has been placed in the public docket (Docket No. OAQPS 78-9, II-A-7), presents a detailed and comprehensive assessment by EPA staff of the key health effect studies contained in the Criteria Document and critical scientific issues relevant to the review of the existing annual NO_2 standard and the need, if any, for a separate short-term (1 to 3 hour) NO_2 standard. This assessment is summarized below.

A variety of respiratory system effects have been reported to be associated with exposure in humans and animals to NO_2 concentrations less than 2.0 ppm. The most frequent and significant NO_2-induced respiratory effects reported in the scientific literature to date include: (1) Altered lung function and symptomatic effects observed in controlled human exposure studies, (2) increased incidence of acute respiratory illness and symptoms observed in outdoor community epidemiological studies and in indoor community epidemiological studies involving homes with gas stoves, and (3) lung tissue damage and increased susceptibility to infection observed in animal toxicology studies. As the Criteria Document concludes, results from these several kinds of studies collectively provide evidence indicating that certain human health effects may occur as a result of exposures to NO_2 concentrations at or approaching recorded ambient NO_2 levels.

It is important to note that the Criteria Document, OAQPS Staff Paper, and CASAC have identified various limitations and uncertainties that must be considered in interpreting the health effects evidence for NO_2. For example, controlled human exposure studies generally provide information on the effects of NO_2 on healthy adults and certain potentially sensitive population groups exposed to single, short-term exposures to NO_2 or to simple combinations of NO_2 and other pollutants. However, these human exposure studies have not examined the health implications of repeated exposure to such short-term NO_2 concentrations. In addition, controlled human exposure studies tested only for mild "reversible" effects and have excluded certain potentially sensitive population groups (e.g., children and elderly individuals) for ethical reasons. While the various animal studies are very useful for identifying the kinds of effects that may be caused in humans due to exposure to NO_2 and probable mechanisms by which NO_2 may affect the respiratory system, there is not a satisfactory method, at this time, to quantitatively extrapolate to human exposure-response relationships. Finally, the existing community epidemiological studies, which represent real-world conditions, provide information on probable associations between NO_2 exposures and observed health effects, but conclusions from these studies must be qualified because of the presence of other pollutants and other confounding factors.

In assessing the health effects evidence for NO_2 EPA has carefully evaluated each study cited in this preamble, taking into account the limitations and uncertainties discussed in the Criteria Document and by CASAC, as appropriate. However, except as noted, neither CASAC nor the Agency found that these limitations disqualified the studies discussed below for standard-setting purposes.

Animal Toxicology Evidence. Animal toxicology studies improve the understanding of human health effects associated with acute and chronic exposures to NO_2 by providing information on health effects and exposure conditions which would be considered unethical for human testing. Thus, a larger array of potential effects, at known levels of NO_2 exposure, can be evaluated in animals than in humans. The major limitation of animal toxicology studies on NO_2 for standard-setting purposes is that methods for quantitatively extrapolating the exposure-response results from animal studies such as those on NO_2 to humans exposed to NO_2 under ambient conditions are still in the developmental stage.

While the animal toxicology literature does not permit estimation of human effect levels at this time, it does indicate a variety of effects from acute, chronic, and chronic with repeated peak exposures to NO_2. Findings from animal studies (e.g., emphysematous alterations in the lung, *(9)* other morphological changes in the lung, *(10)* and increased susceptibility to infection *(11)*, *(12)* involving chronic exposures to 0.5 ppm NO_2 or greater or chronic exposures to 0.1 ppm with repeated peaks of 1.0 ppm NO_2 suggest that chronic exposures to NO_2 may lead to serious adverse health effects in humans. While such exposure levels cannot be quantitatively extrapolated to humans, given the similarities between man and animals, it is likely that the above types of effects observed in several animal species also occur in man, albeit at unknown exposure levels. These effects may include development of chronic respiratory diseases and increased incidence of acute respiratory infection or disease. Less severe and generally reversible effects (e.g., biochemical changes, *(13)*, *(14)* interference with hormone metabolism, *(15)* and possible interference with liver metabolism *(16)* have been reported in animals exposed once to NO_2 concentrations in the range 0.2–0.5 ppm.

Interpretation of the community epidemiology studies involving homes with gas stoves, discussed later in this notice, can be aided by supporting evidence from animal toxicology studies indicating increased susceptibility to infection. It has been demonstrated that long-term (21–33 week) exposures of mice to concentrations as low as 0.5 ppm NO_2 with 1-hour peaks of 2.0 ppm NO_2 can cause complete deterioration of alveolar macrophage cells.*(10)* This effect results in a decreased ability of the pulmonary system to defend against infection. Numerous other animal studies, with exposure periods ranging from three hours to twelve months and exposure concentrations ranging from 0.5 to 7.0 ppm, also show that NO_2 exposures reduce resistance to bacterial lung infections.(*11*),(*12*),(*17–22*)

Controlled Human Exposure Evidence. Controlled human exposure studies provide important data concerning the effects of single, short-term NO_2 exposures on healthy adults and certain groups suspected of being sensitive to NO_2. As discussed above, however, the human exposure studies leave unanswered questions concerning the health impact of repeated short-term exposures or effects on potentially sensitive population groups which have not been tested for ethical reasons, such as children or elderly individuals. Due to current limitations in the sensitivity of pulmonary function testing, controlled human exposure studies are also unable at present to detect any damage to the distal airways of the lung which may be due to NO_2 exposures at or near ambient levels.

The lowest level at which single, short-term peak exposures have been observed to produce effects of definite health concern is approximately 1.0 ppm NO_2. In particular, significant pulmonary function changes have been shown in controlled human exposure studies (*23*), (*24*) in the range of 1.0 to 2.0 ppm for short durations (3 to 10 minutes). The effects were observed in healthy adults and chronic bronchitics at these levels. One study (*25*) indicates that subtle effects that are of uncertain significance for the primary standard, such as mild and reversible symptomatic effects, may occur in some asthmatics after a 2-hour exposure to 0.5 ppm NO_2.

Two controlled human exposure studies (Orehek et al., 1976 (*26*) and Von Nieding et al., 1977 (*27*) report increases in sensitivity to a bronchoconstrictor in asthmatics and healthy adults, respectively, at relatively low levels (0.1 and 0.05 ppm NO_2) for 1–2 hour exposures. The Von Nieding et al. study also involved exposure to 0.025 ppm ozone (O_3) and 0.11 ppm sulfur dioxide (SO_2) in addition to 0.05 ppm NO_2. EPA, however, concurs with the recommendation made by CASAC that these studies not be considered in establishing a lowest observed effect level.(*5*) This conclusion reflects concerns expressed in the Criteria Document and by CASAC over uncertainties in the statistical analysis of the experimental data and uncertainty regarding the significance of responses observed in studies that use a bronchoconstrictor to detect effects. EPA is considering the results of these studies solely as a factor in judging which standard(s) will provide an adequate margin of safety.

Community Epidemiological Evidence. The existing annual primary standard (0.053 ppm) is based in large part on a series of community epidemiology studies (*3*),(*4*),(*5*) conducted in Chattanooga during the late 1960's. The distances of three study communities from a large point source of NO_2 resulted in an apparent gradient of exposure for a six month average of 24-hour values over which illness rates and lung function were determined. The incidence of acute respiratory illness was reported to be higher for each family segment (mothers, fathers, and children) in the high-NO_2 exposure neighborhood than in the intermediate- and low-NO_2 areas. The studies also reported small but statistically significant decreases in lung function in school children living in areas of apparently higher NO_2 concentrations than for children living in areas with lower NO_2 concentrations. However, since measurements of NO_2 for these studies conducted in 1968–1969 employed the Jacobs-Hocheiser method, which was subsequently found to be unreliable, meaningful quantitative estimates of population exposure to NO_2 are not available for the three study areas. In addition, no basis was provided for distinguishing the relative contribution of NO_2 exposures from those of other pollutants present in the study areas. Thus, the Chattanooga studies which used the Jacobs-Hocheiser method to measure NO_2 concentrations provide limited evidence of an association between elevated long-term NO_2 exposures and the occurrence of increased acute respiratory illness and lung function impairment.

