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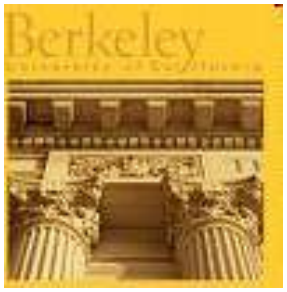

Science and the Protection of Public Health: The Work of EPA's Clean Air Scientific Advisory Committee

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AIR RESOURCES BOARD

Outline

- Clean Air Act
- National Ambient Air Quality Standards
- Clean Air Science Advisory Committee
  - PM
  - Ozone
  - NOx
  - SOx
- Conclusions

Clean Air Act of 1970

- Required that National Ambient Ambient Air Quality Standards (NAAQS) be set to protect public health and welfare

- Established U.S. Environmental Protection Agency

Clean Air Act Requirements for NAAQS

- Reflect latest scientific knowledge
- Margin of safety to address uncertainties associated with inconclusive scientific and technical information, to protect against hazards not yet identified, and to protect sensitive subpopulations
- Cost of implementing the standards not considered

Regulation of Criteria Air Pollutants

- The EPA's Office of Air Quality Planning and Standards is responsible for setting NAAQS
- The EPA carefully reviews the scientific evidence regarding important air pollutants
  - Formerly published in Criteria Documents before issuing or revising NAAQS for the six so-called "criteria pollutants."

Criteria Pollutants

- *Particulate matter*
- *Ozone*
- *Nitrogen dioxide*
- *Sulfur dioxide*
- Carbon monoxide
- Lead

Regulation of Criteria Air Pollutants

- Two types of NAAQS:
  - Primary standards protect against adverse health effects, with an adequate margin of safety, including the health of "sensitive" populations such as asthmatics, children, and the elderly.
  - Secondary standards protect against welfare effects, such as damage to farm crops and vegetation and damage to buildings.
- EPA requires air monitoring for criteria pollutants.
- Regions that have concentrations of the pollutant that are higher than the NAAQS are designated non-attainment areas.

Regulation of Criteria Air Pollutants

- State Implementation Plans (SIPS) are designed to bring air quality into attainment with the NAAQS.
- States may designate to regional agencies authority to develop and enforce air pollution control plans.
- When states or regions are in persistent non-attainment or SIPS are deemed inadequate, the EPA can cause federal funds to be withheld (e.g., funds for highway construction).

Review of NAAQS

- The EPA Criteria Documents (now shorter Integrative Scientific Assessments) have traditionally reviewed three types of health effects research:
  - Toxicological studies
  - Controlled human studies
  - Epidemiological studies

Clean Air Act

- The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies ("Clean Air Science Advisory Committee")
- At 5-year intervals, the committee shall complete a review of the criteria for NAAQS and shall recommend to the Administrator any new NAAQS and revisions of existing criteria and standards as may be appropriate.

