The 2015 National Ambient Air Quality Standards for Ozone

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Primary Ozone Standard

- The Clean Air Act requires a primary standard that is “requisite“ to protect public health with an adequate margin of safety.
- This means that the Administrator must set a standard that, in her judgement, is no more or less stringent that necessary to protect at-risk groups. The Clean Air Act does not require that a primary standard eliminate all risk
- In making a decision about an adequate margin of safety, the Administrator considered the types and severity of health effects, the uncertainties in the science, and the need to protect at-risk groups.

How Does the 2015 Primary Ozone Standard Compare to the 2008 Standard?

- The level of the standard has been strengthened from 75 ppb to 70 ppb.
- The other elements of the standard, including the averaging time and form, were retained without change.
- The new standard is met when the 4^{th} highest daily maximum 8-hour average concentration, averaged over three years, is 70 ppb or lower.

Why Did EPA Revise the Ozone Standard?

- Extensive scientific evidence showed that revising the standard was necessary to protect public health with an adequate margin of safety, as the Clean Air Act requires.
- To determine what standard would provide that requisite degree of protection, EPA considered an expanded body of scientific evidence that includes thousands of studies on ozone's effects on health. EPA focused on new studies that have become available since the 2008 review of the standards.
- Those studies include new clinical studies, which provide the most certain evidence of health effects in adults. Those studies provide information clearly showing that ozone at 72 ppb is harmful to healthy exercising adults – a level which is below the 2008 standard.

What are the Health Effects of Breathing Ozone?

A large body of scientific evidence, spanning several decades, shows that ozone can cause harmful effects on the respiratory system, including:

- Coughing and sore throat or burning sensation in airways
- Reduction in lung function, making it harder to breathe deeply
- Inflammation and damage to the airways
- Aggravation of lung disease, including asthma, emphysema and bronchitis
- Increase in the frequency and severity of asthma attacks
- Repeated damage to developing lungs can affect children into adulthood, causing permanent reduction to the lungs' ability to function, and is likely to be one of the many causes of asthma development.

What are the Health Effects of Breathing Ozone?

These effects can lead to:

- More medication use for people with asthma
- More frequent visits to the doctor
- Missed school days
- Missed work days
- More emergency room visits and hospital admissions
- Increased risk of premature death from lung or heart disease

What Groups Are Most At-risk from Exposure to Ozone and Why?