In a recently published reanalysis of different acute respiratory illness data collected in Chattanooga in 1972–1973, Love et al. (1982)(*28*) report higher rates of respiratory illness for families living in a designated "high pollution" area compared to families living in "intermediate" and "low pollution" areas. This reanalysis relied on NO_2 monitoring data employing the Saltzman method for 24-hour values and, for part of the study period, continuous chemiluminescent monitoring. The absence of reliable daily NO_2 measurements for part of the study, the small magnitude of differences in annual mean concentrations for the three study areas, and the variability of short-term exposure levels across the three study areas led the authors to conclude that the excesses in illness could not be clearly attributed to specific pollutants or exposure periods. While the Love et al. study appeared after completion of the Criteria Document and has not been reviewed by CASAC, EPA concludes that its findings do not suggest any alteration of EPA's assessment of the health effects evidence.

The only other published outdoor epidemiological study reviewed by CASAC or known to EAP which used valid monitoring techniques and reports effects associated with NO_2 is a Japanese study (*29*) of school children. While impairment of pulmonary function was reported, the effects found in the study were generally not associated with NO_2 alone, but rather with various combinations of air pollutants, including SO_2, particulate matter, and O_3. The data from this study are not sufficient to permit quantitative estimates of specific NO_2 levels that might have been associated with pulmonary function impairment.

In summary, the results of the Chattanooga and Japanese community studies provide some qualitative evidence of a possible association between human exposure to low levels of NO_2 and human health effects, but little, if any, quantitative evidence to relate health effects to specific NO_2 concentrations. The findings of these studies are, however, not inconsistent with the hypothesis, discussed below, that NO_2 in a complex mix with other pollutants in the ambient air adversely affects lung function and/or respiratory illness in children.

Evidence from Epidemiological Studies Involving Homes with Gas Stoves. A series of ongoing epidemiological studies have been conducted in the United States and Britain which investigate the effects of indoor air pollution on individuals living in homes with gas stoves compared to those living in homes with electric stoves. Since several investigators have found significantly higher levels of NO_2 in gas stove versus electric stove homes, these studies provide an opportunity to assess the potential health impacts of repeated, short-term peaks and elevated, long-term exposures of NO_2 on children and adults. The use of data from indoor air pollution studies is solely for the purpose of learning about possible health effects associated with NO_2 and is not related to providing protection from indoor sources.

A series of studies by a British group of investigators (*30–33*) Provide some evidence that children living in gas stove homes experienced an increased incidence of acute respiratory illness and respiratory symptoms (e.g., coughing, wheezing) compared to children living in homes which use electric stoves. The authors of the British studies have expressed some concern that the effects observed may be due to factors other than NO_2, such as increased water vapor pressure in gas stove homes in Britain. No information is currently available, however, to confirm or refute the possible contribution of other factors, such as increased humidity, to the increases in acute respiratory illness and sysmptoms observed in these studies. Due to the incomplete analysis of possible confounding or covarying factors (e.g., temperature and humidity) and the lack of short-term NO_2 measurements in the homes of the subjects studied, the apparent relationship between NO_2 exposure and respiratory illness in British "gas stove" studies must be qualified at this time.

Initial results from an ongoing prospective epidemiological study (*34*). (*35*) of six communities in the United States ("Six-City Study") provide suggestive evidence that acute respiratory illness was increased in young children before age 2 who were living in homes which used gas stoves for cooking. The Six-City Study also reports small but statistically significant decrements in pulmonary function measurements in children 6 to 9 years of age who lived in gas stove homes. The authors of the study present a biologically plausible hypothesis that the small impairments observed in these children might, if continued over time make them more susceptible to developing respiratory problems during their adult life.

As part of the Six-City Study, 24-hour average NO_2 concentrations were monitored over a 1-year period in the "activity room" (but not the kitchen) of several (5-11) electric and gas stove homes in each of the six communities studies. (*35*) The monitoring results show that NO_2 levels in the gas stove homes were higher than outside levels, while 24-hour average concentration in electric stove homes generally approximated the NO_2 levels observed in the outdoor air. In the same study, (*35*) continuous measurements made in one kitchen of a gas stove home during a 2-week period found that NO_2 levels exceeding 0.25 ppm and even 0.50 ppm can occur during cooking, with such high levels lasting from minutes to hours. The authors speculate that kitchen annual means may exceed 0.06 ppm NO_2 if one extrapolates from other studies. (*35*) Further, short-term hourly NO_2 kitchen levels during cooking were noted as possibly being 5 to 10 times higher than measured mean values. This is in contrast to annual average NO_2 levels of about 0.02 ppm (and no marked peaks) in homes with electric stoves.

The findings from the Six-City Study provide preliminary evidence suggesting that repeated peak short-term exposures to NO_2 may be associated with increased incidence of acute respiratory illness in young preschool-age children and small decrements in lung function in school age children. The hypothesis that such effects are associated with repeated short-term peak NO_2 exposures is based in part on annual average NO_2 levels not being very different in the gas stove versus electric stove homes studied.

A series of studies (*36*), (*37*) by another group of investigators found no association between the use of gas stoves and increased rates of respiratory disease in either children or adults. However, the number of children used in these studies was approximately a factor of 10 smaller than in both the British and Six-City gas stove studies, which yielded an association between increased prevalence of respiratory illness and gas cooking. The relatively small sample size would tend to lessen the likelihood of these studies finding statistically significant differences, since the main health effects being investigated are relatively small differences in disease and symptom prevalence rates.

The cumulative findings from several animal studies support the hypothesis that NO_2 may be the principal agent responsible for the effects observed in the British and Six-City gas stove studies. As discussed previouly, a variety of animal toxicology studies (*11*), (*12*), (*17–22*) in different species have demonstrated that NO_2 exposure impairs respiratory defense mechanisms and increases susceptibility to infection. The findings from these animal studies provide a plausible basis for inferring that NO_2 is associated with the reported increase in incidence of acute respiratory illness in children living in homes with gas stoves. The results from one animal study (*21*) which showed increased susceptibility to infection also suggest that repeated, short-term peak exposures may be a more important factor than long-term, low-level exposures of equivalent dose in causing or contributing to the effects observed in the gas stove home.

Unfortunately, as discussed previously short-term (less than 24-hour) NO_2 values have been monitored in only one home in the Six-City Study to date.(*35*) Based on a review of other studies which have monitored short-term NO_2 levels in American gas stove homes (other than those studied in the Six-City study), (*38*) it would appear that daily maximum 1-hour NO_2 levels rarely exceed 0.5 ppm, but that residents of gas stove homes are exposed frequently to daily peak 1-hour exposures in the range 0.15–0.30 ppm each year. Based on the same review, (*38*) on any given day peak 1-hour NO_2 levels in the kitchen may range from 0.03 to 0.80 ppm. While there is only a small amount of data available to base conclusions on the frequency of exposure to short-term peak NO_2 levels, the data reviewed in the OAQPS Staff Paper suggest that residents, including children, living in American gas stove homes, such as those included in the Six-City Study, might have been exposed to hourly NO_2 concentrations in the range 0.15 to 0.30 ppm on 20 to 50 percent of the days in a year (approximately 75 to 180 days per year).

Population Groups Most Sensitive to NO_2 Exposures

On the basis for the review of the health effects evidence presented in the Criteria Document, EPA believes that the following groups may be more sensitive to NO_2 exposures: young children, asthmatics, chronic bronchitics, and individuals with emphysema or other chronic respiratory diseases. In addition, there is reason to believe that persons with cirrhosis of the liver or other liver, hormonal, and blood disorders, or persons undergoing certain types of drug therapies may also be more sensitive to NO_2 based on the findings from animal studies showing increased systemic, hematological, and hormonal alterations after exposure to NO_2. Due to the lack of human experimental data for these latter groups, however, EPA is considering the potential effects on such persons only as a factor in providing an adequate margin of safety.