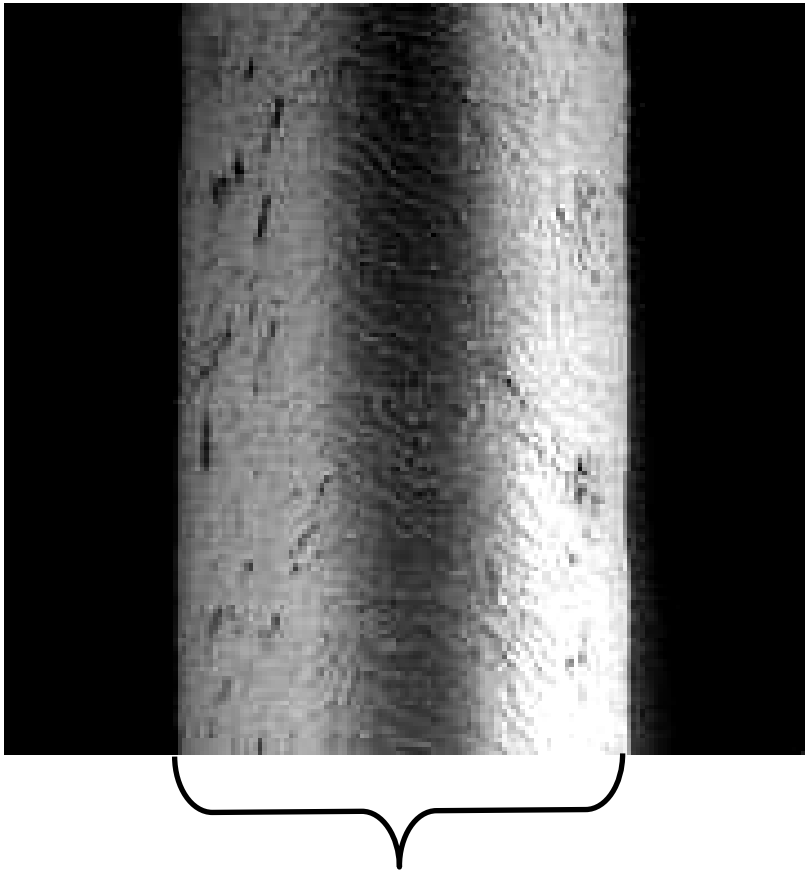
Clean Air Scientific Advisory Committee

- In addition to the seven standing members, about a dozen additional consultants are added for review of each standard.
- The members of CASAC are typically drawn from academia and from industry research organizations.
- The expertise of the panel members ranges from toxicology to agricultural effects to air quality monitoring.
- The committee has enormous influence on EPA's standard-setting process.

CASAC

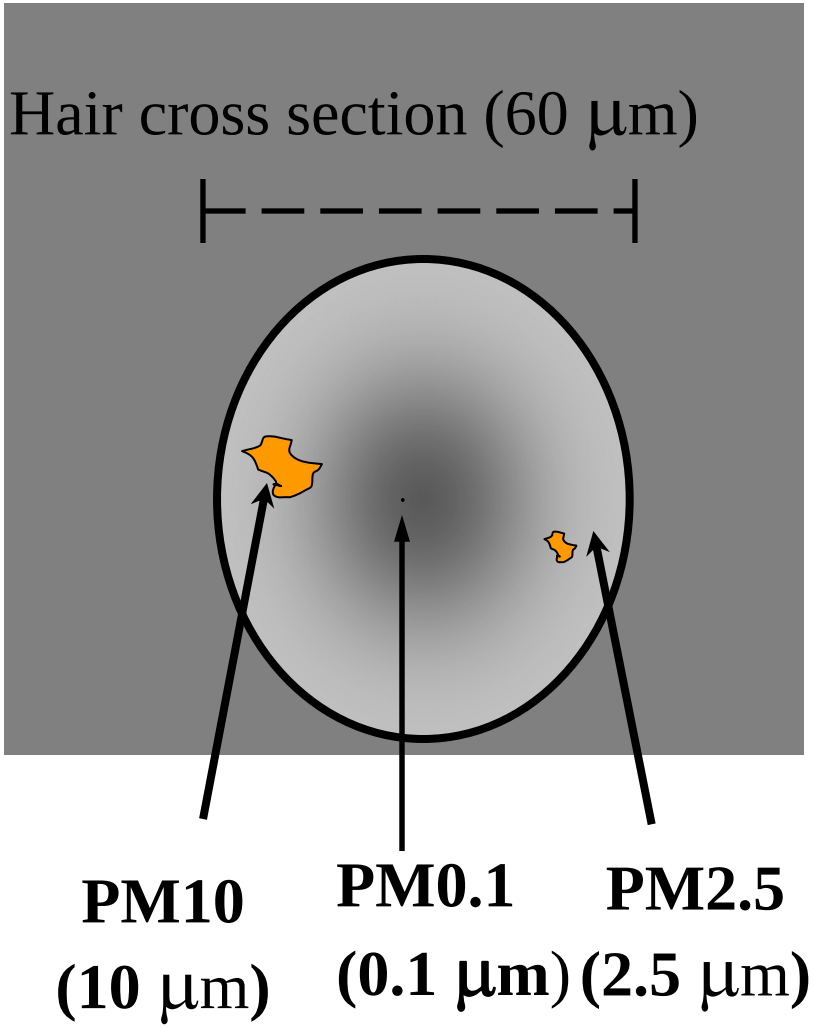
- CASAC convenes public meetings to review drafts of the supporting scientific review, risk assessment, and the proposed standards.
- The panel typically must "reach closure" before EPA moves to the next step of the process.
- EPA staff make changes in the draft documents to satisfy the concerns raised by CASAC.