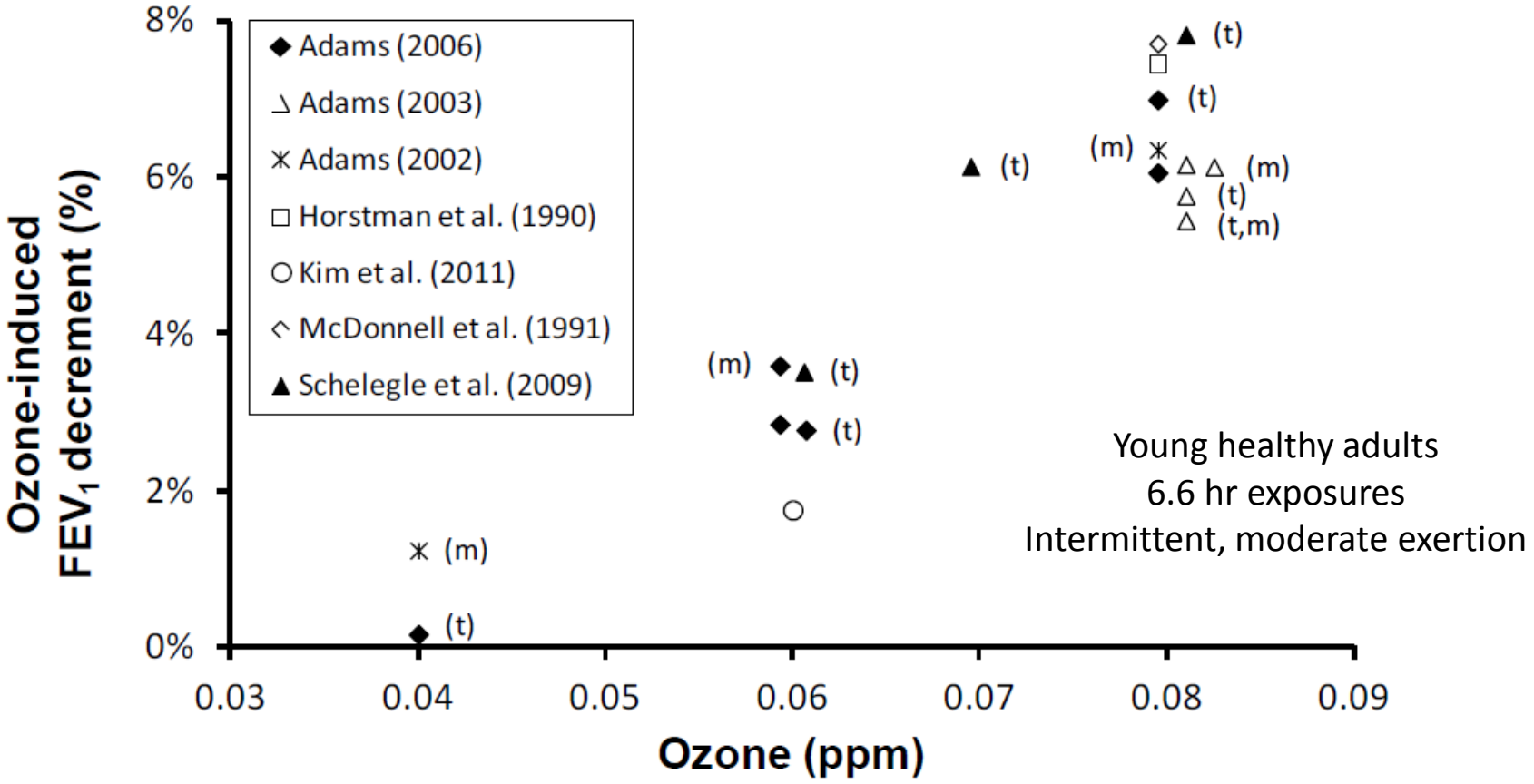
- People most at-risk from breathing air containing ozone include people with asthma, children, older adults, and people who are active outdoors, especially outdoor workers. In addition, people with certain genetic characteristics, and people with reduced intake of certain nutrients, such as vitamins C and E, are at greater risk from ozone exposure.
- Children, including teenagers, are among the most at-risk because their lungs are still developing, they breathe more air per pound of body weight than adults, and they spend more time outside than adults. They are also more likely than adults to have asthma.
- An estimated 6.1 million children in the U.S. have asthma, according to CDC estimates for 2013. That's equal to one in every 12 children in the country.

Respiratory Effects and Short-Term Exposures

Controlled human exposure studies

- **In the 2008 review**, the strongest evidence was for respiratory effects in healthy adults engaged in intermittent, moderate exertion following exposures at or above 80 ppb
  - Decreased lung function, increased respiratory symptoms, increased airway inflammation, increased airway responsiveness, decreased lung host defense
- More limited evidence at 60 ppb for decreased lung function and respiratory symptoms (Adams, 2002; 2006)
- **In the 2015 review**, recent studies by Schelegle et al. (2009) and Kim et al. (2011) have reported respiratory effects in healthy adults following exposures below 80 ppb

Human Clinical Studies: Lung Function



Data are group mean responses

t triangular (ramp up, ramp down) concentration profile

m exposure via facemask

ISA Figure 6-1B

Respiratory Effects and Short-Term Exposures
(Continued)

Epidemiologic studies

- **In the 2008 review**, population-based studies reported positive, and often statistically significant, associations with lung function decrements, respiratory symptoms, medication use, and respiratory emergency department visits and hospital admissions
  - Panel studies reported associations with lung function decrements in children and exercising adults
- **In the 2015 review**, recent multicity and single city population studies reinforce previous evidence for respiratory hospital admissions and emergency department visits
- Associations are consistently positive and often statistically significant, particularly for analyses focused on the warm season
  - Associations remain robust after adjustment for co-pollutants
  - No evidence for discernible threshold within range of daytime concentrations common in U.S. O_3 season, though less certainty regarding shape of concentration-response curve at lower concentrations (i.e., about 20 to 40 ppb)