In EPA's judgment, the available health effects data identify young children and asthmatics as the groups at greatest risk from ambient exposures to NO_2. Several epidemiological studies (30),(31),(34) in gas stove homes suggest that young children are at increased risk of respiratory symptoms and infection from exposures to elevated levels of NO_2. Although there are no data on this question, this increased sensitivity may be due to (1) the higher activity level of children which can increase the dose experience, (2) a potential difference in the delivered dose of NO_2, which is independent of activity levels, (3) some inherently greater biological sensitivity of children to NO_2, or (4) a combination of some or all of these potential factors.

One human clinical study *(25)* provides evidence that some asthmatics suffer mild symptomatic effects (e.g., nasal discharge, headaches, dizziness, and labored breathing) after light to moderate exercise during an exposure to 0.5 ppm NO_2 for two hours.

Other groups that may be susceptible to NO_2 exposures are chronic bronchitics and individuals suffering from emphysema. One human clinical study *(24)* reports increased airway resistance in a group of chronic brochitics following approximately three-minute exposures at or above 1.6 ppm NO_2. Although there are no human experimental studies of NO_2 involving individuals with emphysema, it seems reasonable to include such persons in the category of high risk individuals since they suffer from major impairment in breathing capacity even in the absence of NO_2.

The U.S. Bureau of the Census *(39)* estimated that the total number of children under five years of age in 1970 was 17,163,000 and the number between five and thirteen years was 36,575,000. Data from the U.S. National Health Survey *(40)* for 1970 indicate that there were 6,526,000 chronic bronchitics, 6,031,000 asthmatics, and 1,313,000 emphysematics at the time of the Survey. Although there is overlap on the order of about one million persons for these last three categories, it is estimated that over twelve million persons experienced these chronic respiratory conditions in the U.S. In 1970.

Margin of Safety Considerations

Selecting an ambient air quality standard with an adequate margin of safety requires that uncertainties in the health effects evidence be considered in arriving at the standard. While the lowest NO_2 concentrations reliably linked to identifiable health effects due to single or repeated peak exposures appear to be in the range of 0.5–1.6 ppm NO_2 (based in symptomatic effects *(25)* and pulmonary function impairment *(23, 24)*, a clear threshold for adverse health effects has not been established. Several factors make it difficult, if not impossible, to identify the minimum NO_2 level associated with adverse health effects.

As discussed earlier, for ethical reasons, clinical investigators have generally excluded from studies individuals who may be very sensitive to NO_2 exposures, such as children, elderly individuals, and people with severe pre-existing cardio-pulmonary diseases. In addition, human susceptibility to health effects varies considerably among individuals. Thus, it is not certain that the available experimental evidence for NO_2 has accounted for the full range of effects and human susceptibility. Finally, there is no assurance that all adverse health effects related to low level NO_2 exposures have been identified.

Factors that have been considered in assessing whether the current NO_2 standard provides an adequate margin of safety include: (1) Concern for potentially sensitive populations that have not been adequately tested, (2) concern for repeated peak exposures and delayed effects seen in animal studies but seldom examined in controlled human exposure studies, (3) implications of the Orehek et al. (1976) study*(26)* in which a bronchoconstrictor was used, (4) possible synergistic or additive effects between NO_2 and other pollutants or environmental stresses,*(27)* and (5) uncertainty about the exposure levels and averaging times associated with effects reported in the "gas stove" studies.

Determinations Concerning the Averaging Time and Standard Level

As discussed previously, EPA is required both to review the adequacy of the existing 0.053 ppm annual NO_2 standard and to determine whether a short-term (less than 3 hours) NO_2 standard is required to protect public health. Although the scientific literature supports the conclusion that NO_2 does pose a risk to human health, there is no single study or group of studies that clearly defines human exposure-response relationships at or near current ambient NO_2 levels. This situation exists because of both methodological limitations of health effects research and the lack of sufficient studies involving population groups suspected of being particularly sensitive to NO_2. Based on the review of the health effects evidence presented in the Criteria Document, however, both EPA and the CASAC have concluded that the studies reviewed above have demonstrated the occurrence of health effects resulting from both short-term and long-term NO_2 exposures. However, the various uncertainties in the health effects data make it impossible to specify at this time the lowest level at which adverse health effects are believed to occur in humans due to either short- or long-term NO_2 exposures.

Annual Standard. In reviewing the scientific basis for an annual standard, EPA finds that the evidence showing the most serious health effects associated with NO_2 exposures (e.g., emphysematous alterations in the lung and increased suceptibility to infection) comes from animal studies conducted at concentrations well above those permitted in the ambient air by the current annual standard. The major limitation of these studies for standard-setting purposes is that currently there is no satisfactory method for quantitatively extrapolating exposure-response results from these animal studies directly to humans. However, the seriousness of these effects, the biological similarities between humans and test animals, and the absence of animal studies showing that these effects do not occur at NO_2 exposure levels at or near ambient concentrations suggest that there is some risk, presently unquantifiable, to human health from long-term exposure to elevated NO_2 levels.

Other evidence suggesting health effects relating to long-term, low-level exposures, such as the community epidemiology and gas stove community studies, provides some qualitative evidence of a relationship between human exposure to near ambient levels of NO_2 and adverse health effects. However, various limitations in these studies (e.g., unreliable monitoring data, lack of sufficient monitoring data, and inadequate treatment of potential confounding factors such as humidity and other pollutants) preclude derivation of quantitative dose-response relationships.

Given the uncertainty associated with the extrapolation from animal to man, the seriousness of the observed effects, and the inability to determine from the available data an effects level for humans, EPA believes it would be prudent public health policy to maintain the current annual standard of 0.053 ppm. While it is not possible currently to quantify the margin of safety provided by the existing annual standard. Two observations are relevant: (1) A 0.053 ppm standard is consistent with CASAC's recommendation to set the annual standard at the lower end of the range (0.05 to 0.08 ppm) cited in the OAQPS Staff Paper to ensure an adequate margin of safety against both long-term and short-term health effects, *(8)* (2) a 0.053 ppm standard would keep annual NO_2 concentrations considerably below the long-term levels for which serious chronic effects have been observed in animals. Therefore, the Agency is proposing to retain the annual standard at 0.053 ppm. The Agency welcomes comments on this proposal, the arguments presented for selecting this standard, and any additional information on the efects of chronic exposure to NO_2.

Short-Term Standard. EPA also has carefully examined the health effects data base to determine whether a separate short-term standard is needed at this time. As discussed previously, adverse health effects (e.g., significant but reversible changes in lung function) in humans resulting from single, short-term peak exposures have been observed only at relatively high NO_2 concentrations (above 1 ppm). However, since such levels do not appear to occur in the ambient air, the Agency does not believe that existing information from clinical studies necessitates a short-term standard designed to limit single hourly exposures. While animal studies report some responses from single, short-term exposures in the range of 0.2 to 0.5 ppm $NO_2$the health significance of these findings for humans has not been established.

Finally, both EPA and CASAC have extensively examined the community indoor epidemiology studies (the "gas stove" studies) and concluded that there is some limited and in-conclusive evidence that repeated peak NO_2 exposures may cause increases in acute respiratory illness and small decrements in lung function in children. The findings from numerous animal studies demonstrating reduced resistance to infection due to NO_2 exposure support the hypothesis that NO_2 is the primary agent responsible for the effects observed in the gas stove studies. While the Criteria Document warns that considerable caution should be used in drawing firm conclusions from the gas stove studies, the tentative conclusion is that the observed health effects can be attributed, at least in part, to NO_2. In addition, findings from animal toxicology studies suggest that short-term, peak exposures probably are more important in causing such effects than long-term peak exposures of equivalent dose. The CASAC also stated that the effects observed in the Six-City Study*(34)* may be caused by repeated, short-term peak exposures rather than long-term, lower level NO_2 concentrations, although this has not yet been conclusively demonstrated. Both CASAC and the study authors have cautioned EPA against overinterpretation of these data in reviewing the basis and need for NO_2 primary standards.