Particle Size



Human Hair

(60 μm diameter)



PM10

(10 μm)

PM0.1

(0.1 μm)

PM2.5

(2.5 μm)

The PM Standard-2006

What CASAC recommended:

- Primary Standard
  - Annual $PM_{2.5}$ standard=13-14 $\mu g/m^3$
  - 24-hr $PM_{2.5}$ standard=30-35 $\mu g/m^3$
  - Coarse particles: change indicator to $PM_{10-2.5}$
- Secondary Standard
  - Affirmed staff recommendation of separate sub-daily (4-8 hr) secondary standard to protect urban visibility

The PM Standard

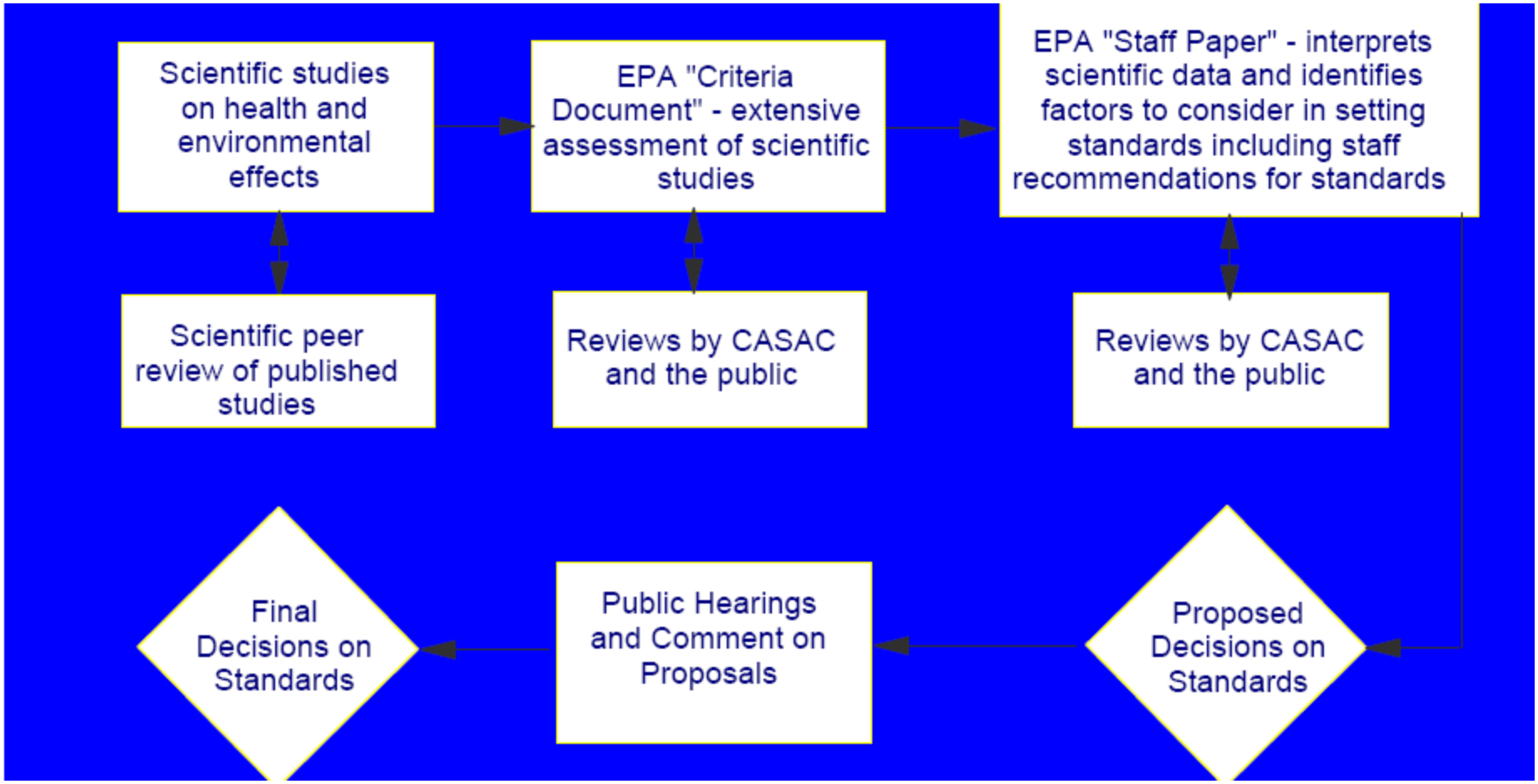
What the Administrator promulgated:

- Primary Standard
  - Annual $PM_{2.5}$ standard=15 $\mu g/m^3$
  - 24-hr $PM_{2.5}$ standard=35 $\mu g/m^3$
  - Coarse particles: continue to use PM_{10} as the indicator; level=150 $\mu g/m^3$
- Secondary Standard
  - Set secondary standard equal in all respects to the primary standard

PM Standard-2006

- EPA administrator Johnson announced proposed new NAAQS for PM citing “uncertainties in the science.”
- CASAC takes the unusual step of publicly disagreeing with this position.
- In the three public meetings, the EPA got a lot of negative publicity about the failure to accept CASAC’s scientific judgment.
- In response, the EPA announced that a thorough review of the NAAQS review process would be conducted.
- The EPA announced that the Staff paper would be eliminated in order to “streamline” the process.

Old Review of NAAQS



I testified before the Senate Environment and Public Works Committee in 2007 Against the elimination of the Staff Paper.

Uncertainty

Viewpoint of the Scientist:

On the one hand

On the other hand

Viewpoint of the Policy Maker:

I need a one-handed scientist. Give me your bottom line!

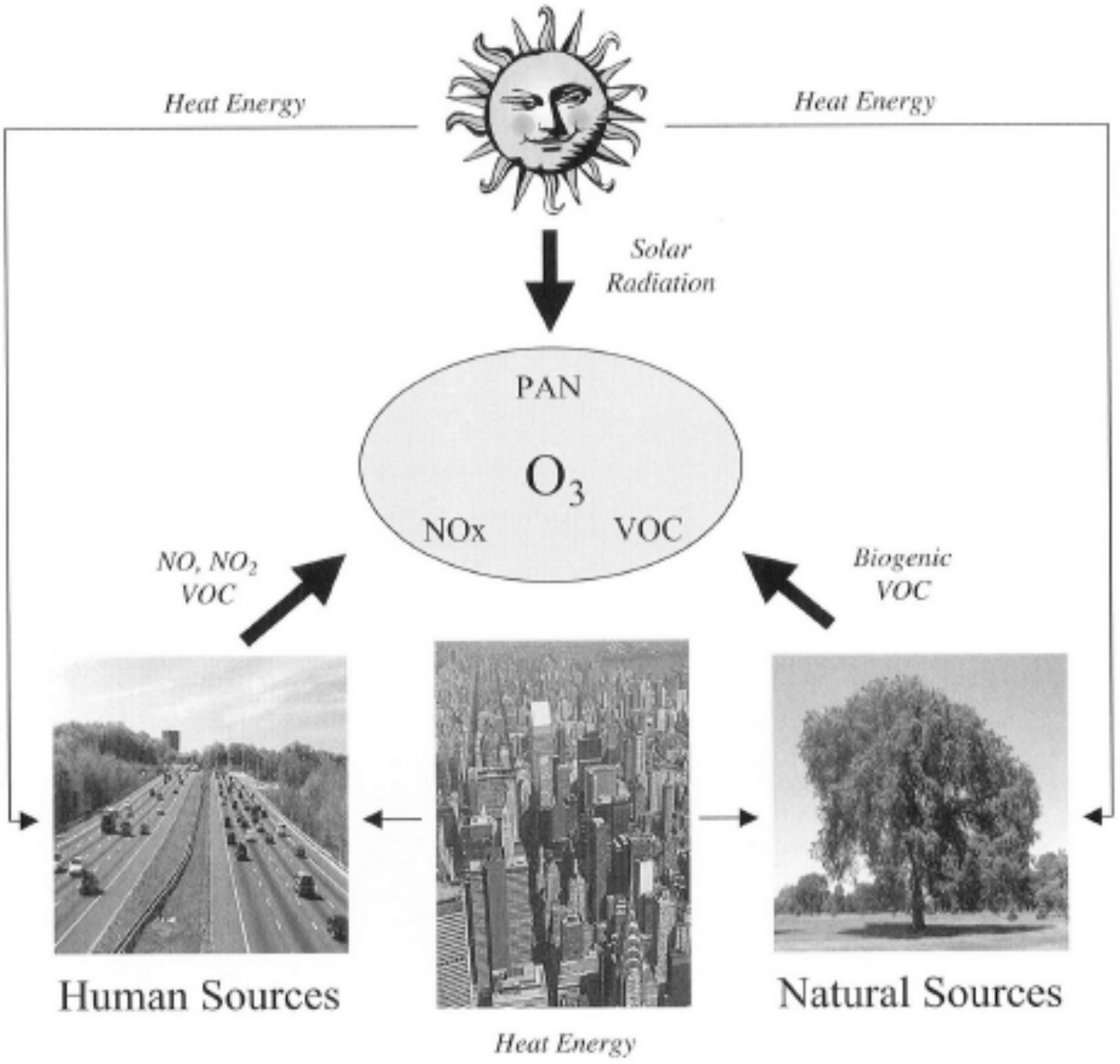
Uncertainty can be addressed by:

deferring action until you have more information

or

acting conservatively to assure a margin of safety

Ozone Formation in the Atmosphere



The Ozone Standard-2008

What CASAC recommended:

- Primary standard
  - Reduction of 8-hr standard to between 0.060 ppm-0.070 ppm
  - Specify level to the nearest thousandth of a ppm
- Secondary standard
  - Change form of secondary standards to a cumulative, seasonal standard between 7 ppm-15 ppm·hr

Ozone Standard-2008

What EPA staff proposed:

- Set 8-hr primary standard within range of 0.070 to 0.075 ppm
- Specify level to the nearest thousandth of a ppm
- Replace current secondary standard with a cumulative, seasonal standard of 7-21 ppm·hr

The Ozone Standard-2008

What the Administrator promulgated:

- Reduced 8-hr primary standard to 0.075 ppm
- Set secondary standard equal to the primary standard

If the Administrator did not accept the scientific advice of EPA's own advisory committee, whose advice did he take?

This became evident in the setting of the secondary ozone standard.

Example of a Poor Interaction Between Scientists and Policy Makers

Interagency Review of the Ozone Secondary Standard

July, 2007

- Cumulative, seasonal form recommended for consideration as an option by the Administration in proposed rule

March 6, 2008

- Memo to Administrator Johnson from Ms. Dudley of OMB saying the secondary standard cannot have different form from the primary standard

March 7, 2008

- Memo from Peacock to Dudley carefully refuting Dudley's memo

March 13, 2008

- Memo from Dudley saying President Bush did not want a different form for the secondary standard

March 13, 2008

- Press conference postponed from 1PM to 6PM to allow EPA staff to rewrite the new rule to conform with OMB/White House wishes

Ozone Standard-2008

- The then Chair of CASAC, Dr. Rogene Henderson, was asked to testify before the House Committee on Ethics and Government Reform on the setting of the ozone standards.

- Statements in regard to setting of the secondary standard:

  – “Willful ignorance triumphed over sound science.”
  – “Setting standards by fiat behind closed doors is not to our benefit”

Assumptions

Scientific evidence should inform policy decisions to protect public health and the environment.

Scientists and policy makers should be capable of communicating in a meaningful fashion.

New NAAQS Review Process

(from Peacock memo of December 7, 2006)

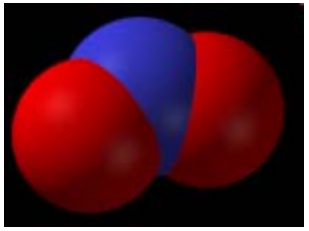
- Planning: Early workshop and Integrated Plan (IP) (CASAC reviews draft IP)
- Integrated Science Assessment (ISA) (CASAC reviews up to two drafts)
- Risk/Exposure Assessment (REA): Developed at the same time as the ISA. (CASAC reviews up to two drafts)
- Policy Assessment/Rule Making (PA) : Replaces Staff Paper. Contains scientific justification for various policy options. (CASAC reviews the PA at the same time as the public in the form of an ANPR published in the Federal Register)

CASAC's Response to New NAAQS Review

- The first Policy Assessment/ANPR of the new review process was for the lead standard.
  - Different from what was described in the Peacock memo of December 2007.
  - The lead ANPR was in the standard format used in other parts of the Agency to announce the start of a rule-making process.
  - The scientific justifications had been removed from the review process.
- A strong letter of protest was sent to the Administrator in January 2008.
- In September 2008, the EPA replied that it would stick to the original plan and keep science in the ANPR.

Nitrogen Dioxide (NO_2)

- NO_2 is an oxidant gas like ozone, but not as potent.
- NO_2 reacts with H_2O to form HNO_3 (nitric acid).
- NO_2 is an important precursor of ozone.



Public Health Policy Implications: NO_2

- The primary NAAQS for NO_2 was an annual arithmetic mean value not to exceed 0.053 ppm.
  - This NAAQS had not been changed since it was promulgated in 1971.
- Based on the data re: NO_2 exposure and both lower respiratory infection in children and asthma exacerbations, is an annual average the best way to protect public health?

