Message

Sent: 10/15/2018 8:27:02 PM
To: Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]
Subject: CASAC Talking Points

Last week, EPA announced the appointment of five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). This seven-member panel, required under Section 109 of the Clean Air Act, provides critical advice related to National Ambient Air Quality Standards (NAAQS). EPA also tasked this panel with leading the review any necessary changes to the NAAQS for ozone or particulate matter.

There are several reasons the Agency announced these moves:

1. The new chartered CASAC is filled with qualified, independent experts who are have decades of experience working on ozone and particulate matter issues. This includes several individuals who have served or actively participated in previous NAAQS reviews for ozone and particulate matter. The full line up: Dr. Anthony (Tony) Cox, Cox Associates (Chair); Dr. James Boylan, Georgia Department of Natural Resources; Dr. Mark Frampton, University of Rochester Medical Center; Dr. Sabine Lange, Texas Commission on Environmental Quality; Dr. Timothy Lewis, U.S. Army Corps of Engineers; Dr. Corey Masuca, Jefferson County (AL) Department of Health; Dr. Steven Packham, Utah Department of Environmental Quality
2. Tasking the chartered CASAC with overseeing these reviews ensures the early engagement of the advisors who ultimately provide advice to the Administrator and is consistent with the clear requirements of the Clean Air Act*, regulations implementing the Federal Advisory Committee Act**, and CASAC's charter***
3. As outlined in the May 2018 "Back-to-Basics Process for Reviewing NAAQS" memorandum, any changes to the particulate matter and ozone NAAQS would be finalized by late 2020. In order to meet these deadlines, which reflect Congress' intent for a five-year review cycle, relying on the expertise of these seven PM and ozone experts ensures robust advice without requiring the selection of more than 40 unaccountable advisors. This move ensures there are the right number of expert cooks in the kitchen.
4. EPA did not disrupt any scientific advice process. A stand-alone ozone review panel has not yet been created and the particulate matter review panel was established to operate from 2015 and 2018. The latter panel was engaged by EPA over an "integrated review plan" but it did not provide scientific advice for any of the key assessments for the NAAQS review process. Several members of the new chartered CASAC, including Dr. Mark Frampton and Dr. James Boylan, served on that panel and will continue providing advice. EPA welcomes feedback on these science assessments from any and all members of the scientific community and public.
5. Members of Congress and state groups have raised concerns about balance and independence for the Obama Administration's PM and ozone review panels. For example, see letters from the U.S. Senate Environment and Public Works Committee, U.S. House Science Committee, and The Council of State Governments – West.

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Appointment

From: Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]
Sent: 8/29/2018 11:46:53 AM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Harlow, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a9a34e31fc4fe6b2beaddda2affa44-Harlow, Dav]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]

Subject: Conference Call with TCEQ (Confirmed)
Attachments: RE: Presentation; Confirmed 9/7 at 1:00pm ET: Presentation; RE: Confirmed 9/7 at 1:00pm ET: Presentation
Location: WJC-N 5400 + Dial: [redacted] Participant Code: [redacted]

Start: 9/7/2018 5:00:00 PM
End: 9/7/2018 6:00:00 PM
Show Time As: Busy

To: Clint Woods, Bill Wehrum, David Harlow, Justin Schwab
Outside Attendees (by phone):

- Sabine Lange
- Michael Honeycutt
- Lindsey Jones

RE: Presentation | Confirmed 9/7 at 1:00pm ET: Pres... | RE: Confirmed 9/7 at 1:00pm ET: Pr...

Message

From: Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]
Sent: 8/29/2018 7:28:17 PM
To: lindsey.jones@tceq.texas.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09020d7269b14016ae089f885bf5dd84-lindsey.jon]
Subject: Confirmed 9/7 at 1:00pm ET: Presentation

Hi Lindsey,

Perfect - so you are confirmed for a one hour conference call with Bill Wehrum, Clint Woods, David Harlow and Justin Schwab on Friday, September 7 at 1:00pm ET (see call in details below).

Dial: Personal Privacy
Participant Code: Personal Privacy

Please send in advance the names of the TCEQ staff who will be participating on your end. And if you need anything else, let me know.

Emily Atkinson
Special Assistant
Management Analyst
Immediate Office of the Assistant Administrator
Office of Air and Radiation, USEPA
Room 5406E, 1200 Pennsylvania Avenue NW
Washington, DC 20460
Voice: 202-564-1850
Email: atkinson.emily@epa.gov

From: Lindsey Jones [mailto:Lindsey.Jones@tceq.texas.gov]
Sent: Wednesday, August 29, 2018 3:17 PM
To: Atkinson, Emily <Atkinson.Emily@epa.gov>
Subject: RE: Presentation

Hi Emily,

That date and time would be fine.

