



**Comments on
First Draft of EPA's Risk and Exposure Assessment
to Support the Review of the NO₂ Primary NAAQS**

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Comments prepared on behalf of UARG

Several Key Issues with REA

*I address the first 2 issues in these slides.
(The 3rd and 4th issues are addressed in the
written comments I have also provided for CASAC)*

- 1. REA does not establish a linkage between its “benchmark exposure levels” and evidence of enhanced risks**
 - No apparent basis for using a benchmark of 200 ppb
 - Linkages between REA and ISA are not clear
- 2. Selection of cities in REA is not representative**
- 3. “Roll up” to simulate exposures at current standard is far too extreme to provide any useful information**
- 4. Concern that the Exposure Analysis and the Air Quality Characterization are inconsistent with each other.**

Risk Assessment Needs Clear Linkage of Scientific Evidence of Risk

- No “concentration-response” relationship attempted
- Uses “benchmarks” of 200 ppb, 250 ppb and 300 ppb
 - **WHAT DO THESE MEAN IN TERMS OF “RISK”?**
 - *The “lower- middle- and upper end of the range identified in the ISA as the lowest levels at which controlled human exposure studies have provided sufficient evidence for the occurrence of NO₂-related airway responsiveness”*
 - Relevant studies identified in Table 1 of REA

Table 1 of REA Is Supposed to Support Choice of Benchmark Levels in Range of 200 to 300 ppb

Study	NO ₂ Exposure Level (ppm)	Exposure Duration	Study Population	Allergen versus non-specific	Metric Used	Number of Subjects	Exercise	Statistically Significant	Statistically Non Significant
Tummichiffe, 1994	0.4	1-hour	Mild asthmatics	Allergen	Lung function	8	No	X	
Devalia, 1994	0.4	6-hours	Mild asthmatics	Allergen	Lung function	8	No		X
Strand, 1997	0.26	30-minutes	Mild asthmatics	Allergen	Lung function	18	No	X	
Strand, 1998	0.26	30-minutes (4x per day)	Mild to Moderate asthmatics	Allergen	Lung function	16	No	X	
Barck, 2005	0.26	15-minutes (3x over 2 days)	Mild asthmatics	Allergen	Lung function	18	No		X
Barck, 2005	0.26	15-minutes (3x over 2 days)	Mild asthmatics	Allergen	Inflammatory Markers (sputum, blood)	18	No	X	
Barck, 2002	0.26	30-minutes	Mild asthmatics	Allergen	Inflammatory Markers (BAL)	13	No	X	
Bylin, 1985	0.3	20-minutes	Mild asthmatics	Non-specific	Lung function	8	No	X	
Mohsenin, 1987	0.5	1-hour	Asthmatics	Non-specific	Lung function	8	No	X	
Strand, 1996	0.26	30-minutes	Mild asthmatics	Non-specific	Lung function	19	No	X	
Jörres, 1990	0.25	30-minutes	Mild asthmatics	Non-specific	Lung function	14	No	X	
Rubenstein, 1990	0.3	30-minutes	Asthmatics	Non-specific	Lung function	9	Yes		X
Jörres, 1991	0.25	30-minutes	Mild asthmatics	Non-specific	Lung function	11	Yes		X
Witten, 2005	0.4	3-hours	Mild asthmatics	Allergen	Inflammatory Markers (sputum)	15	Yes		X
Jörres, 1991	0.25	30-minutes	Mild asthmatics	Non-specific	Lung Function	11	Yes		X
Jenkins, 1999	0.4	3-hours	Mild asthmatics	Allergen	Lung function	11	Yes	X	
Jenkins, 1999	0.2	6-hours	Mild asthmatics	Allergen	Lung function	11	Yes		X
Witten, 2005	0.4	3-hours	Mild asthmatics	Allergen	Lung function	15	Yes		X
Roger, 1990	0.15-0.6	75-minutes	Mild asthmatics	Non-specific	Lung function	21	Yes		X

A table like this does not exist in the ISA

Table 1 Re-Ordered by Exposure Levels:

Shows No Risk-Related Basis for a Benchmark of 200 ppb

<u>Study</u>	<u>NO2(ppm)</u>	<u>Duration</u>	<u>Significant?</u>
Roger, 1990	0.15	1.25-hr	NO
Jenkins, 1999	0.2	6-hr	NO
Jörres, 1990	0.25	30-min	
Jörres, 1991 (*)	0.25	30-min	NO
Barck, 2005	0.26	15-min (3x in 2days)	NO
Barck, 2005	0.26	15-min (3x in 2days)	
Strand, 1997	0.26	30-min	
Barck, 2002	0.26	30-min	
Strand, 1996	0.26	30-min	
Strand, 1998	0.26	30-min (4x/day)	
Bylin, 1985	0.3	20-min	
Rubenstein, 1990	0.3	30-min	NO
Tunncliffe, 1994	0.4	1-hr	
Witten, 2005	0.4	3-hr	NO
Jenkins, 1999	0.4	3-hr	
Witten, 2005	0.4	3-hr	NO
Devalia, 1994	0.4	6-hr	NO
Mohsenin, 1987	0.5	1-hr	
Roger, 1990	0.6	1.25-hr	NO

Exposures
~200 ppb

Exposures
~250 ppb

Exposures
≥ 300 ppb

5 | (*) Table 1 of REA has 2 identical entries for Jörres, 1991. The apparent duplicate was deleted in the above.

Selection Criteria for Cities Creates an Unrepresentative Characterization of US Exposure Levels

For Air Quality Characterization:

- Cities with a monitor whose annual average NO₂ is among the worst 10% of all US NO₂ monitors, or with at least one reading above 200 ppb (1995-2006)

For Exposure Modeling:

- Cities with a monitor whose annual average NO₂ is among the worst 10% of all US NO₂ monitors, and with at least one reading above 200 ppb (2001-2006)
 - *Philadelphia and Los Angeles*
- Add the city with greatest number of hours above 200 ppb
 - *Detroit*
- Add cities with a worst-10% average or exceedances earlier
 - *Atlanta and Phoenix*

Summary

- **The combined effect of**
 1. BENCHMARKS AT WHICH EFFECTS ARE NOT DOCUMENTED
 2. ANALYSIS OF ONLY THE WORST-CASE CITIES

produces a characterization of NO₂ exposures that overstates the magnitude of the potential risks
- **This is exacerbated by the 2 other concerns discussed in my written comments (handout), i.e.,**
 - Unreasonable “roll up” of NO₂ data to simulate current NAAQS
 - Apparent inconsistencies in NO₂ data in the 2 parts of the REA

Extrapolations to Simulate 53 ppb Annual Average NO₂ Are Extremely Large

