GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

Ozone and PM NAAQS Reviews

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NACAA Criteria Pollutants Committee
Monthly Conference Call
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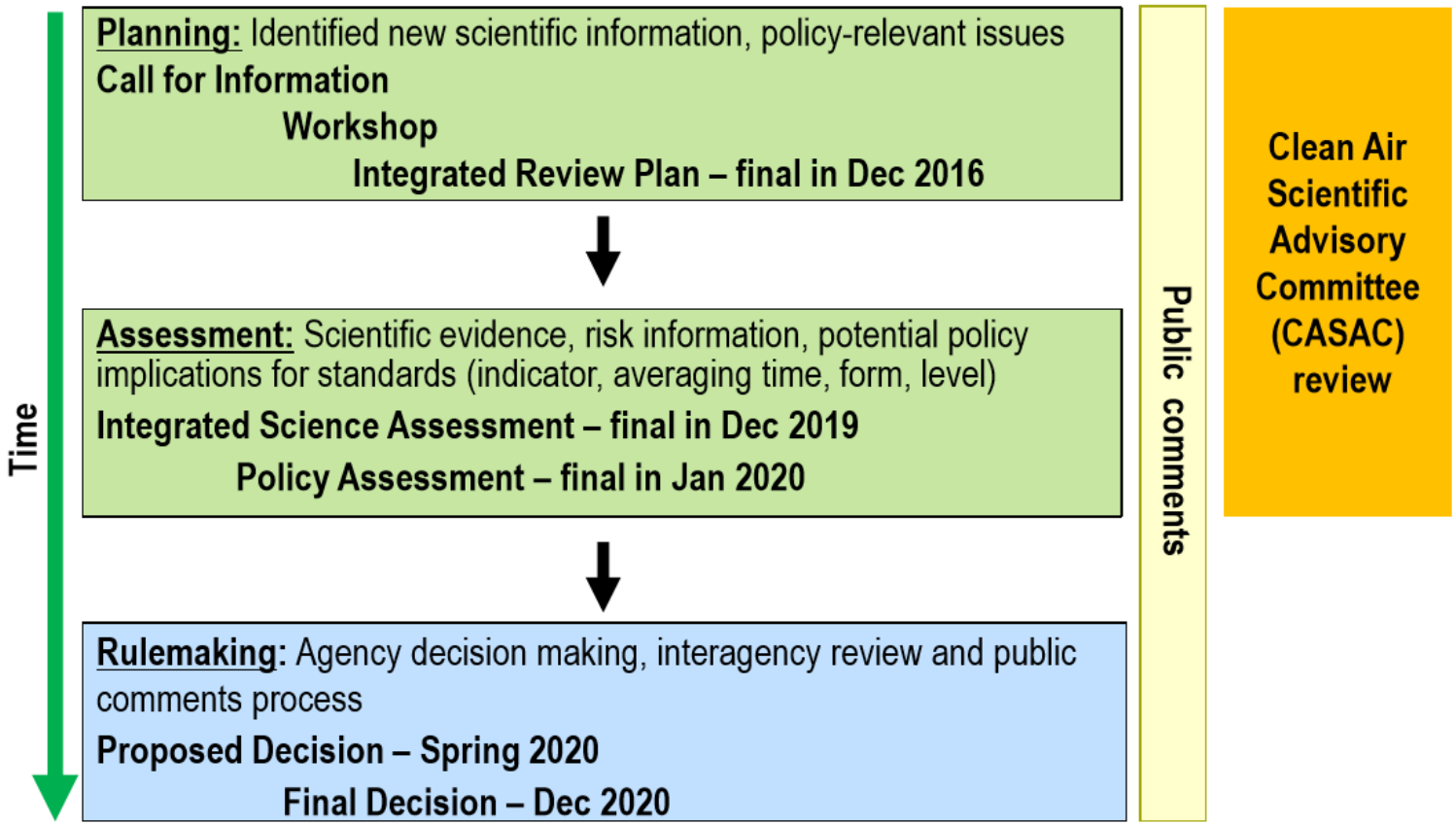
PM NAAQS REVIEW