While the findings from the gas stove studies are preliminary and must be qualified, in EPA's judgment they do suggest that multiple exposures to peak short-term NO_2 concentrations may pose some unquantified health risk for young children. This judgement is based on EPA's assessment of (1) community studies reporting adverse health effects for young children potentially exposed to repeated peak NO_2 concentrations in gas stove homes, and (2) several toxicology studies which report biological damage in animals exposed repeatedly to short-term peak NO_2 concentrations. Unfortunately, as previously stated, indoor community studies have not adequately controlled for potential confounding variables (factors that vary with NO_2) that could alter the magnitude of the observed relationship between NO_2, and the health effects variables and the statistical significance of the relationship. Moreover, even if such effects are attributable solely to NO_2, neither the indoor community studies nor the animal toxicology studies adequately address what short-term concentration levels and frequencies of exposure produce them. (Information on NO_2 exposures in gas stove homes is limited to totally separate studies that indicate the 1–2 hour levels in the range of 0.15 to 0.30 ppm may occur on 75 to 180 days per year).*(38)*

Analysis of Short-Term Peaks in the Ambient Air

Despite the uncertainties mentioned above, both the Agency and the CASAC are concerned that frequent and repeated exposures for one to two hours to NO_2 levels in the range of 0.15 to 0.30 ppm may be of concern for children. For that reason, the Agency conducted an analysis of existing ambient air quality data to determine the frequency and levels of short-term ambient concentrations in areas that have annual average concentrations less than or equal to 0.053 ppm (the existing primary standard level). While the evidence concerning the health effects from short-term exposures is limited and uncertain, the purpose of the analysis was to assess the extent to which alternative annual standards would protect against short-term concentrations.

The results of the analysis are discussed in the OAQPS Staff Paper (OAQPS 78-9, II-A-7) for ambient data collected during 1977 through 1979. A similar analysis of ambient data collected during the period 1979–1981 has been placed in the docket (OAQPS 78-9, II-A-9). The Agency is conducting an exposure analysis to determine the actual population exposure to various concentrations given the daily activity patterns of exposed populations and will make it available before promulgation.

The results of the air quality analyses indicate that the number of short-term peak NO_2 concentrations in areas currently experiencing annual levels at the lower end of the CASAC range of 0.05–0.03 ppm is far less than the number of short-term peak concentrations estimated to occur in gas stove homes. Based on a detailed statistical analysis of the new data, if air quality just met the current NO_2 annual standard, EPA's best estimate is that daily maximum 1-hour concentrations would not be expected to exceed even 0.15 ppm (the lowest end of the range of potential concern) on more than 35 days per year. For all counties with annual averages currently at or below the existing 0.053 annual standard and having at least one day with a maximum 1-hour value at or above 0.15 ppm, the mean number of days with daily maximum concentrations exceeding 0.15 ppm is only 7.1 days, and the median is 3.5 days. As mentioned previously, data collected in homes separate from the community health studies indicate that levels in the range of 0.15 to 0.30 ppm NO_2 may have occurred for 1–2 hour periods on 20 to 50 percent of the days in the year (approximately 75 to 180 days per year). *(38)* For the reasons discussed above, it is not clear whether repeated exposures to NO_2 at these levels have any health significance.

Because of the large scatter in the NO_2 air quality data, the Agency could not derive a highly correlated relationship between annual concentrations and one hour levels at the same site. Therefore meeting a specified annual average does not assure that a given specified short-term level will not be exceeded (or depending on the level, will not be exceeded many times). However, there is a trend of lower one hour maxima being associated with lower annual averages. Despite the lack of a firm relationship between these averaging times, it has also been observed that where the annual average is at or below the current 0.053 standard, days with one-hour concentrations in excess of any specified level (including levels in the range of 0.15 to 0.30 ppm) tend to be fewer in number than at locations where the 0.053 ppm level is exceeded. Based on a review of the information presented in the Criteria Document and the OAQPS Staff Paper, CASAC concluded that

> * * * the primary annual standard to control long-term NO_2 concentrations can * * * be set at a level that also provides adequate protection against repeated short term exposures.

The staff paper suggests an annual standard set within the range of .05–.03 ppm. Based on the above discussion, the need to provide adequate protection against repeated short-term peak exposures, and due to the uncertainties of the data base, the CASAC recommends that you consider selecting a primary annual standard level at the lower end of the .05–.08 ppm range to ensure an adequate margin of safety of protection against both long-term and short-term health effects.

Proposed Action on Standard. Based on the data presented in the Criteria Document, analyses summarized in the OAQPS Staff Paper and docket report (II–A–9), and CASAC's recommendations, the Agency concludes that the current 0.053 ppm annual average standard adequately protects against adverse health effects associated with long-term exposures and provides some measure of protection against possible short-term health effects. EPA is continuing to evaluate the evidence bearing on whether a separate short-term standard is requisite to protect public health. Consequently, EPA is not proposing to set a separate short-term standard at this time.

On the basis of the preceding analyses and in view of CASAC's recommendation, EPA proposes to retain the existing 0.053 ppm annual standard. In assessing whether this standard will protect the public health with an adequate margin of safety, the Agency has considered the following factors, all of which have been discussed previously in the OAQPS Staff Paper and in this notice: (1) Concern for potentially sensitive populations that have not been adequately tested, (2) concern for repeated peak exposures and delayed effects, seen in animal studies but seldom tested in human clinical studies, (3) implications of the Orehek et al. (1976) study (*26*) in which a bronchoconstrictor was used, (4) possible synergistic or additive effects with other pollutants or environmental stresses (*27*), (5) uncertainty about exposure levels and averaging times associated with effects reported in the gas stove studies, and (6) uncertainties regarding the relationship between annual average and short-term peak NO_2 concentrations based on air quality analyses discussed above.

In view of the uncertainties mentioned above, EPA specifically solicits public comments on the proposal to retain the current 0.053 ppm annual NO_2 primary standard and the need, if any, for a separate short-term primary NO_2 standard. Public comments on this issue should identify any scientific evidence that supports any particular standard level and other relevant elements of the standard, such as averaging time, number of exceedances, and form of the standard.

Welfare Effects and the Secondary Standard

As indicated above, section 109(b) of the Clean Air Act mandates the setting of secondary NAAQS to protect the public welfare from any known or anticipated adverse effects associated with an air pollutant in the ambient atmosphere. A variety of effects on public welfare have been attributed to NO_2 and NO_x compounds. These effects include increased rates of acidic deposition, symtomatic effects in humans, vegetation effects, materials damage, and visibility impairment. The OAQPS Staff Paper (OAQPS 78–9, II–A–7) discusses each of the welfare effects of concern in detail. The following discussion summarizes the welfare-related effects discussed in the OAQPS Staff Paper, and CASAC's comments relating to the secondary NO_2 NAAQS.

The issue of acidic deposition was not directly assessed in the OAQPS Staff Paper because EPA has followed the guidance given by CASAC on this subject at its August 20–22, 1980 public meeting on the draft document, "Air Quality Criteria for Particulate Matter and Sulfur Oxides." The CASAC concluded that acidic deposition is a topic of extreme scientific complexity because of the difficulty in establishing firm quantitative relationships between emissions of relevant pollutants, formation of acidic wet and dry deposition products, and effects on terrestrial and aquatic ecosystems. Secondly, acidic deposition involves, at a minimum, the criteria pollutants of oxides of sulfur, oxides of nitrogen, and the fine particulate fraction of suspended particulates. Finally, the Committee felt that any document on this subject should address both wet and dry deposition, since dry deposition is believed to account for at least one-half of the total acid deposition problem. For these reasons, the Committee felt that a separate comprehensive document on acidic deposition should be prepared prior to any consideration of using NAAQS as a regulatory mechanism for control of acidic deposition. CASAC also suggested that a discussion of acidic precipitation be included in the criteria documents for both NO_x and particulate matter/sulfur oxides as well. In response to these recommendations, EPA is in the process of developing an acidic deposition document that will provide comprehensive treatment of this subject. EPA anticipates that a draft of this document will be reviewed by CASAC in the early summer of this year.