Total Mortality and Short-Term Exposures

- Total Mortality: Recent multicity and single city studies considerably strengthen the evidence for mortality in the current review
- Associations with mortality consistently positive and statistically significant, particularly in analyses of the warm season (A-1)
  - As for respiratory effects, no evidence for discernible threshold within range of daytime concentrations common in U.S. O_3 season, though less certainty regarding shape of concentration-response curve at lower concentrations (i.e., about 20 to 40 ppb)

Respiratory Effects and Long-Term Exposures

- Long-term epidemiologic studies typically evaluate associations with seasonal averages of daytime peak O_3 concentrations (e.g., 8-hour, 1-hour max)
- Recent epidemiologic studies have greatly expanded the body of evidence for effects associated with long-term O_3 exposure
  - For example: new onset asthma; asthma severity and control; asthma hospital admissions and ED visits; respiratory mortality
  - Association with respiratory mortality is robust to adjustment for confounding by PM (other endpoints not evaluated in co-pollutant models)
- Collective evidence from the California Children's Health Study provides important information on genetic variability related to susceptibility and protective factors (anti-oxidant, anti-inflammatory)
- Experimental studies in nonhuman primates support the biological plausibility of repeated exposures contributing to development of asthma and irreversible, morphological changes in the lung

How Does the 2015 Ozone Standard Protect Public Health?

- In selecting the level of the standard, EPA focused on new studies that have become available since EPA last reviewed the standards in 2008.
  - New clinical studies, which provide the most certain evidence of health effects in adults, provide information clearly showing that ozone at 72 ppb is harmful to healthy exercising adults.
  - The revised 2015 ozone standard of 70 ppb is below the level shown to cause adverse health effects in the clinical studies.
- In addition, EPA focused on children's exposure. Combined, the results of the clinical studies and risk and exposure analyses show that a standard of 70 ppb essentially eliminates exposures that have been shown to cause adverse health effects, protecting 99.5 percent of children from even single exposures to ozone at or above 70 ppb.

What Are the Benefits of the 2015 Primary Ozone Standard?

- EPA estimated the benefits of meeting the new standard of 70 ppb, and they are significant.
- Reducing ozone and particle pollution nationwide (excluding California) in 2025 will avoid:
  - 320 to 660 premature deaths
  - 230,000 asthma attacks among children
  - 160,000 days when kids miss school
  - 28,000 missed work days
  - 630 asthma-related emergency room visits
  - 340 cases of acute bronchitis among children

What is the Air Quality Index?

- The Air Quality Index (AQI) is EPA's color-coded tool for telling the public how clean or polluted the air is, and recommending steps people can take, if necessary, to reduce their daily exposure to pollution.
    - The AQI converts ozone concentrations to a number on a scale from 0 to 500. This scale is used by cities and states across the country to report current and daily ozone concentrations and for daily ozone air quality forecasting.

What are the revised AQI breakpoints?

- EPA updated the breakpoints for each AQI category for ozone, based on the strengthened primary (health) 8-hour ozone standard and on information from the health studies that were examined as part of the review of the standard.
- The agency set the 100 value of the index the level of the ozone health standard. That's 70 parts per billion, or ppb.
- An AQI of 100 is the upper end of the "Moderate" or "Code Yellow" range. Above this level EPA begins cautioning at-risk groups.
- The "Unhealthy for Sensitive Groups" or "Code Orange" range (AQI of 101-150) now begins at 71 ppb and extends to 85 ppb.
- EPA did not change the level at the top of the index (an AQI value of 500). This level is typically set equal to the Significant Harm Level, a level that represents imminent danger.

AQI for Ozone

AQI Category	Index Values	Breakpoints (ppb, 8-hour average)
Good	0 - 50	0-54
Moderate	51 - 100	55-70
Unhealthy for Sensitive Groups	101 – 150	71-85
Unhealthy	151 – 200	86-105
Very Unhealthy	201 – 300	106-200
Hazardous	301 –500	201 to the Significant Harm Level*

**The Significant Harm Level for ozone is 600 ppb, two-hour average*

How Did EPA Set the Breakpoints?

- Revisions to the breakpoints are based on estimated health outcomes at relevant ambient concentrations.
- Revisions also allow for each category to span at least a 15–20 ppb category range for more accurate air quality forecasting.
- The breakpoint at the lower end of the moderate category is set at 55 ppb.
  - Consistent with past practice of making a proportional adjustment to this AQI breakpoint, relative to an AQI value of 100 (*i.e.,* 70 ppb).
  - Below the lowest concentration (*i.e.,* 60 ppb) that has been shown in controlled human exposure studies of exercising, healthy adults to cause moderate lung function decrements and airway inflammation in a small proportion of people.