Process and Schedule for This Review of the PM NAAQS



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PM ISA REVIEW

Draft PM ISA
Health Effects: Causality Determinations

HUMAN HEALTH EFFECTS					
		ISA	Current PM Draft ISA		
		Indicator	$PM_{2.5}$	$PM_{10-2.5}$	UFP
Health Outcome	Respiratory	Short-term exposure			
		Long-term exposure			
	Cardiovascular	Short-term exposure			
		Long-term exposure		*	
	Metabolic	Short-term exposure	*	*	*
		Long-term exposure	*	*	*
	Nervous System	Short-term exposure	*		*
		Long-term exposure	*	*	*
	Reproductive: Male/Female Reproduction and Fertility	Long-term exposure			
	Reproductive: Pregnancy and Birth Outcomes				
	Cancer	Long-term exposure	*	*	
	Mortality	Short-term exposure			
		Long-term exposure		*	

Causal | Likely causal | Suggestive | Inadequate

* = new determination or change in causality determination from 2009 PM ISA

CASAC LETTER ON PM ISA (4/11/19)

- "Overall, the CASAC finds that the Draft ISA does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to particulate matter (PM). The CASAC recommends that the following fundamental limitations be remedied in a second draft of the ISA for CASAC review.
  - Lack of comprehensive, systematic review
  - Inadequate evidence for altered causal determinations
  - Clearer discussion of causality and causal biological mechanisms and pathways - specifically including pulmonary inflammation."

CASAC LETTER ON PM ISA (4/11/19)

- "The CASAC finds that the Draft ISA does not present adequate evidence to conclude that there is likely to be a causal association between longterm $PM_{2.5}$ exposure and nervous system effects; between long-term UFP exposure and nervous system effects; or between long-term $PM_{2.5}$ exposure and cancer."

CASAC LETTER ON PM ISA (4/11/19)

- "The need for substantial revisions to the Draft ISA to provide clearer definitions, and technical details and methods in order to enable meaningful independent scientific review leads to the following two process recommendations:
  1. The CASAC recommends development of a Second Draft ISA for CASAC review.
  2. The CASAC recommends that the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise)… The panel should be appointed in time to review the Second Draft ISA."

FINAL PM ISA RELEASED (DEC. 2019)

- 85 FR 4655, "To address these comments in the Final PM ISA, the EPA:
  1) Added text to the Preface and developed a new Appendix to more clearly articulate the process of ISA development;
  2) revised the causality determination for long-term ultrafine particle (UFP) exposure and nervous system effects to suggestive of, but not sufficient to infer, a causal relationship; and
  3) added additional text to the Preface of the PM ISA as well as text in the health effects chapters to clarify the discussion of biological plausibility and its role in forming causality determinations."

DRAFT ISA vs. FINAL ISA

United States Environmental Protection Agency

HUMAN HEALTH EFFECTS

ISA			Current PM Draft ISA		
		Indicator	$PM_{2.5}$	$PM_{10-2.5}$	UFP
Health Outcome	Respiratory	Short-term exposure			
		Long-term exposure			
	Cardiovascular	Short-term exposure			
		Long-term exposure		*	
	Metabolic	Short-term exposure	*	*	*
		Long-term exposure	*	*	*
	Nervous System	Short-term exposure	*		*
		Long-term exposure	CASAC?	*	CASAC?
	Reproductive: Male/Female Reproduction and Fertility	Long-term exposure			
	Reproductive: Pregnancy and Birth Outcomes	Long-term exposure			
	Cancer	Long-term exposure	CASAC?	*	
	Mortality	Short-term exposure			
		Long-term exposure		*	

Causal | Likely causal | Suggestive | Inadequate

* = new determination or change in causality determination from 2009 PM ISA

HUMAN HEALTH EFFECTS

ISA			Final PM ISA		
		Indicator	$PM_{2.5}$	$PM_{10-2.5}$	UFP
Health Effect Category	Respiratory	Short-term exposure			
		Long-term exposure			
	Cardiovascular	Short-term exposure			
		Long-term exposure		▲	
	Metabolic	Short-term exposure	*	*	*
		Long-term exposure	*	*	*
	Nervous System	Short-term exposure	▲		▲
		Long-term exposure	*	*	EPA
	Reproductive: Male/Female Reproduction and Fertility	Long-term exposure			
	Reproductive: Pregnancy and Birth Outcomes	Long-term exposure			
	Cancer	Long-term exposure	▲	▲	
	Mortality	Short-term exposure			
		Long-term exposure		▲	