Thank you!
Lindsey

From: Atkinson, Emily <Atkinson.Emily@epa.gov>
Sent: Wednesday, August 29, 2018 2:13 PM
To: Lindsey Jones <Lindsey.Jones@tceq.texas.gov>
Subject: RE: Presentation

Hi Lindsey,

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Could you all be available for a one hour conference call on Friday, September 7 at 1:00pm ET?

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From: Lindsey Jones [mailto:Lindsey.Jones@tceq.texas.gov]
Sent: Wednesday, August 29, 2018 1:51 PM
To: Atkinson, Emily <Atkinson.Emily@epa.gov>
Subject: RE: Presentation

Of course. I will call you at the number in your signature block shortly.

From: Atkinson, Emily <Atkinson.Emily@epa.gov>
Sent: Wednesday, August 29, 2018 12:50 PM
To: Lindsey Jones <Lindsey.Jones@tceq.texas.gov>
Subject: RE: Presentation

Hi Lindsey,

Would you have time for a quick chat?

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From: Lindsey Jones [mailto:Lindsey.Jones@tceq.texas.gov]
Sent: Wednesday, August 29, 2018 10:28 AM
To: Atkinson, Emily <Atkinson.Emily@epa.gov>
Cc: Lewis, Josh <Lewis.Josh@epa.gov>
Subject: RE: Presentation

Hi Emily,

Friday at 1:00 pm Eastern will be fine. Just for my clarification, is this time instead of Thursday?

Best,
Lindsey

From: Atkinson, Emily <Atkinson.Emily@epa.gov>
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To: Lindsey Jones <Lindsey.Jones@tceq.texas.gov>
Cc: Lewis, Josh <Lewis.Josh@epa.gov>
Subject: RE: Presentation

Hi Lindsey,

Circling back on this request for Clint Woods. Delaney Rakosnik is out of the office and I am stepping in to get this meeting scheduled.

Please let me know if Friday, September 7 at 1:00pm for 30 minutes could work on your end.

Emily

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From: Rakosnik, Delaney
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To: lindsey.jones@tceq.texas.gov
Cc: Lewis, Josh <Lewis.Josh@epa.gov>; Atkinson, Emily <Atkinson.Emily@epa.gov>
Subject: FW: Presentation

Hi Lindsey,

Do you happen to have time on Sept 7th at 1pm (EST) for this conversation?

Many thanks,

Delaney Rakosnik
Staff Assistant
Immediate Office of the Assistant Administrator
Office of Air and Radiation, USEPA
Room 5406A, 1200 Pennsylvania Avenue NW
Washington, DC 20460
Voice: 202-564-0935
Email: rakosnik.delaney@epa.gov

From: Lindsey Jones <Lindsey.Jones@tceq.texas.gov>
Date: August 24, 2018 at 5:40:30 PM EDT
To: "Woods, Clint" <woods.clint@epa.gov>
Subject: RE: Presentation

Clint,

Absolutely. We can pretty much make any time that day work, though we have a slight preference for time after 10 am Central.

Best,
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From: Woods, Clint <woods.clint@epa.gov>
Sent: Friday, August 24, 2018 3:58 PM
To: Lindsey Jones <Lindsey.Jones@tceq.texas.gov>
Subject: RE: Presentation

Lindsey,

Thanks so much! Any chance next Thursday the 30th might work to schedule a continuation of our conversation?

Clint Woods
Deputy Assistant Administrator
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202.564.6562

From: Lindsey Jones [mailto:Lindsey.Jones@tceq.texas.gov]
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To: Woods, Clint <woods.clint@epa.gov>
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Hi Clint,

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Thank you for your time,
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Wonderful! Sabine Lange, Michael Honeycutt, and I will be in attendance. Thank you for your help!

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Message

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Sent: 10/9/2018 1:35:55 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Draft CASAC Release

Headline: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee
Sub-Headline: Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process

Deliberative Process / Ex. 5

For more information, visit EPA's NAAQS review [link] and CASAC [link] websites.

Message

From: Lewis, Josh [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B22D1D3BB3F84436A524F76AB6C79D7E-JOLEWIS]
Sent: 10/4/2018 7:50:10 PM
To: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Harlow, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a9a34e31fc4fe6b2beaddda2affa44-Harlow, Dav]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
CC: Dominguez, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ced433b4ef54171864ed98a36cb7a5f-Dominguez,]; Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]
Subject: For review: PM2.5 Precursor Demonstration Guidance
Attachments: OMB 12866 Review_Precursor Demonstration Guidance -10022018.docx; PM2.5 precursor guidance_summary.docx

Importance: High

2nd of the new packages for review. Note this would be signed by Peter after it clears OMB.