How Did EPA Set the Higher Breakpoints?

For the higher breakpoints, we used information from clinical studies of young, healthy, exercising adults to estimate lung function decrements.

- **Lung function decrements** are often measured in terms of decreases in forced expiratory volume in one second (FEV_1).
    - If your large airways are open, you can exhale most of the air in your lungs in one second. If your airways constrict (close up), you will be able to exhale a smaller proportion of the air in your lungs in one second – the FEV_1 decrement.
- **Moderate lung function decrements** are FEV_1 decrements ≥ 10% and < 20%. The Clean Air Scientific Advisory Committee advised that an FEV_1 decrement of ≥ 10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease, and an FEV_1 decrement ≥ 15% is a scientifically relevant surrogate for adverse health outcomes for healthy people.
- **Large lung function decrements**, or FEV_1 decrements ≥ 20%, would likely interfere with normal activity for many healthy people. For most people with lung disease, large lung function decrements would not only interfere with normal activity but would increase the likelihood that they would seek medical treatment.

Lung Function Decrements

AQI Value	Concentration (ppb, 8-hour avg)	Health Benchmark
150-151	85	Up to 25% of exposed people are likely to have **moderate** lung function decrements (*i.e.,* 25% have FEV_1 decrements ≥ 10%; 12% have FEV_1 decrements ≥ 15%), and up to 7% are likely to have **large** lung function decrements
200-201	105	Up to 38% of exposed people are likely to have **moderate** lung function decrements (*i.e.,* 38% have FEV_1 decrements ≥ 10%; 22% have FEV_1 decrements ≥ 15%), and up to 13% are likely to have **large** lung function decrements.
300-301	200	Up to 25% of exposed individuals are likely to have **large** lung function decrements which would interfere with daily activities for many of them and likely cause people with lung disease to seek medical attention.

What Are the Immediate Health Effects of Ozone Exposure?

- Scientific evidence shows that ozone can cause a number of harmful effects on the respiratory system, including difficulty breathing and inflammation of the airways.
- For people with lung diseases such as asthma and COPD (chronic obstructive pulmonary disease), ozone can aggravate their diseases, leading to increases in medication use, doctor and emergency room visits, and hospital admissions.

At What Levels Might We Experience These Effects?

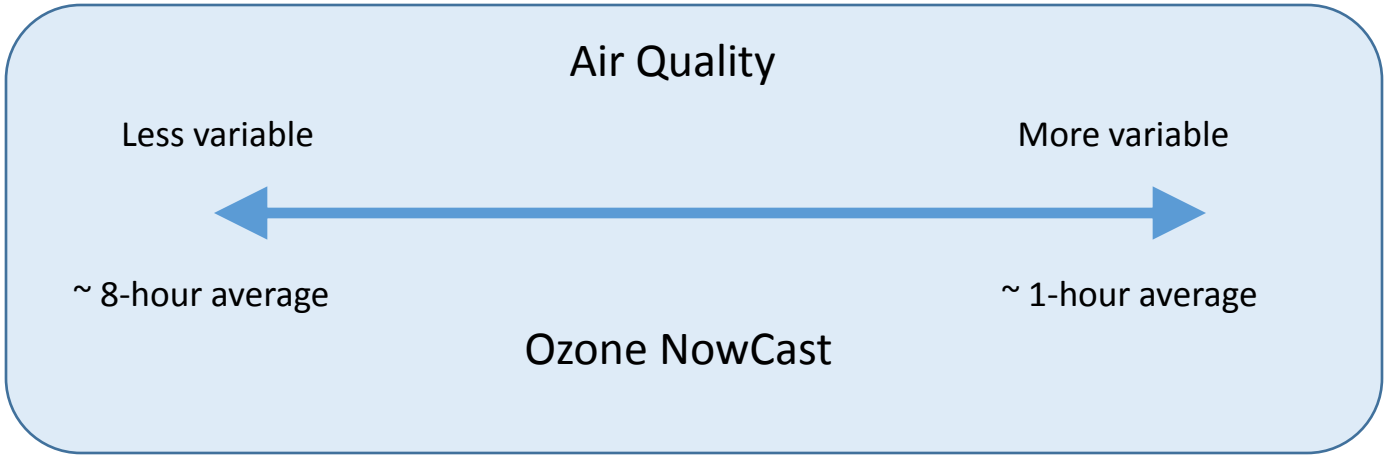
- There is no way to know how any particular person is likely to respond, but we do know that as ozone levels increase, the number people affected and the seriousness of the effects increase.
- At-risk populations include people with asthma, children, older adults, and people who are active outdoors, especially outdoor workers. In addition, people with certain genetic characteristics, and people with reduced intake of certain nutrients, such as vitamins C and E, are at greater risk from ozone exposure.
    - These people are cautioned in the Unhealthy for Sensitive Groups category, the general public in the Unhealthy category.