NO_2 ISA

- "The strongest evidence for an association between NO_2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms and ED visits and hospital admissions."
- This conclusion is "based on numerous studies, including panel and field studies, multi-pollutant studies that control for the effects of other pollutants, and studies conducted in areas where the whole distribution of ambient 24-hr avg NO_2 concentrations was below the current NAAQS level of 0.053 ppm (53 ppb) (annual average)."

NO_2 ISA

- “Evidence from human clinical studies, especially for airway hyperresponsiveness in asthmatic individuals, was generally supportive of the epidemiologic evidence.”
- “The epidemiologic and experimental evidence together show coherence for effects of NO_2 exposure on host defense or immune system effects providing plausibility and mechanistic support for respiratory symptoms and ED visits for respiratory disease.”

NO_2 Risk Exposure Assessment

- Exposure Assessment
  - NO_2 air quality in 18 locations around the country was used as a surrogate for exposure.
  - Exposures were estimated for persons with asthma based on time spent in microenvironments in Atlanta, GA.
- Risk Assessment
  - Occurrences of NO_2-related respiratory ED visits in Atlanta were estimated.

NO_2 REA

- "Given current air quality, virtually all asthmatics in Atlanta could experience 6 or more exposures to NO_2 concentrations greater than or equal to 0.1 ppm; ~ 60% of Atlanta asthmatics could experience at least one exposure to NO_2 concentrations ≥ to 0.3 ppm."
- "The experimental evidence provides support for an averaging time of shorter duration than 24 hours (e.g., 1-hr) while the epidemiologic evidence provides support for both 1-hr and 24-hr averaging times."
- "The scientific evidence reasonably supports a range of standard levels from 50 ppb to 200 ppb, with strong support for a level ≤ 100 ppb."
- Final rule: 1-hr 100 ppb

Sulfur Dioxide (SO_2)

- Generated primarily from combustion of sulfur-containing coal and oil
- Also a constituent of diesel exhaust

Public Health Policy Implications: SO_2

- The primary NAAQS for SO_2 was an annual average of 0.030 ppm and a 24-hr average of 0.14 ppm.
- Based on the data re: short-term peak exposures to SO_2 and acute airway narrowing in individuals with asthma, is a multi-hour average the best way to protect public health?

SO_2 ISA

- The ISA concludes that there is sufficient evidence to infer “a causal relationship between respiratory morbidity and short-term exposure to SO_2.”
- The strongest evidence is from human exposure studies demonstrating increased respiratory symptoms and decreased lung function in exercising asthmatics exposed for 5-10 minutes to ≥ 200 ppb SO_2.
- Supporting this conclusion is a larger body of epidemiological studies published since the last review observing associations between ≥1-hour SO_2 concentrations and respiratory symptoms, ED visits, and hospital admissions.

SO_2 Risk Exposure Assessment

- Exposure assessment
  - SO_2 air quality levels were used as a surrogate for exposure.
  - Exposures were estimated for persons with asthma living in Greene County and St. Louis, MO based on time spent in various microenvironments, as well as time spent at elevated ventilation rates (i.e., exercising).
- Risk assessment
  - A quantitative risk assessment for lung function responses associated with 5-min exposures was conducted.

SO_2 REA

- 5-30% of exercising asthmatics will experience moderate or greater lung function decrements following exposure to 200-300 ppb SO_2 for 5-10 minutes.
- In St. Louis, ~ 46% (48,000) of asthmatics would be expected to experience at least one SO_2 exposure concentration ≥ 200 ppb while at elevated ventilation rates.

SO_2 REA

- “Taken together, the scientific evidence and the risk and exposure information suggest that the current annual SO_2 standard does not provide adequate protection from the health effects associated with shorter-term exposures to SO_2.”
- “The evidence and exposure and risk information reasonably support a 1-hour daily maximum standard within a range of 50-150 ppb.”
- Final rule: 1-hr 75 ppb

Conclusions

- The Clean Air Act (CAA) requires that air quality standards be established to protect the public health with a reasonable margin of safety.
- CASAC is mandated by the CAA to review the scientific evidence on which each standard is based.
- EPA policy makers should accept CASAC's judgment on what the scientific evidence shows.
- Individuals with asthma represent a sensitive group who can develop exacerbations when exposed to ozone, NO_2, and SO_2.