Message

From: Konkus, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=555471B2BAA6419E8E141696F4577062-KONKUS, JOH]
Sent: 10/15/2018 9:30:24 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Re: CASAC Talking Points

Thanks

John Konkus
Environmental Protection Agency
Deputy Associate Administrator
Office of Public Affairs

On Oct 15, 2018, at 5:29 PM, Woods, Clint <woods.clint@epa.gov> wrote:

FYI - More detail/background on this stuff with quotes. Thanks!

From: Woods, Clint
Sent: Monday, October 15, 2018 5:15 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>
Subject: CASAC Talking Points

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Message

From: Shoaff, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC16FB09CF2C44ADB34A7405DC331532-JSHOAFF]
Sent: 9/24/2018 2:24:32 PM
To: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Tsirigotis, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d19c179f3ccb4fadb48e3ae85563f132-PTSIRIGO]; Koerber, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c513901d4fd49f9ab101a6f7a7a863e-Koerber, Mike]
CC: Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]
Subject: FW: New IQG Case: RFC 18003 - NATA/Ethylene Oxide
Attachments: RFC 18003 Request.pdf

Bill et al,

Thought you might want to be aware of this new IQG case, see attached. Our QA poc, Tom Eagles, just received it from OEI and will likely touch base with Kelly R. in OAQPS for awareness and need for SME with request. Thx.

John

JOHN SHOAFF | DIRECTOR
OFFICE OF AIR POLICY & PROGRAM SUPPORT (OAPPS)
OFFICE OF AIR & RADIATION | U.S. EPA | WJC NORTH 5442-B
1200 PENNSYLVANIA AVE. NW | MC 6103A | WASHINGTON, D.C. | 20460 | USA
Shoaff.john@epa.gov | **1-202-564-0531 DIRECT | 1-202-257-1755 MOBILE**

From: Kirby, Kevin
Sent: Monday, September 24, 2018 10:05 AM
To: Eagles, Tom <Eagles.Tom@epa.gov>
Subject: New IQG Case: RFC 18003 - NATA/Ethylene Oxide

Good Morning Tom,
We just received a new RFC challenge dealing with the NATA framing of EO.
Could you please help me discern the SMEs for this so that I can get a Scoping Team meeting scheduled ASAP.
As you know, we stretch to get the response out within 90 days.
Thanks,
Kevin

Kevin J. Kirby
Enterprise Data Architect
US Environmental Protection Agency

OEI/OEIP/EQMD
202 566-1656 desk

September 20, 2018

Information Quality Guidelines Staff
Mail Code 2811R
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Request for Correction under the Information Quality Act: 2014 National Air Toxics Assessment (NATA)

Dear Sir or Madam:

The Ethylene Oxide Panel of the American Chemistry Council (ACC), hereby submits this Request for Correction under the Information Quality Act (IQA) of 2000, Section 515 of the 2001 Treasury and General Government Appropriations Act, Pub. L. No. 106-554, the Office of Management and Budget (OMB) Guidelines for Ensuring and Maximizing the Quality, Utility, and Integrity of Information Disseminated by Federal Agencies,[1] and the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA).[2] ACC represents producers and users of ethylene oxide (EO).

ACC seeks the correction of EO information disseminated in the 2014 update to the National Air Toxics Assessment (NATA), released on August 22, 2018.[3] The 2014 NATA relies upon the "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)"[4] to determine the risk value for EO. As detailed below, the 2014 NATA does not meet the IQA's data quality requirements because the EO IRIS Assessment is not the best available science. Therefore, the 2014 NATA risk estimates for EO should be withdrawn and corrected to reflect scientifically-supportable risk values. Moreover, EPA should not use the EO IRIS Assessment's inhalation unit risk estimate (URE) of 5×10^{-3} per $\mu g/m^3$, which corresponds to a one-in-a-million increased cancer risk concentration of 0.1 parts per trillion (ppt), to calculate EO risk in

[1] 67 Fed. Reg. 8452 (Feb. 22, 2002) (OMB Guidelines).

[2] Available at https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf (EPA Guidelines).

[3] Available at https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results (2014 NATA).