Causal | Likely causal | Suggestive | Inadequate

* = no evidence to evaluate in 2009 PM ISA

▲ = change in causality determination from 2009 PM ISA

PM PA REVIEW

Preliminary Conclusions on the Current Primary $PM_{2.5}$ Standards

- The available scientific information can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary $PM_{2.5}$ standards
- Basis for this preliminary conclusion:
  - Long-standing body of health evidence, strengthened in this review, supporting relationships between short- and long-term $PM_{2.5}$ exposures and various outcomes, including mortality and serious morbidity effects
  - Recent U.S. and Canadian epidemiologic studies reporting positive and statistically significant health effect associations for $PM_{2.5}$ air quality likely to be allowed by the current standards
  - Analyses of pseudo-design values indicating substantial portions of study area health events/populations in locations with air quality likely to have met the current $PM_{2.5}$ standards
  - Risk assessment estimates that the current primary standards could allow thousands of $PM_{2.5}$-associated deaths per year – most at annual average $PM_{2.5}$ concentrations from 10 to 12 $\mu g/m^3$ (well within the range of overall mean concentrations in key epidemiologic studies)

CASAC LETTER ON PM PA (12/16/19)

- "…some CASAC members conclude that the Draft PM PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current 2012 $PM_{2.5}$ annual standard."
- "Other members of CASAC conclude that the weight of the evidence…does reasonably call into question the adequacy of the 2012 annual $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS) to protect public health with an adequate margin of safety."
- "CASAC also finds, in agreement with the EPA, that the available evidence does not reasonably call into question the adequacy of the current 24-hour $PM_{2.5}$ standard, PM_{10} standard, or secondary PM standards and concurs that they should be retained."

CASAC LETTER ON PM PA (12/16/19)

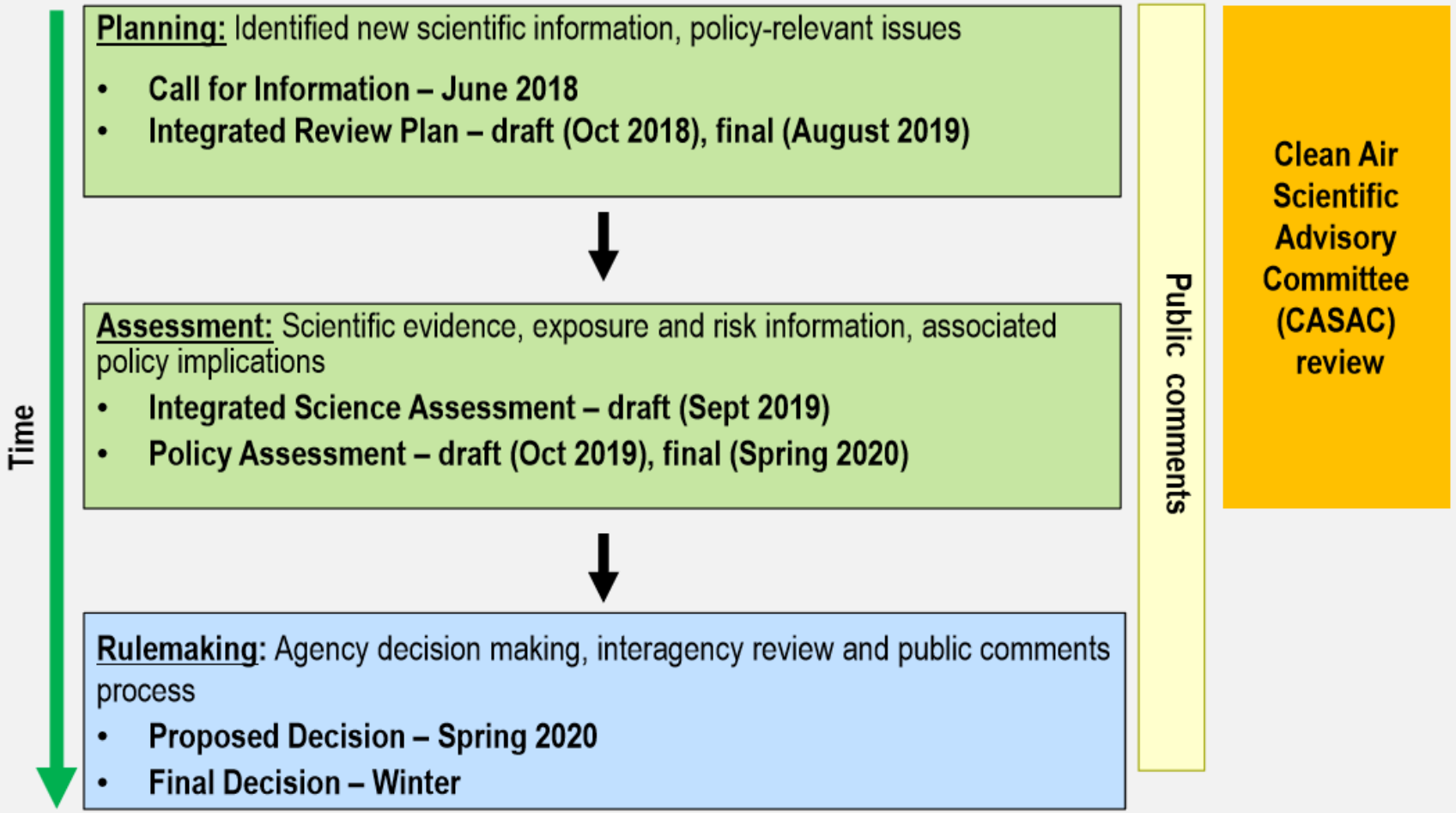
- "The CASAC recommends that the final PM PA provide quantitative uncertainty and sensitivity analyses to provide a clearer technical and scientific basis for data interpretation and policy making."
- "The CASAC recommends that it be provided an opportunity to review a revised draft of the PM PA based on the final PM ISA."