Will the EPA Provide a 1-hour Equivalency To the 8-hour Standard in Order to Better Communicate in Real-Time What the Risks of Exposure at Certain Levels Are?

- EPA will be using the NowCast to provide hourly estimates of 8-hour exposures.
- The NowCast is simply a way to express real-time air quality in the context of the AQI. For ozone, it is an average of the previous 8 hours. If air quality is more variable, then recent hours are weighted more heavily.
- The NowCast is useful for communicating a health-protective AQI value in real-time.
- Already in use for PM, the NowCast will be adopted for ozone reporting on AirNow.gov before May 2016.
- While the PM NowCast focused on an averaging period between three and 12 hours, the ozone NowCast will use between one and eight hours.

The Ozone NowCast Method

- An average of the previous 8 hours
- If air quality is less variable, the hours are weighted more evenly (approaching an 8-hour average)
- If air quality is more variable, recent hours are weighted more heavily (approaching the most recent hourly average)



With the Updated AQI Will We See More Unhealthy Days?

- Generally, yes. Because the AQI breakpoints reflect the strengthened ozone air quality standard, ozone will trigger unhealthy days at lower concentrations than in the past.
- Of course, if the daily maximum 8-hour ozone value doesn't reach 71 ppb, then you won't see an unhealthy day.
- If you look at data over the last 5 years, the new breakpoints would have resulted in an average increase of 10 unhealthy days per year among major U.S. cities.

Won’t the Updated AQI Make It Appear That Air Quality is Getting Worse?

- While there may be more unhealthy days, the trend over time will look the same – which for most areas shows that air quality is improving.
- Additionally, when the EPA’s air quality database is updated to reflect the new breakpoints, all historical data will be updated. So you’ll be able to see how Code Orange or Code Red days for your area changed over time based on the new breakpoints.

The Ozone Daily Max Value is Computed a Little Differently. Does That Change How the AQI Value is Computed?

- When EPA revised the ozone standard in 2015, the agency determined that the daily maximum 8-hour ozone concentration would be based on 17 consecutive moving 8-hour periods in each day, beginning with the 8-hour period from 7:00 a.m. to 3:00 p.m., and ending with the 8-hour period from 11:00 p.m. to 7:00 a.m.
- This procedure is designed to eliminate ‘‘double counting’’ exceedances of the standard based on overlapping 8-hour periods from two consecutive days with up to 7 hours in common, which was allowed under previous 8-hour ozone standards.
- For the purposes of computing the daily AQI value for ozone, we will use the daily max that is based on the 17 8-hour periods, consistent with the new standard. Real-time reporting will not be affected.
- Since ozone concentrations typically peak during the afternoon hours, EPA expects that the new calculation procedure will have little, if any impact upon the daily AQI values in most locations.

Previous 8-hour ozone standards

Day 1	12 am	1	2	3	4	5	6	7	8	9	10	11	12 pm	1	2	3	4	5	6	7	8	9	10	11	12 am	1	2	3	4	5	6				
Day 2																									12 am	1	2	3	4	5	6	7	8	9	10

- Previous ozone standards considered 24 overlapping 8-hour averages
- The first 8-hour average began at 12am and ended at 7:59 am and the last began at 11pm and ended at 6:59 am of the next day.
- Because the 8-hour averages for each day started at 12am, the hours from 12am to 6:59am were “double counted.”
- This double-counting could result in daily exceedances on different days influenced by the same hours.