[4] EPA/635/R-16/350Fa (December 2016) (EO IRIS Assessment).

its ongoing Clean Air Act (CAA) Section 112 risk and technology review (RTR) rulemakings and other regulatory actions.[5]

As producers and users of EO, ACC members are directly impacted by the errors in the 2014 NATA. The risk estimates based on the EO IRIS value have significant regulatory implications for ACC member companies who produce commercial products of value to consumers using EO. Correcting these deficiencies will result in more accurate estimates of potential risk that will lead to improved regulatory outcomes, the dissemination of more accurate information to the public, and overall reduced misconception.

This Request for Correction is organized into four sections. The Executive Summary provides a high level overview of the key reasons why the 2014 NATA does not meet the objectivity, accuracy, integrity and utility requirements of the IQA and the OMB and EPA Guidelines due to its reliance on the EO IRIS Assessment. The second section provides background information on the 2014 NATA and the EO IRIS Assessment. The third section highlights the information in the EO IRIS Assessment that is not scientifically supportable. In the last section, each of the key deficiencies in the EO IRIS Assessment is discussed in detail with supporting scientific evidence.

I. Executive Summary

In the 2014 NATA, EPA relies on updated benchmarks for several substances, including EO. For EO, EPA updated its cancer risk calculations to reflect the URE in the EO IRIS Assessment. The use of the URE value, however, results in inaccurate and misleading conclusions about EO risk.

The EO IRIS Assessment is based on a supralinear spline slope for lymphoid and breast cancer exposure-response analyses from an epidemiology study conducted by the National Institute for Occupational Safety and Health (NIOSH). **This supralinear risk assessment model predicts high risk at low exposures, lower risk at higher exposures, and estimates an unrealistically low concentration of 0.1 ppt.** This 10^{-6} risk specific concentration (RSC) is the lower bound lifetime chronic exposure level of EO that corresponds to an increased cancer risk of one-in-a-million. **Both the supralinear slope and the RSC are implausible based on the epidemiological evidence and biological mode of action.**

[5] In a recently proposed RTR rule, EPA solicits comment on whether it should ban the use of EO for one of the source categories. *NESHAP; Surface Coating of Large Appliances; Printing, Coating, and Dying of Fabrics and Other Textiles; and Surface Coating of Metal Furniture Residual Risk and Technology Reviews,* 83 Fed. Reg. 46262, 46294 (Sept. 12, 2018).

In addition, these implausible levels lack utility for regulatory purposes. **The RSC in the EO IRIS Assessment is 19,000 times lower than the air-concentration equivalent yielding normal, endogenous levels of EO in the human body. Likewise, the RSC is orders of magnitude lower than ambient levels of EO.** Thus, if the EO IRIS Assessment is to be believed, normal human metabolism and/or breathing ambient air is sufficient to cause cancer. The EO IRIS Assessment does not provide a meaningful basis for assessing and managing risk for EO.

As outlined below, the EO IRIS Assessment is substantially flawed and can be corrected by using the approach published by Valdez-Flores et al. (2010),[6] which models potential mortality excesses for lymphohematopoietic tissue (LH) cancers from the two strongest epidemiological studies (NIOSH and Union Carbide Corporation (UCC)) using a log-linear Cox proportional hazard model. **Valdez-Flores et al. (2010) estimated ranges for the maximum likelihood estimate (MLE) and the 95% lower confidence limit of the environmental concentration corresponding to an extra risk of one in a million [LEC (1/million)] of, respectively, 1.5-9.2 parts per billion (ppb) and 0.5-1.2 ppb.** The major reason for the large difference between these values and the EO IRIS Assessment estimates is that the IRIS Program uses a supralinear spline model and Valdez-Flores et al. (2010) uses the log-linear Cox model.

EPA's cancer risk assessment guidelines caution that "a steep slope [i.e., supralinear] also indicates that errors in an exposure assessment can lead to large errors in estimating risk."[7] This is relevant to the EO IRIS Assessment because the NIOSH exposure model has a much higher level of uncertainty between the late 1930s and 1978 when there was inadequate (1976-78) or no exposure data (<1976) to independently validate the model. Furthermore, the NIOSH exposure model was modified when estimating exposures prior to 1978 by fixing the effect of a key variable (calendar year) in the model.

Specifically, Hornung et al. (1994) determined that Calendar Year is a major predictor of exposure in the model after 1978, but they did not allow this variable to impact exposures in the model prior to 1978.[8] Hornung et al. (1994) surmised that Calendar Year acts as a surrogate for improvement in work practices. **Thus, the arbitrary decision to alter the model prior to 1978 essentially assumes there were no evolving work practices in contract sterilizer facilities**

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[6] Valdez-Flores C, Sielken RL Jr, Teta MJ. 2010. Quantitative cancer risk assessment based on NIOSH and UCC epidemiological data for workers exposed to ethylene oxide. Regul Toxicol Pharmacol, 56(3): 312-20.