As defined in section 302(h) of the Act, welfare effects include effects on personal comfort and well being. Mild symptomatic effects were observed in 1 of 7 bronchitics and in 7 of 13 asthmatics during or after exposure to 0.5 ppm NO_2 for 2 hours in the Kerr et al. (1979) study. (*25*) The authors indicate that the symptoms were mild and reversible and included slight headache, nasal discharge, dizziness, chest tightness and labored breathing during exercise. In EPA's judgment, these mild symptomatic effects affect personal comfort and well being and could be considered adverse in certain situations. CASAC generally agreed with this judgment, but felt that short-term peaks associated with these effects are rarely observed in areas where the current annual standard of 0.053 ppm was met.

Evidence in the Criteria Document and information provided by plant physiologists (*41–43*) have indicated that visible injury to vegetation due to NO_2 alone occurs at levels which are above ambient concentrations generally occurring within the U.S., except around a few point sources. Several studies (*44–48*) on the effects of NO_2 alone on vegetation have failed to show plant injury at concentrations below 2 ppm for short-term exposures. For long-term exposures, such as a growing season, the lowest concentration reported to depress growth is approximately 0.25 ppm. (*43*) The concentrations which produced injury or impaired growth in these studies are higher than those which would be expected to occur in the atmosphere for extended periods of time in areas attaining a 0.053 ppm annual standard.

In regard to vegetation effects from NO_2 in combination with other pollutants, plant responses to pollutant mixtures appear to vary with concentration, ratio(s) of pollutants, sequence of exposure, and other variables. Studies examining exposure to NO_2 and SO_2 as well as to O_3 and SO_2 (*49*), (*50*) have shown that the synergistic response is most pronounced near the threshold doses of the gas combinations tested and that, as concentrations increase beyond the threshold doses, the synergistic response diminishes, often becoming additive, or in some cases, antagonistic. Therefore, although the limited evidence available indicates that low levels of NO_2 and SO_2 can have a synergistic effect, this type of response is extremely variable and has not been sufficiently documented as to low-level effects. CASAC concurred with EPA's judgment that the data do not suggest significant effects of NO_2 on vegetation at or below current ambient levels and that an annual standard of 0.053 ppm would provide sufficient protection against significant effects on vegetation.

In regard to visibility impairment due to NO_2, the scientific evidence indicates that light scattering by particles is generally the primary cause of degraded visual air quality and that aerosol optical effects alone can impart a reddish brown color to a haze layer. Thus while it is clear that particles and NO_2 contribute to brown haze, the CASAC concurred with EPA's judgment that the quantitative relationships between NO_2 concentrations and visibility impairment useful in selecting the level of a secondary standard based on visibility have not been sufficiently established.

Finally, while NO_2 has been qualitatively associated with materials damage, CASAC concurred with EPA's judgment that the available data do not suggest major effects of NO_2 on materials for concentrations at or below the current annual standard of 0.053 ppm.

Based on an evaluation of symptomatic effects in humans, vegetation damage, visibility impairment, and materials damage and the levels at which these effects are observed, it is EPA's judgment that the current annual standard provides adequate protection against both long- and short-term welfare effects and that there is no need for a different secondary standard. For these reasons, EPA proposes to retain the secondary standard with the same level, and averaging time as the primary standard.

Form of the Standards

EPA proposes to retain the current form of the primary and secondary NAAQS for NO_2 which specifies that the annual arithmetic average must not exceed 0.053 ppm (100$\mu g/m^3$). However, EPA is considering changing the form of the standards to a statistical form and using the available annual arithmetic averages from the last three years of data to determine compliance. This would mean that the standards would be expressed as an expected annual arithmetic average (i.e., the expected annual average would be determined by averaging the annual arithmetic averages available from several years of data). EPA has previously promulgated or proposed changing from deterministic to statistical forms for the ozone and carbon monoxide standards, both of which have short-term (less then 24-hour) averaging times (44 FR 8202, 45 FR 55066).

This alternative is being considered because the current deterministic form of the standards does not fully take into account the random nature of meteorological variations. In general, annual mean NO_2 concentrations will vary from one year to the next, even if precursor emissions remain constant, due to the random nature of meteorological conditions which affect the formation and dispersion of NO_2 in the atmosphere. This means that with the deterministic form compliance with the standard, and consequently emission control requirements, may be determined on the basis of a year with unusually adverse weather conditions. At the same time, it should be noted that the problem of year to year variability is much less significant for annual average concentration standards than for short-term standards.

A change to a statistical form annual average standard could result in a slightly less stringent standard. This is because control measures would be determined by the average of the annual arithmetic averages available from up to three years of data rather than the single highest annual average in that period. While this difference would probably be small, it is of concern in assessing the health protection afforded by the primary standard and would be considered in choosing the level of the annual standard if EPA decided to restate it in a statistical form.

While EPA does not propose to make a change in the form of the NO_2 standards at this time, comments are solicited from the public on the form of the standards and the desirability of using the average of the available annual arithmetic mean concentrations from the last three years of data for determining attainment of the NO_2 primary and secondary standards.

EPA is proposing to make some minor changes in the Part 50 regulations concerning the NO_2 standards. These include restating the NO_2 primary and secondary standards to improve understanding by the public and explicitly adding a rounding convention to aid in the interpretation of the standards by State and local air pollution agencies.

Significant Harm Levels

Section 303 of the Clean Air Act authorizes the Administrator to take certain emergency actions if pollution levels in an area constitute "an imminent and substantial endangerment to the health of persons." EPA's regulations governing adoption and submittal of SIP's contain a provision (40 CFR 51.16) that requires the adoption by States of contingency plans to prevent ambient pollutant concentrations from reaching specified significant harm levels. The existing significant harm levels for NO_2 were established in 1971 (36 FR 24002) at the following levels:

2.00 ppm (3750 $\mu g/m^3$)—1-hour average
0.50 ppm (937 $\mu g/m^3$)—24-hour average

On the basis of EPA's reassessment of the early data and assessment of more recent scientific evidence, no modifications are being proposed to the existing significant harm designations. EPA has assessed the medical evidence on exposure to higher NO_2 concentrations that could lead to significant harm. This assessment can be found in Chapter 15 of the Criteria Document. Table 15-3 of the Criteria Document indicates the types and levels of effects reported for exposure to high levels of NO_2.

Regulatory and Environmental Impacts

Regulatory Impact Analysis

As has been noted, the Clean Air Act specifically requires that NAAQS be based on scientific criteria relating to the level that should be attained to protect public health and welfare adequately. The courts (*1*), (*2*) have interpreted the Act as excluding any consideration of the cost or feasibility of achieving such a standard in determining the level of the ambient standards. However, to comply with Executive Order 12291, EPA must judge whether a regulation is a "Major" regulation for which a regulatory impact analysis (RIA) is required. The Agency has judged the NO_2 NAAQS proposal to be a major action, and, therefore, has analyzed the costs and benefits associated with attainment of alternative ambient NO_2 standards. In view of the court decisions mentioned above, EPA's analysis, "Regulatory Impact Analysis of the National Ambient Air Quality Standard for Nitrogen Dioxide (Draft)," has not been considered in issuing this proposal and will not be considered in final action on this proposal. The document is available from the address given above in the Availability of Related Information section of this notice. A final RIA will be issued at the time of promulgation.

Both the RIA and this proposal were submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291. Any comments from OMB and any EPA responses to those comments are available for public inspection at EPA's Central Docket Section, Docket No. OAQPS 78-9, West Tower Lobby, Gallery I, Waterside Mall, 401 M Street, S.W., Washington, D.C.

The draft RIA contains estimates of the projected costs of alternative control strategies associated with attainment of alternative annual standards and the projected number of urban areas exceeding alternative annual standard levels. EPA's approach to addressing benefits in the RIA focuses on reductions in exposure to short- and long-term NO_2 concentrations that are expected upon attainment of alternative annual standards. Several simplifying assumptions were made so that exposure estimates could be produced for the RIA. EPA is in the process of preparing an exposure analysis report based on the "NAAQS Exposure Model" (NEM) (*51*) which will provide exposure estimates for two urban areas based on fewer simplifying assumptions. That document will be completed and submitted to the public docket (OAQPS 78–9) prior to promulgation. Finally, the draft RIA contains estimates of the incremental cost per exposure reduction associated with attainment of alternative annual standards.