New (2015) 8-hour ozone standards

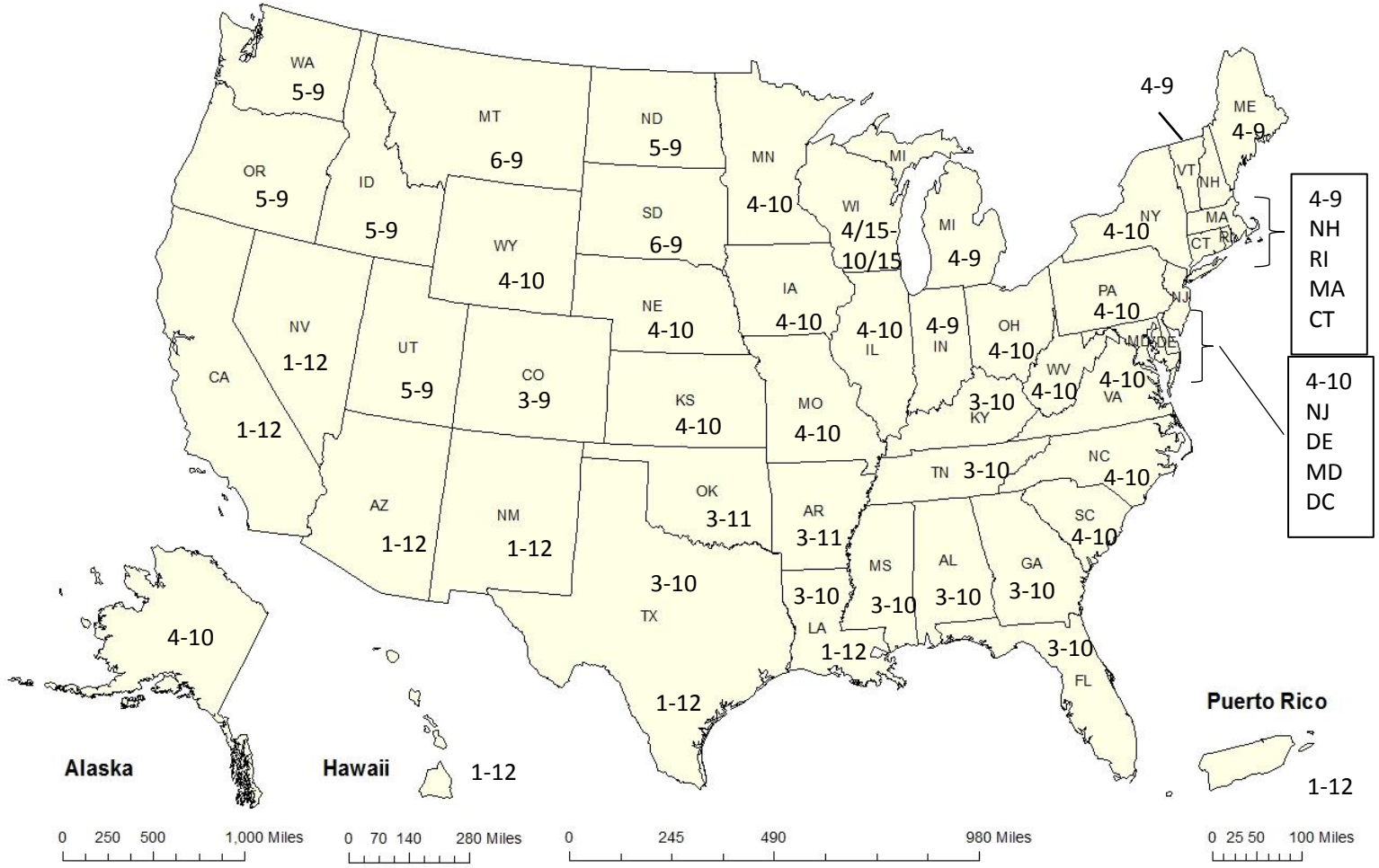
Day 0	12 am	1	2	3	4	5	6																										
Day 1								7	8	9	10	11	12 pm	1	2	3	4	5	6	7	8	9	10	11	12 am	1	2	3	4	5	6			
Day 2																																7	8	9	10

- The new ozone standards eliminate double counting by starting the daily averages at 7am every day.
- The first 8-hour average begins at 7am and ends at 2:59 pm and the last begins at 11pm and ends at 6:59 am of the next day.