[7] EPA, Guidelines for Carcinogen Risk Assessment (March 2005), at 3-19. Available at https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment

[8] Hornung RW, Greife AL, Stayner LT, Steenland NK, Herrick RF, Elliott LJ, Ringenburg VL, Morawetz J. 1994. Statistical model for prediction of retrospective exposure to ethylene oxide in an occupational mortality study. Am J Ind Med, 25(6): 825-36.

between 1938 and 1977 that influence exposure to workers. The EO IRIS Assessment did not critically evaluate the assumptions and uncertainties of the NIOSH exposure model.

Moreover, the EO IRIS Assessment makes an unsubstantiated and counter-intuitive claim that the EO sterilization process was historically constant and stable prior to 1978. Yet, even the authors of the NIOSH study predict higher exposures before installation of engineering controls ("e.g., increased ventilation and better door seals") in 1978, when OSHA standards were higher.[9] **Below, we provide information on evolving regulatory standards, residue levels of EO, equipment, engineering and processing practices that indicate that the NIOSH exposure model incorrectly predicted that exposures would decrease in earlier years compared to the 1970s for the most exposed jobs (e.g. sterilizer operator). In general, *underestimating exposures will overestimate risk*, and the EPA cancer risk assessment guidelines caution that use of a supralinear model will further exacerbate the impact of these exposure errors.**

The rationale for selecting the supralinear spline model is based on incorrect statistical procedures and visual misrepresentation of the data. The EO IRIS Assessment incorrectly calculates the statistical significance (e.g., p- and AIC values) of the supralinear spline dose-response model because it fails to account for the statistical impact of the trial-and-error exploration of different arbitrary values used in the EO IRIS Assessment's dose-response model, such as the exposure level where the slope changes in the model from a very steep slope to a shallow slope (i.e. the "knot").[10] In addition, the figures used to compare visual fits use categorical data rather than the individual cases that were modeled. Once the individual cases are used, the log-linear Cox model fits the data just as well as the more complex and ill-advised supralinear spline model. The log-linear Cox model best meets the objective of selecting the more parsimonious model with fewer assumptions and variables.

Biologically, selection of the log-linear Cox model is more consistent with the mode of action for EO. This is supported by the EO IRIS Assessment, which concludes it is "highly plausible that the dose-response relationship over the endogenous range is sublinear … that is, that the slope of the dose-response relationship for risk per adduct would increase as the level of endogenous adducts increases."[11]

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[9] Steenland K, Stayner L, Greife A, Halperin W, Hayes R, Hornung R, Nowlin S. 1991. Mortality among workers exposed to ethylene oxide. N Engl J Med, 324(20): 1402-07.

[10] *See, e.g.,* Li W, He C, Freudenberg J. 2011. A mathematical framework for examining whether a minimum number of chiasmata is required per metacentric chromosome or chromosome arm in human. Genomics, 97(3): 186-92.

[11] EO IRIS Assessment, at 4-95.

Both the UCC and NIOSH studies should be included in the dose-response modeling so that the risk estimates are based on the best available human data. Although the NIOSH study cohort is much larger, both studies have comparable power for males when considering the number of events of interest, i.e., lymphohematopoietic tissue cancers. The EO IRIS Assessment excludes the UCC cohort based primarily on a comparison of the exposure assessments for both studies. The EO IRIS Assessment dismisses the UCC exposure estimates as "crude," "largely-uninformative," "much less extensive," and "greater likelihood for exposure misclassification," as compared with the NIOSH study, which is described as "well-validated" and "high-quality." These descriptions lack objectivity and obscure the fact that the majority of the UCC cohort exposure estimates are based on contemporary data from different plants with identical or comparable processes. **Although the NIOSH exposure model was validated with data after 1978, there were no contemporary data between the late 1930s and mid-1970s to validate the final model. Thus, the UCC exposure assessment uncertainties are no greater than the NIOSH study uncertainties and, therefore, are not a valid reason to exclude the UCC cohort.**

The EPA Science Advisory Board's (SAB) peer review of the draft EO IRIS Assessment did not remedy the shortcomings of the final EO IRIS Assessment. The presumption of objectivity that sometimes attaches to documents that have been peer reviewed does not apply in this case because authors of the NIOSH study influenced the analysis of the data as well as the responses to the SAB's comments. This influence compromised the objectivity and independent analysis of the NIOSH study, and especially the NIOSH exposure model, in the draft and final EO IRIS Assessments.