The cost and economic analysis section of the RIA is a hypothetical analysis using generalized data. Because of the complex nature of the task and wide scope of the problem, the analysis cannot be as specific as those performed by States in their SIP development process. Thus, results of the RIA can only be used in a qualitative sense and cannot be used to determine the actual attainment status of an area or the control strategies that should be implemented in a non-attainment area. The analysis predicts that only a few areas of the United States may have ambient levels near or above the proposed 0.953 ppm NO_2 NAAQS. By 1990, depending upon the assumptions used, the RIA estimates that between zero and two urban areas will need controls beyond the federal motor vehicle control program (FMVCP) for cars and trucks. These additional controls could be a motor vehicle inspection and maintenance (I&M) program or retrofit controls for utility or commercial boilers. Net annualized 1990 costs of adding these controls are estimated to be $40–$210 million in constant 1980 dollars. These costs are in addition to approximately $1,970–$2,100 million per year required for the NO_x portion of the FMVCP, and in addition to almost $150–$245 million per year incurred by industry to meet NO_x new source performance standards (NSPS). FMVCP and NSPS expenditures are not directly related to a NO_2 NAAQS, and therefore do not vary with the alternative ambient standards investigated.

Environmental Impacts

Environmental impacts associated with control of NO_x emissions have been examined in a draft environmental impact statement (EIS) that is available in the docket (OAQPS 78–9, II–A–8). The EIS indicates that controlling NO_x emissions probably results in biological, ecosystem, and esthetic benefits.

Impact on Small Entities

The Regulatory Flexibility Act requires that all federal agencies consider the impacts of final regulations on small entities, which are defined to be small businesses, small organizations, and small governmental jurisdictions (5 U.S.C. 601 et seq.). EPA's analysis pursuant to this Act is summarized in a section of the draft report, "Cost and Economic Assessment of Regulatory Alternatives for NO_2 NAAQS." An NAAQS for NO_2 by itself has no direct impact on small entities. However, it forces each State to design and implement control strategies for those areas not in attainment. Three possible sources of impacts on small entities include (1) the FMVCP for cars and trucks, (2) the I&M program, and (3) the stationary source control program.

FMVCP requirements fall primarily on automobile manufacturers, none of which are classified as small businesses. Additionally, the incremental cost of NO_x control, which is passed on to purchasers of motor vehicles—including small entities—is a small fraction of the purchase price and, thus, the impact to these purchasers should be negligible.

An I&M program for NO_x control may have a slight negative economic impact on small entities, but it may also have a positive economic impact on some small entities. The estimated per vehicle average annual cost for an NO_x I&M program is expected to be less than $25 for a failed vehicle and $0.50 for a passed vehicle. These costs should not impose a significant negative economic impact on small entities. On the other hand, some small entities, such as gas stations and garages will be repairing failed vehicles resulting in a net increase in receipts due to an NO_x I&M program. In addition, if a decentralized I&M program is implemented using small businesses to inspect motor vehicles, then their net receipts will also increase due to receipt of the inspection fee, most of which they retain. (The remainder goes to the governmental unit sponsoring the area-wide I&M program.)

Finally only the largest stationary source NO_x entities hypothetically need to implement controls to attain an annual NO_2 standard. These large entities are among the largest facilities within their standard industrial class, and therefore are not likely to be small entities.

Based on the analysis summarized above, EPA concludes that no small entity group will be significantly negatively affected due to reaffirmation of the 0.053 ppm NO_2 NAAQS. Therefore, pursuant to 5 U.S.C. 605(b) the Administrator certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Impact on Reporting Requirements

There are no reporting requirements directly associated with an ambient air quality standard promulgated under section 109 of the Clean Air Act (42 U.S.C. 7409). There are, however, reporting requirements associated with related sections of the Act, particularly sections 107, 110, 160, and 317 (42 U.S.C. 7407, 7410, 7460, and 7617). EPA anticipates that this proposal will not result in any significant changes in those reportng requirements since it would retain the existing level and averaging times for the primary and secondary standards.

Revisions to Part 50 Regulations

In proposing to reaffirm the annual NO_2 standards, EPA has proposed some minor revisions to Part 50 which are described above in the section Form of the Standards.

Part 51 Regulations and SIP Development

Part D of the Clean Air Act Amendments of 1977 required States to submit revisions to their State implementation plans (SIP's) by January 1, 1979 which provided for attainment of the ambient air quality standards that were not being attained as of the date of those Amendments. Currently, there are several counties in each of three major metropolitan areas (Los Angeles, Chicago, and Denver) that are classified in whole or part as being "nonattainment" for NO_2. Since today's action proposes a reaffirmation of the NO_2 ambient standards upon which the 1979 NO_2 SIP's were based, this action will not alter any requirements of those Part D SIP's.

Federal Reference Method

The measurement principle and calibration procedure applicable to reference methods for measuring ambient NO_2 concentrations to determine compliance with the standards are not affected by this proposal. The measurement principle and the current calibration procedure are set forth in Appendix F of 40 CFR Part 50. Reference methods—as well as equivalent methods—for monitoring NO_2 are designated in accordance with 40 CFR Part 53. A list of all methods designated by EPA as reference of equivalent methods for measuring NO_2 is available from any EPA Regional Office, or from EPA, Department E (MD-76), Research Triangle Park, N.C. 27711.

Public Participation

Due to the many complex issues which developed as criteria document revision and standard reevaluation proceeded, EPA established a standard review docket on January 31, 1980 (45 FR 6958). With this proposal, the docket already established for criteria document revision (Docket No. ECAO-CD-78-2) is being incorporated in this standard review docket (Docket No. OAQPS 78-9).

As discussed earlier in this notice, EPA has solicited public comments on succesive drafts of the revised Criteria Document and on successive drafts of the OAQPS Staff Paper. Comments on the three drafts of the revised Criteria Document have been considered in the final document, issued simultaneously with this proposal. A summry of EPA's responses to these comments has been placed in the public docket (Docket No. OAQPS 78-9).

The Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board has held four public meetings (January 30, 1979; November 12–14, 1980; February 6, 1981; and November 18, 1981) to review various drafts of the revised Criteria Document and OAQPS Staff Paper. Transcripts of all four meetings are available in docket number OAQPS 78-9. The CASAC's June 19, 1981, closure letter (*6*) to the Administrator stated that the Criteria Document was scientifically adequate for standard-setting purposes. The CASAC's July 6, 1982, closure letter (*8*) to the Administrator stated that the revised OAQPS Staff Paper (*7*) was a balanced and thorough interpretation of the scientific evidence pertaining to NO_2. During August 1982, EPA released the final OAQPS Staff Paper (*7*) which reflects the various suggestions and comments made by CASAC and members of the public.

During the CASAC meetings mentioned above and afterwards, comments were received on a variety of issues related to the review of the NO_2 standards. These comments are summarized below and have been considered in the development of this proposal.

During the public review process the areas of greatest controversy centered on various aspects of the primary standard. Many of the health studies of potential relevance to the primary standards were criticized by both the CASAC and members of the public. In particular, some commenters saw the epidemiology studies conducted in Japan by Kagawa and Toyama (1975) (*29*) and in Chattanooga, Tennessee by Shy et al. (1970) (*3,4*) and Pearlman et al. (1971) (*5*) as providing only limited qualitative support for the view that NO_2 may affect lung function and/or the onset of respiratory illness in children. Their criticism was based primarily on problems associated with the collection of air quality data.

Several epidemiology studies assessing NO_2 exposures to people living in homes with gas stoves were carefully reviewed by CASAC and generated considerable public comment. Comments submitted by industrial representatives and individual scientists indicated that various uncontrolled factors (e.g., humidity, carbon monoxide, formaldehyde) may confound the results. In addition, CASAC concluded (*8*) that the Melia et al. studies (*30–33*) do not provide quantitative dose-response data for NO_2 exposures due to the absence of short-term NO_2 measurements in the residences of the subjects evaluated. Similarly, the Speizer et al. study (*34*) was criticized for its scarcity of short-term NO_2 monitoring data.