FINAL PM PA RELEASED (01/27/20)

- "In Chapter 3 and Appendices B and C, we have made a number of changes:
  a. We have reduced the emphasis on evidence for long-term ultrafine particle exposures and nervous system effects to reflect the change in the final ISA's causality determination from "likely to be causal" to "suggestive of, but not sufficient to infer, a causal relationship."
  b. We have expanded the characterization and discussion of the evidence related to exposure measurement error in epidemiologic studies, the potential confounders examined by key studies, the shapes of concentration-response functions, and the results of causal inference and quasi-experimental studies.
  c. We have expanded and clarified the discussion of uncertainties in the risk assessment, and we have added additional air quality model performance evaluation for each of the urban study areas included in the risk assessment.
  d. We have provided additional detail on the procedure for deriving concentration-response functions used in the risk assessment."

OZONE NAAQS REVIEW

Process and Schedule for this Review of the Ozone NAAQS



OZONE ISA REVIEW

EPA United States Environmental Protection Agency

Summary
Causality Determinations - Health

Health Effects		
Short-term Exposure		
	2013 Ozone ISA	Current Ozone ISA
Respiratory Effects	Causal	Causal
Metabolic Effects	No Causality Determination	Likely to be Causal*
Cardiovascular Effects	Likely to be Causal	Suggestive of, but not sufficient to infer
Nervous System Effects	Suggestive of, but not sufficient to infer	Suggestive of, but not sufficient to infer
Mortality	Likely to be Causal	Suggestive of, but not sufficient to infer
Long-term Exposure		
Respiratory Effects	Likely to be Causal	Likely to be Causal
Metabolic Effects	No Causality Determination	Likely to be Causal*
Cardiovascular Effects	Suggestive of, but not sufficient to infer	Suggestive of, but not sufficient to infer
Nervous System Effects	Suggestive of, but not sufficient to infer	Suggestive of, but not sufficient to infer
Reproductive Effects – Fertility and Reproduction	Suggestive of, but not sufficient to infer	Suggestive of, but not sufficient to infer
Reproductive Effects – Pregnancy and Birth Outcomes		Suggestive of, but not sufficient to infer
Cancer	Inadequate	Inadequate
Mortality	Suggestive of, but not sufficient to infer	Suggestive of, but not sufficient to infer

Red text = new determination or change in causality determination from 2013 Ozone ISA
* New Causality Determination

EPA United States Environmental Protection Agency

Summary
Causality Determinations - Welfare

Ecological Effects		
	2013 Ozone ISA	Current Ozone ISA
Visible Foliar Injury	Causal	Causal
Reduced Vegetation Growth	Causal	Causal
Reduced Plant Reproduction	No separate causality determination; included with plant growth	Causal
Increased Tree Mortality	No Causality Determination	Likely to be Causal
Reduced Crop Yield	Causal	Causal
Altered Herbivore Growth and Reproduction	No Causality Determination	Likely to be Causal
Altered Plant-Insect Signaling	No Causality Determination	Likely to be Causal
Reduced Carbon Sequestration	Likely to be Causal	Likely to be Causal
Reduced Productivity	Causal	Causal
Alterations of Below-ground Biogeochemistry	Causal	Causal
Alteration of Terrestrial Community Composition	Likely to be Causal	Causal
Alteration of Ecosystem Water Cycling	Likely to be Causal	Likely to be Causal
Effects on Climate		
	2013 Ozone ISA	Current Ozone ISA
Radiative Forcing	Causal	Causal
Temperature, Precipitation and Climate-related Variables*	Likely to be Causal	Likely to be Causal