II. The 2014 NATA and the EO IRIS Assessment

The 2014 NATA uses emissions information to help state, local, and tribal air agencies identify which pollutants, emission sources, and places may warrant a better understanding for any possible risks to public health from air toxics. EPA further uses NATA results to improve data in emission inventories; identify where to expand air toxics monitoring; help target risk reduction activities; identify pollutants and source types of greatest concern; help decide what other data to collect; better understand risks from air toxics; and work with communities to design their own assessment.

The 2014 NATA results list EO emissions information across a range of categories, including location, cancer risks, hazard quotients, source type (e.g., stationary sources, mobile, airports, etc.). In building the NATA, EPA must select specific risk levels for certain air toxics that can lead to determinations of acceptable or unacceptable thresholds. Since air toxics have no universal, predefined risk levels that clearly represent acceptable or unacceptable thresholds,

EPA makes case-specific determinations and general presumptions that apply to certain regulatory programs that further inform the interpretation of risk in the NATA. These benchmarks are drawn from a range of sources and updated. EPA notes that several substances' benchmarks were updated since the 2011 NATA, including EO. Specifically, EPA states that its risk value for EO was updated in 2016—the newly finalized IRIS value. As such, EPA updated its cancer risk calculations to reflect this new updated benchmark value. Due to the use of the EO IRIS value, more areas show elevated risks driven by EO in the 2014 NATA than in the 2011 NATA, even if emissions levels have stayed the same, or even decreased, in these areas.

The alleged elevated cancer risk driven by EO in the 2014 NATA has already caused alarm in some communities around facilities with EO emissions. This, in turn, has created media attention, and coverage of the issue has created further confusion and concern in the surrounding community. All of this could have been avoided had EPA relied on the best available science in calculating the unit risk estimate for cancer.

As discussed in detail below, the use of the updated EO IRIS value in the 2014 NATA and its Technical Support Document is extremely problematic given the EO IRIS Assessment's numerous shortcomings. A simple comparison of the results of the EO IRIS Assessment to the "real world," however, demonstrates its lack of credibility. Specifically, the RSC is 19,000 times *lower* than the normal, endogenous levels of EO in the human body. Likewise, the RSC is orders of magnitude *lower* than ambient levels of EO. Thus, if the EO IRIS Assessment is to be believed, normal human metabolism and/or breathing ambient air, without more, is sufficient to cause cancer. It strains scientific credibility to conclude that the EO IRIS Assessment presents a legitimate basis for determining risk for EO.

III. Request for Correction

The 2014 NATA relies upon the EO IRIS Assessment's inhalation URE of 5×10^{-3} per $\mu g/m^3$ to calculate EO risk. This URE implies a corresponding RSC of 0.1 ppt. The use of these values, however, results in inaccurate and misleading conclusions about EO risk because they are not supported by the scientific data. The RSC is also unrealistic, given that it is orders of magnitude lower than levels of EO in ambient air and levels that are consistent with normal, endogenous levels of EO present in human bodies.

A more reasonable and scientifically supportable approach to an exposure response analysis yields ranges for the MLE (1.5-9.2 ppb) and LEC (0.5-1.2 ppb) that are more than three orders of magnitude greater than the RSC.[12] Moreover, the ranges of MLE and LEC values are

[12] Valdez-Flores et al. (2010).

conservative because (a) extra risk was calculated despite no statistically significant slope in the exposure-response analyses; (b) the NIOSH data was included without adjustment for likelihood of underestimation of exposures; and (c) the limited evidence of cancer risk based on the entire body of epidemiologic evidence (see Appendix 2). The 2014 NATA risk estimates for EO should be withdrawn and corrected to reflect these risk values. Moreover, EPA should not use the EO IRIS Assessment's RSC of 0.1 ppt or URE of 5 x 10^{-3} per $\mu g/m^3$ to calculate EO risk in its ongoing CAA Section 112 risk and technology review or other rulemakings.

A. The 2014 NATA Does Not Meet the Objectivity, Integrity, and Utility Requirements of the IQA and the OMB and EPA Guidelines.

Congress enacted the Information Quality Act (IQA) to "ensur[e,] and maximiz[e,] the quality, objectivity, utility and integrity of information (including statistical information) disseminated by Federal agencies" such as EPA.[13] The IQA required OMB to issue government-wide guidance, which each federal agency was to follow in its issuance of its own guidelines. The purpose of the EPA Guidelines is to apply the OMB Guidelines to the Agency's particular circumstances, and to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information … disseminated by the agency that does not comply with the [OMB] guidelines…."[14] The 2014 NATA, therefore, must meet the OMB Guidelines as well as the EPA Guidelines.