Ozone Monitoring Season

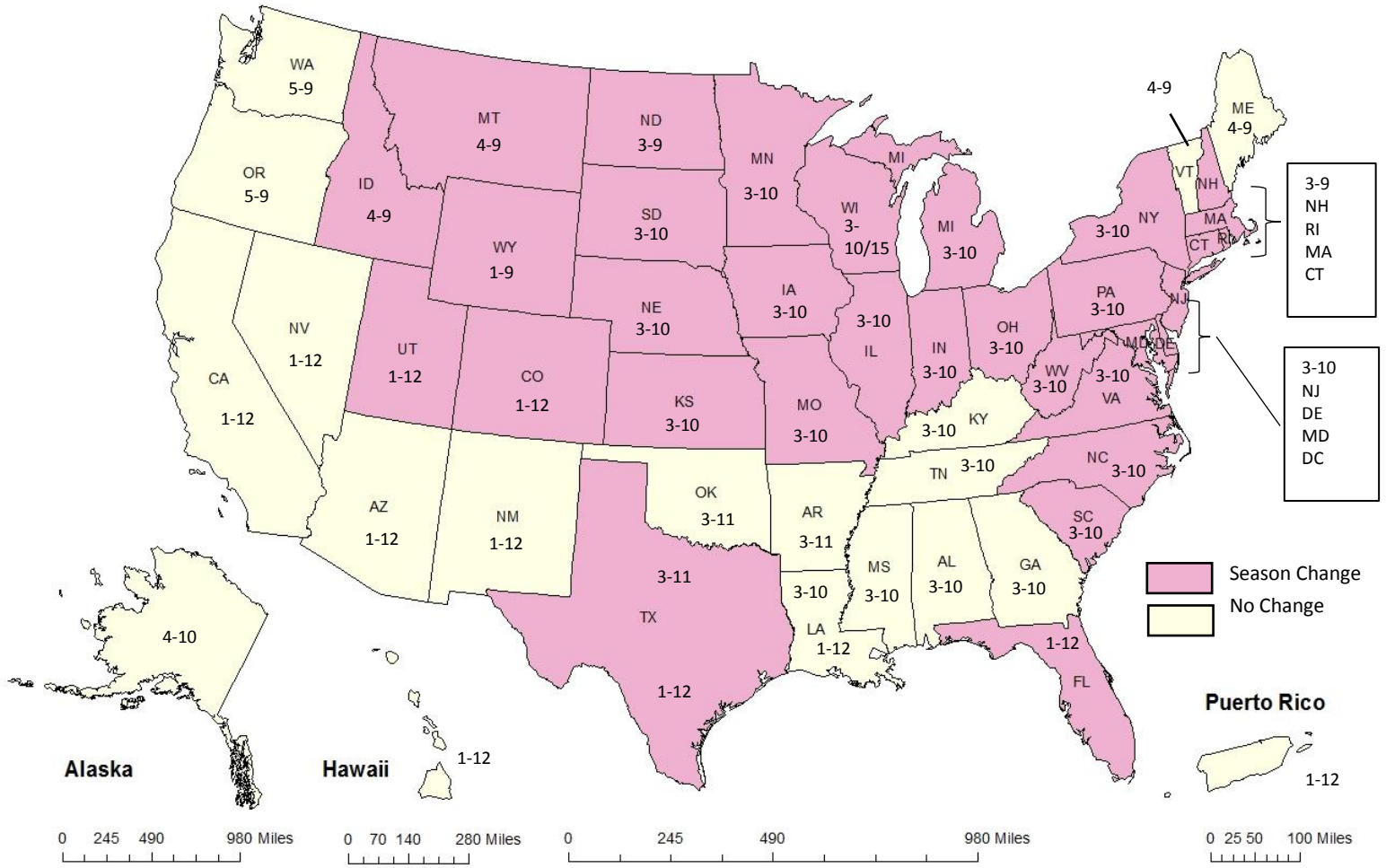
- Final rule extends ozone monitoring season for 32 states and D.C.
  - Effective January 1, 2017
  - One month extension for 22 states and D.C.
  - Additional extensions of two months to seven months for 10 states, including states where ozone can be elevated during the winter
  - Year-round seasons for all NCore multi-pollutant sites
- All ozone season waivers were revoked when the rule became effective (December 28, 2015) days after publication in the Federal Register
  - Regions and states with existing waivers should pursue new waivers as appropriate.
  - Regional Administrators will still be allowed to approve changes to states' ozone monitoring seasons without rulemaking.
- Does not affect the CSAPR trading program ozone season (remains May 1 – Sept 1).