In trying to identify the lowest convincingly demonstrated health effects level, the CASAC focused primarily on the human controlled exposure studies. With respect to short-term exposures, the Committee concluded (*8*) that "none of the controlled human exposure studies offer definitive evidence that adverse health effects occur at levels below one part per million (ppm)." Two studies in particular which generated much public controversy were conducted by Orehek et al. (1976) (*26*) and Von Nieding et al. (1977). (*27*) These studies reported effects after short-term exposure of human subjects to 0.1 ppm NO_2 or less, but CASAC recommended that the studies "not be considered in establishing a lowest observed effect level." However, CASAC did recommend that these studies be used in judging which standard provides an adequate margin of safety.

After considering these factors, the CASAC advised EPA that, while no single study provides a basis for retaining or revising the primary standards for NO_2, an accumulation of evidence from animal toxicology, human clinical, and epidemiological studies furnishes both qualitative and quantitative support for such action. CASAC also concluded that any revised primary NO_2 standard(s) needs to protect against both short- and long-term effects. However, after reviewing data on the short-term peaks observed in areas meeting alternative annual standards under consideration, CASAC concluded that an annual average standard could provide protection against both short- and long-term exposures of concern. Further, CASAC recommended that the Agency maintain a primary annual standard for NO_2 at the lower end of the 0.05 to 0.08 ppm range to ensure an adequate margin of safety against both long-term and short-term health effects.

Regarding the secondary standard review, CASAC agreed with EPA that acidic deposition was such a complex issue that it should be evaluated separately in a critical assessment document. CASAC concurred with the OAQPS Staff Paper conclusion that an annual secondary standard in the 0.05 to 0.08 ppm range would provide sufficient protection against other adverse effects on the environment and public welfare.

In developing this proposal, EPA has carefully reviewed CASAC's comments and recommendations on the NO_2 standards review, which are summarized in the two closure letters (*6*,)(*8*) to the Administrator. Based on this review, EPA believes that this proposal is consistent with CASAC's recommendations and comments.

List of Subjects in 40 CFR Part 50

Air pollution control, Carbon monoxide, Ozone, Sulfur Oxides, Particulate matter, Nitrogen dioxide, Lead.

Dated: February 17, 1984.

William D. Ruckelshaus,

Administrator.

References

(*1*) "Lead Industries Association, Inc. v. EPA," 647 F. 2d 1130 (D.C. Cir. 1980), *cert. den.* 101 S. Ct. 621 (1980).

(*2*) "American Petroleum Institute v. Costle," 665 F. 2d 1176 (D.C. Cir. 1981), *cert. den.* 102 S. Ct. 1737 (1982).

(*3*) Shy, C. M., J. P. Creason, M. E. Pearlman, K. E. McClain, F. B. Benson, and M. M. Young. "The Chattanooga school children study: effects of community exposure of nitrogen dioxide. I. Methods, description of pollutant exposure and results of ventilatory function testing." *J. Air Pollut. Control Assoc.* 20(8): 539–545, 1970.

(*4*) Shy, C. M., J. P. Creason, M. E. Pearlman, K. E. McClain, F. B. Benson, and M. M. Young. "The Chattanooga school study: effects of community exposure to nitrogen dioxide. II. Incidence of acute respiratory illness." *J. Air Pollut. Control Assoc.* 20(9): 582–583, 1970.

(5) Pearlman, M. E., J. F. Finklea, J. P. Creason, C. M. Shy, M. M. Young, and R. J. M. Horton. "Nitrogen dioxide and lower respiratory illness," *Pediatrics 47*(2): 391–398, 1971.

(6) Friedlander, Sheldon K., Chairman, Clean Air Scientific Advisory Committee (CASAC). "Memorandum to EPA Administrator. Subject: CASAC Review of the Air Quality Criteria Document for Nitrogen Oxides." June 19, 1981.

(7) U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. "Review of the national ambient air quality standards for nitrogen oxides: assessment of scientific and technical information (OAQPS Staff Paper)." EPA 450/5–82–002. Research Triangle Park, North Carolina, August 1982.

(8) Friedlander, Sheldon K., Chairman, Clean Air Scientific Advisory Committee (CASAC). "Memorandum to EPA Administrator. Subject: CASAC Review and Closure of the OAQPS Staff Paper for Nitrogen Oxides." July 6, 1982.

(9) Port, C. D., D. L. Coffin, and P. Kane. "A comparative study of experimental and spontaneous emphysema," *J. Toxicol. Environ. Health 2:* 589–604, 1977.

(10) Aranyi, C., J. Fenters, R. Ehrlich, and D. Gardner. "Scanning electron microscopy of alveolar macrophages after exposure to O_2, NO_2, and O_3," *Environ. Health Persp. 16:* 180, 1976.

(11) Ehrlich, R. and M. C. Henry. "Chronic toxicity of nitrogen dioxide. I. Effect on resistance to bacterial pneumonia," *Arch. Environ. Health 17:* 860–865, 1968.

(12) Ito, K. "Effect of nitrogen dioxide inhalation on influenza virus infection in mice," *Jap. J. Hygiene 26:* 304–314, 1971. (In Japanese).

(13) Menzel, D. B., M. D. Abou-donia, C. R. Roe, R. Ehrlich, D. E. Gardner, and D. L. Coffin. "Biochemical indices of nitrogen dioxide intoxication of guinea pigs following low-level long-term exposure." In: Proceedings International Conference on Photochemical Oxidant Pollution and Its Control. Vol. II, September, 1973, B. Dimitriades (ed.). EPA–600/3–77–001b. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 1977. pp. 577–587.

(14) Sherwin, R. P., J. B. Margolick, and E. A. Aguilar. "Acid phosphatase in density equilibrium fractions of the lungs of guinea pigs exposed intermittently to 0.4 ppm nitrogen dioxide," *Fed. Proc. 33:* 633, 1974. (Abstr.).

(15) Menzel, D. B. "Pharmacological mechanisms in the toxicity of nitrogen dioxide and its relation to obstructive respiratory disease," *In:* Nitrogen Oxides and Their Effect on Health. S. D. Lee, ed., Ann Arbor Science, Ann Arbor, 1980. pp. 199–216.

(16) Miller, F. J., J. A. Graham, J. W. Illing, and D. E. Gardner. "Extrapulmonary effects of NO_2 as reflected by pentobarbital-induced sleeping time in mice," *Tox. Lett.*, 1980. (Accepted for publication).

(17) Hattori, S., and K. Takemura. "Ultrastructural changes in the bronchiolar alveolar system caused by air pollution and smoking," *J. Clin. Electron Microsc. Soc. Japan 6:* 350, 1974. (In Japanese).

(18) Hattori, S. "Alterations of broncho-alveolar system by polluted air: Experimental consideration," *Clinician 219:* 4–8, 1973. (In Japanese).

(19) Nakajima, T., S. Kusumoto, C. Chen, and K. Okamoto. "Effects of prolonged continuous exposure to nitrogen dioxide on the quantity of reduced glutathione in lungs of mice and their histopathological changes. Appendix: Effects of nitrite and nitrate on the glutathione reductase." Osaka Prefectural Pub. Health Inst., *Res. Reports, Labor Sanitation Series. 7:* 35–41, 1969. (In Japanese).

(20) Hattori, S., R. Tateishi, T. Horai, and T. Nakajima. "Morphological changes in the bronchial alveolar system of mice following continuous exposure to NO_2 and CO," *J. Jap. Soc. Chest Disease 10:* 16–22, 1972. (In Japanese).

(21) Gardner, D. E., F. J. Miller, E. J. Blommer, and D. L. Coffin. "Relationship between nitrogen dioxide concentration, time, and level of effect using an animal infectivity model," In: Proceedings International Conference on Photochemical Oxidant Pollution and Its Controls. Vol. I, EPA–600/3–77–001a. U.S. Environmental Protection Agency, January 1977. pp. 513–525.