OMB Guidelines include clear definitions to guide agency practices in adhering to the IQA. These include:

- "'Information' means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms."[15]

- "'Influential,' when used in the phrase 'influential scientific, financial, or statistical information,' means that the agency can reasonably determine that dissemination of the information will have a clear and substantial impact on important public policies or important private sector decisions."[16]

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[13] *See* Pub. L. No. 106-554. The IQA was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. §3501 et seq., which requires OMB, among other things, to "develop and oversee the implementation of policies, principles, standards, and guidelines to …apply to Federal agency dissemination of public information."

[14] Pub. L. No. 106-554.

[15] OMB Guidelines, at 8460.

[16] *Id.*

- "'Objectivity' involves two distinct elements, presentation and substance. 'Objectivity' includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner.... In addition 'Objectivity' involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods."[17]

- "'Utility' refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. As a result, when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information."[18]

The 2014 NATA is influential scientific risk assessment information and must adhere to a rigorous standard of quality.[19] The 2014 NATA is "influential" scientific risk assessment information as set forth in the EPA Guidelines because it "will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions" and involves "controversial scientific ... issues."[20] Results from the NATA are used by government agencies, non-governmental organizations, and air quality experts to gauge which hazardous air pollutants (HAP) and emission sources may raise health risks in certain places. These places are then given more attention and EPA uses the NATA to, among other things, target ways to achieve risk reduction.

The NATA can also lead to the development of local community-supported plans to reduce emissions as presented in each NATA version's results. Additionally, the National Research Council (NRC) has recognized the NATA as one of the largest EPA efforts to "develop baseline cancer risk estimates and hazard index calculations using dose-response information and exposure estimates."[21] In this context, NRC further acknowledges the importance of the NATA as a "tool for exploring control priorities" and its function "as a preliminary attempt to establish a

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[17] *Id.* at 8459.

[18] *Id.*

[19] Quality includes objectivity, utility, and integrity.

[20] *See* EPA Guidelines, at 19-20 (internal citations omitted); OMB Guidelines, at 8455.

[21] National Research Council, "Air Quality Management In the United States" (2004), at 247. Available at https://www.nap.edu/read/10728/chapter/1.

baseline for tracking progress in reducing HAP emissions."[22] Therefore, the 2014 NATA, and its underlying data, must adhere to a rigorous standard of quality, including meeting the higher standard of reproducibility.

With regard to the analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, the OMB and EPA Guidelines also require either adoption or adaption to "the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B))."[23] In ensuring the objectivity of influential scientific risk information (i.e., the substance of the information is accurate, reliable and unbiased), the EPA Guidelines have adapted these principles by requiring the use of the "best available science and supporting studies" and the collection of data using by "accepted methods or the best available methods" using "a 'weight-of-evidence' approach that considers all relevant information and its quality."[24]

EPA has failed to apply a transparent and systematic weight-of-evidence approach in assessing the cancer risks of EO exposures in the 2014 NATA. Moreover, as detailed below, because the 2014 NATA relies upon the EO IRIS Assessment to determine the risk value for EO, the 2014 NATA is not based on the best available science.

B. The EO IRIS Assessment Does Not Meet Scientific Standards from Multiple Standpoints.

The EO IRIS Assessment is not the best available science because it: (1) exclusively relies on a NIOSH study despite its flawed exposure assessment; and (2) applies a supra-linear spline model, which is implausible based on the epidemiological and biological evidence and deficient due to statistical miscalculations and visual misrepresentations.

1. The EO IRIS Assessment incorrectly describes the NIOSH exposure model as a "state-of-the-art" validated regression model to estimate historical exposures prior to 1978. In fact, this "state-of-the-art" validated model was tested with post-1978 data only and arbitrarily altered for years prior to 1978. Specifically, a variable considered to be a major predictor of exposure after 1978 was not allowed in the model to impact exposures prior to 1978. The

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[22] *Id.*

[23] *See* EPA Guidelines, at 22-23; OMB Guidelines, at 8460.

[24] *See* EPA Guidelines, at 21-22. "In this approach, a well-developed, peer-reviewed study would generally be accorded greater weight than information from a less well-developed study that had not been peer-reviewed, but both studies would be considered." *Id.* at 26. The definition of best available science mirrors that articulated in Chlorine Chemistry Council v. EPA, 206 F.3d 1286 (D.C. Cir. 2000), referring to "the availability at the time an assessment is made." *See* EPA Guidelines, at 23.

reliability, validation and likelihood of exposure misclassification prior to 1978 were not objectively evaluated.