Red text = new determination or change in causality determination from 2013 Ozone ISA
*Referred to as "Climate Change" in the 2013 Ozone ISA

CASAC LETTER ON OZONE ISA (2/19/20)

- "The CASAC recommends that the following key points be addressed in the final Ozone ISA:
  - Critically review, synthesize, and discuss available scientific evidence on how changes in public health effects depend on changes in ambient ozone exposures. This is a crucial scientific topic for informing the Ozone PA and should be thoroughly addressed in the Ozone ISA.
  - Clarify criteria used to select, evaluate, weight, and summarize studies; provide details of how the criteria were applied to individual studies and what the results were; and explain how key conclusions were derived from the results.
  - Clarify the meaning and derivation of stated key causal conclusions. Causal determination judgments stated in the Draft Ozone ISA are ambiguous, and sometimes appear subjective and arbitrary."

CASAC LETTER ON OZONE ISA (2/19/20)

- "On overarching process issues, the CASAC strongly recommends that the EPA consider restoring a traditional interactive discussion process in which the CASAC can interact directly with external expert panels, while also keeping the option of obtaining written responses from external experts to specific questions."
- "The CASAC offers additional process recommendations in its review of the EPA's Draft Ozone Policy Assessment (PA)"

OZONE PA REVIEW

Primary Standard: Preliminary Conclusions

- Health effects evidence newly available in this review is generally consistent with evidence base in last review.
- Exposure and risk estimates for air quality conditions just meeting the current standard generally reflect the ranges of estimated exposures and risks from the last review.
- Preliminary PA conclusion is that the available evidence and quantitative information, including uncertainties, do not call into question the adequacy of protection provided by the current standard, and thus, support consideration of retaining the current standard, without revision.
- Accordingly, the draft PA does not identify alternative standards for further evaluation.

Secondary Standard: Preliminary Conclusions

- Welfare effects evidence is generally consistent with evidence base in last review.
  - Growth-related effects: Exposure estimates for air quality conditions meeting the current standard virtually all at/below 19 ppm-hrs (the W126 index associated with 6% RBL for median species).
    - Focus on RBL as surrogate for other vegetation-related effects continues to be supported by the current information as approach for judging adequacy of protection provided by the current standard
  - Visible foliar injury: Current evidence does not indicate the occurrence of elevated severity or extensive leaf damage in areas that meet current standard
  - Climate effects: Evidence does not support climate risk estimation for O_3 concentrations that meet current standard.
- Preliminary conclusion is that the available evidence and quantitative information, including uncertainties, do not call into question the adequacy of protection provided by the current standard, and thus, support consideration of retaining the current standard, without revision.
  - Accordingly, the draft PA does not identify alternative standards for further evaluation.

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CASAC LETTER ON OZONE PA (2/19/20)

- "…some CASAC members conclude that the Draft Ozone PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current primary ozone standard."
- "Other members of the CASAC agree with the previous CASAC's findings and recommendations in their review of the 2014 Second Draft Ozone PA. In that review, the previous CASAC opined that a primary standard set at 70 ppb may not be protective of public health with an adequate margin of safety."
- "The CASAC also finds, in agreement with the EPA, that the available evidence does not reasonably call into question the adequacy of the current secondary ozone standard and concurs that it should be retained."

CASAC LETTER ON OZONE PA (2/19/20)

- "On overarching process issues, the CASAC strongly recommends that the EPA consider restoring a traditional interactive discussion process in which the CASAC can interact directly with external expert panels, while also keeping the option of obtaining written responses from external experts to specific questions."
- "The CASAC strongly recommends that the EPA work with experts in causal analysis, biological causation, management science, decision analysis, and risk analysis to improve the causal determination framework.
- "The CASAC recommends that it be given an opportunity to review a second draft of the Ozone PA (with an updated Risk and Exposure Assessment) after the final ISA for ozone is released."

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