(22) Ehrlich, R., J. C. Findlay, J. D. Fenters, and D. E. Gardner. "Health effects of short-term exposures to inhalation of NO_2-O_3 mixtures," *Environ. Res. 14:* 223–231, 1977.

(23) Suzuki, T., and K. Ishikawa. "Research of effect of smog on human body," *Research and Report on Air Pollution Prevention 2:* 199–221, 1965. (In Japanese).

(24) Von Nieding, G., H. M. Wagner, H. Krekeler, U. Smidt, and K. Muysers. "Minimum concentrations of NO_2 causing acute effects on the respiratory gas exchange and airway resistance in patients with chronic bronchitis," *Int. Arch. Arbeitsmed. 27:* 338–348, 1971. Translated from German by Mundus Systems for Air Pollution Technical Information Center, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina.

(25) Kerr, H. D., T. J. Kulla, M. L. McIlhany, and P. Swidersky. "Effect of nitrogen dioxide on pulmonary function in human subjects: An environmental chamber study," *Environ. Res. 19:* 392–404, 1979.

(26) Orehek, J., J. P. Massari, P. Gayrard, C. Grimaud, and J. Charpin. "Effect of short-term, low-level nitrogen dioxide exposure on bronchial sensitivity of asthmatic patients," *J. Clin. Invst. 57:* 301–307, 1976.

(27) Von Neiding, G., H. M. Wagner, H. Lollgen, and K. Krekelar. "Acute effects of ozone on lung function of men," *VDI-Ber. 270:* 123–129, 1977.

(28) Love, G. J., S. Lan, C. M. Shy, and W. B. Riggan. "Acute respiratory illness in families exposed to nitrogen dioxide ambient air pollution in Chattanooga, Tennessee," *Arch. Env. Health 37*(2): 75–80, 1982.

(29) Kagawa, J., and T. Toyama. "Photochemical air pollution: Its effects on respiratory function of elementary school children," *Arch. Environ. Health 30:* 117–122, 1975.

(30) Melia, R. J. W., C. du V. Florey, D. S. Altman, and A. V. Swan. "Association between gas cooling and respiratory disease in children," *Brit. Med. J. 2:* 149–152, 1977.

(31) Melia, R. J. W., C. du V. Florey, and S. Chinn. "The relation between respiratory illness in primary schoolchildren and the use of gas for cooking. I—Results from a national survey," *Int. J. Epid. 8:* 333, 1979.

(32) Goldstein, B. D., R. J. W. Melia, S. Chinn, C. du V. Florey, D. Clark, and H. H. John. "The relation between respiratory illness in primary schoolchildren and the use of gas for cooking. II—Factors affecting nitrogen dioxide levels in the home," *Int. J. of Epid. 8:* 339, 1979.

(33) Florey, C. du V., R. J. W. Melia, S. Chinn, B. D. Goldstein, A. G. F. Brooks, H. H. John, I. B. Craighead, and X. Webster. "The relation between respiratory illness in primary schoolchildren and the use of gas for cooking. III—Nitrogen dioxide, respiratory illness and lung infection," *Int. J. Epid. 8:* 347, 1979.

(34) Speizer, F. E., B. G. Ferris, Jr., Y. M. M. Bishop, and J. Spengler. "Respiratory disease rates and pulmonary function in children associated with NO_2 exposure," *Am. Rev. Resp. Dis., 121:* 3–10, 1980.

(35) Spengler, J. D., B. G. Ferris, Jr., and D. W. Dockery. "Sulfur dioxide and nitrogen dioxide levels inside and outside homes and the implications on health effects research," *Environ. Sci. Techn. 13:* 1271–1276, 1979.

(36) Mitchell, R. I., R. Williams, R. W. Cote, R. R. Lanese, and M. D. Keller. "Household survey of the incidence of respiratory disease in relation to environmental pollutants," In: WHO International Proceedings: Recent Advances in the Assessment of the Health Effects of Environmental Pollutants. Paris, June 24–28, 1974.

(37) Keller, M. D., R. D. Lanese, R. I. Mitchell, and R. W. Cote. "Respiratory illness in households using gas and electric cooking," *Environ. Res. 19:* 495–515, 1979.

(38) U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. "OAQPS Staff Paper," pp. 32–38.

(39) U.S. Bureau of the Census. 1970 Census of Population, Vol. 1, Part 1. U.S. Dept. of Commerce, Washington, D.C., 1973.

(40) U.S. Dept. of Health, Education, and Welfare (DHEW). Prevalence of Selected Chronic Respiratory Conditions, United States, 1970. DHEW Publication No. (HRA) 74–1511. Series 10, Number 84, Rockville, MD. September 1973.

(41) Heck, W. W., North Carolina State University, Raleigh, N.C. Personal Communication with P. M. Johnson, U.S. EPA, February 1980.

(42) Tingey, D. T., U.S. EPA, Corvallis, OR. Personal Communication with P. M. Johnson, U.S. EPA, February 1980.

(43) *Ibid.* Written correspondence to P. M. Johnson, U.S. EPA, May 23, 1980.

(44) Korth, M. W., A. H. Rose, and R. C. Stahman. "Effects of hydrocarbon to oxides of nitrogen ratios on irradiated auto exhaust. Part 1," *J. Air Pollut. Control Assoc. 14:* 168–175. 1964.

(45) Haagen-Smit, A. J., E. F. Darley, M. Zaithlin, H. Hull, and W. Noble. "Investigation of injury to plants from air pollution in the Los Angeles Area," *Plant Physiol. 27:* 18–34. 1952.

(46) Heck, W. W. "Plant injury induced by photochemical reaction products of propylene-nitrogen dioxide mixtures," *J. Air Pollut. Control Assoc. 14:* 255–261. 1964.

(47) Taylor, O. C., C. R. Thompson, D. T. Tingey, and R. A. Reinert. "Oxides of nitrogen," In: Responses of Plants to Air Pollution, J. B. Mudd and T. T. Kozlowski, eds. Academic Press, Inc., New York, N.Y. 1975, pp. 121–139.

(48) Thompson, C. R., E. G. Hensel, G. Kats, and O. C. Taylor, "Effects of continuous exposure of navel oranges to NO_2" *Atmos. Environ. 4:* 349–355, 1970.

(49) MacDowall, F. D. N., and A. F. W. Cole. "Threshold and synergistic damage to tobacco by ozone and sulfur dioxide," *Atmos. Envir. 5:* 553–559, 1971.

(50) Tingey, et al. "Foliar injury responses of 11 plant species to ozone/sulfur dioxide mixtures," *Atmos. Envir. 2:* 201–208, 1973.

(51) Biller, W. F. et al. "A general model for estimating exposure associated with alternative NAAQS," presented at 74th Annual Meeting of the Air Pollution Control Association, Philadelphia, PA, June 21–26, 1981.

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

For the reasons set forth in the preamble, EPA proposes to amend Title 40, Chapter I, Part 50 of the Code of Federal Regulations as follows:

1. 40 CFR Part 50 is amended by revising § 50.11 to read as follows:

§ 50.11 National primary and secondary ambient air quality standards for nitrogen dioxide.

(a) The level of the national primary ambient air quality standard for nitrogen dioxide is 0.053 parts per million (100 micrograms per cubic meter) for an annual arithmetic mean concentration.

(b) The level of the national secondary ambient air quality standard for nitrogen dioxide is 0.053 parts per million (100 micrograms per cubic meter) for an annual arithmetic mean concentration.

(c) The levels of the standards shall be measured by:

(1) A reference method based on Appendix F and designated in accordance with part 53 of this Chapter, or

(2) An equivalent method designated in accordance with part 53 of this Chapter.

(d) The standards are attained when the annual arithmetic mean concentration is less than or equal to 0.053 ppm, rounded to three decimal places (fractional parts equal to or greater than 0.0005 ppm should be rounded up).

(42 U.S.C. 7403)

[FR Doc. 84-4313 Filed 2-22-84; 8:45 am]
BILLING CODE 6560-50-M