Current Ozone Monitoring Seasons – Begin and End Month



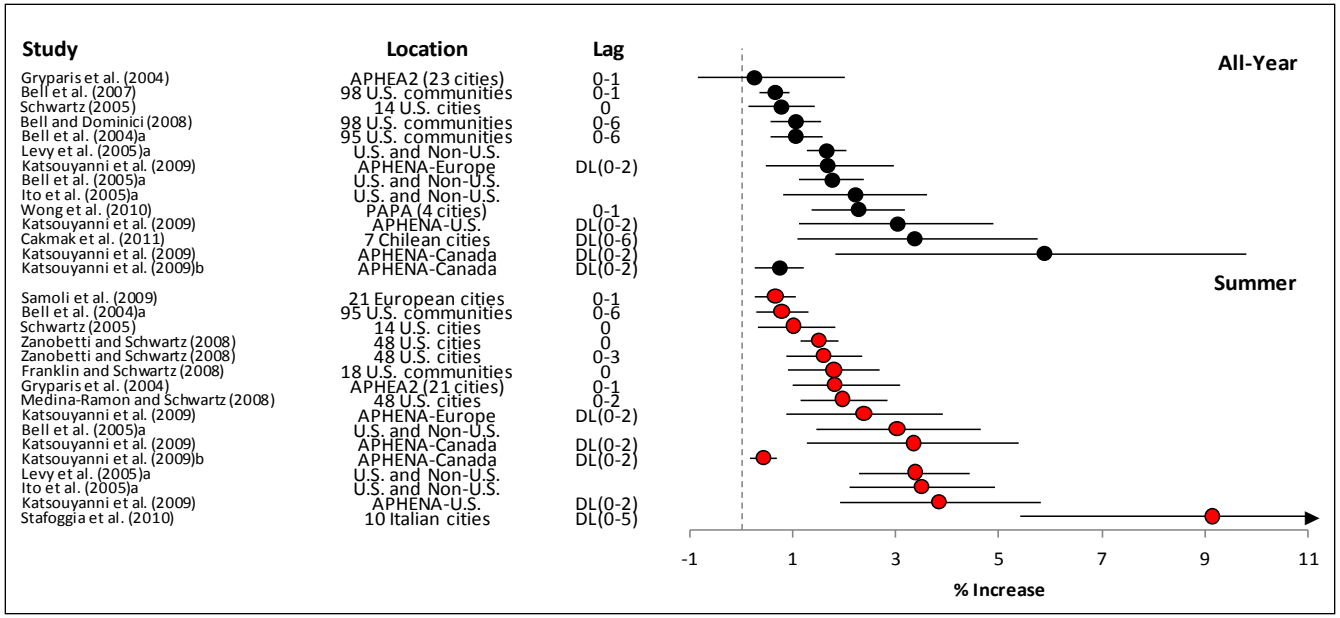
Revised Ozone Monitoring Seasons – Begin and End Month

Effective January 1, 2017



Appendix

A-1: Risk Estimates Total (Nonaccidental) Mortality (Figure 6-27 ISA)



Summary of mortality risk estimates for short-term O_3 exposure and all-cause (nonaccidental) mortality from all-year and summer season analyses.

Note: Effect estimates are for a 40 ppb increase in 1-h max, 30 ppb increase in 8-h max, and 20 ppb increase in 24-h avg O_3 concentrations. An "a" represent multicity studies and meta-analyses from the 2006 O_3 AQCD. Bell et al. (2005), Ito et al. (2005), and Levy et al. (2005) used a range of lag days in the meta-analysis: Lag 0, 1, 2, or average 0-1 or 1-2; single-day lags from 0 to 3; and lag 0 and 1-2; respectively. A "b" represents risk estimates from APHENA-Canada standardized to an approximate IQR of 5.1 ppb for a 1-h max increase in O_3 concentrations (see explanation in Section 6.2.7.2).