2. The results of NIOSH's statistical model for exposures prior to 1978 were not provided in the 2014 Draft EO IRIS Assessment or in the cited NIOSH publications. In the appendices of the final EO IRIS Assessment, two new figures (Figures D-22 and D-33) present new information on estimated exposures by worker, but no explanation or critical evaluation was added. There is a lack of transparency in the EO IRIS Assessment of these influential data used to derive the EO cancer slope factor.

3. The EO IRIS Assessment repeatedly asserts that the NIOSH exposure estimates were well-validated using a state-of-the-art model, when in fact there was no validation of exposure estimates prior to 1978. These assertions regarding verification procedures are incorrect for the late 1930s to 1978.

4. In response to public and SAB comments questioning the lower than expected exposures in earlier years predicted by the statistical regression model, the IRIS Program states that the decrease is related to the sterilizer volume. In other words, the model predicts that smaller sterilizer volume results in lower exposures. This response essentially uses the output of the model to answer a question about whether the model assumptions are correct, instead of independently verifying the validity of these assumptions. This circular reasoning does not address the underlying concern of whether the model assumption that Sterilizer Volume has an inverted parabolic (that is, an upside-down U-shaped) relationship with predicted EO exposure is correct. It also does not address whether other factors that might result in increased exposure during early years were properly accounted for in the model.

5. The EO IRIS Assessment makes the unsubstantiated claim that "the sterilization processes used by the NIOSH cohort workers were fairly constant historically, unlike chemical production processes, which likely involved much higher and more variable exposure levels in the past."[25] In fact, there was an evolution in technology and practices associated with the sterilization processes between the late 1930s and early 1970s. Data and information from industrial sterilization operators and the literature refute this claim.

6. Comparisons of relative reliability made between the NIOSH and UCC studies are inaccurate. These comparisons were a key basis upon which the IRIS Program rejected the UCC Study as a source of epidemiology study data for cancer risk assessment. The EO IRIS Assessment does not acknowledge and appropriately consider limitations of the NIOSH

[25] EO IRIS Assessment, at 4-4.

exposure assessment posed by low extrapolations of NIOSH cohort exposures to EO prior to the late 1970s without any corroborating data or any supporting engineering/process considerations derived from or directly relevant to that period of time.

7. The EO IRIS Assessment relies solely on the NIOSH study of sterilant workers and fails to incorporate the important findings from the UCC study of workers in EO producing and using operations. The IRIS Program considered and characterized three factors in its selection of the NIOSH study: cohort size, exposure data, and confounding. Based on these factors, the IRIS Program dismissed the UCC study as a basis for EO cancer risk estimation. In considering cohort size, the IRIS Program ignored the most important comparison—the number of lymphohematopoietic tissue cancers, not the total cohort size.

8. The use of the supralinear spline model for the lymphoid and breast cancers in the final EO IRIS Assessment is based on an invalid statistical analysis. Because the analysis did not correctly calculate degrees of freedom associated with that fitted model, it contains erroneous measures of absolute and relative goodness of fit of that model. When both the p-values and Akaike Information Criterion (AIC) values characterizing fit quality are corrected, the supralinear spline model does not fit the NIOSH lymphoid tumor data statistically significantly better than the log-linear Cox model.

9. The selection of the supralinear spline model for the lymphoid tumors is also based on misleading illustrations of "visual fits" that do not convey either the actual data that were fit or the relative goodness of fit to these data of log-linear and supralinear spline models. Only in a footnote does the IRIS Program indicate that the visual comparison misrepresents the log-linear model being compared. Consequently, and erroneously, the fit to the data appears far worse than the supralinear spline model. The data plotted in that figure also were summary data that misrepresent the true magnitude of the scatter of the data that were used for model fitting.

10. The selection of a spline model as the preferred model for EO cancer risk estimation assumes a supralinear increase in tumor response in the low-dose exposure region with a subsequent plateauing of response at higher exposures. The body of cancer epidemiologic studies, including the NIOSH studies, does not support such a pattern of risk. While certain NIOSH sub-analyses suggest increases in male lymphoid tumors and female breast cancers, the findings are limited to the highest cumulative exposure groups, not the lowest.

11. The use of a supralinear spline model for cancer risk estimation is inconsistent with the assumed mode-of-action of EO toxicity and tumorigenicity. Such a model predicts higher risk at low exposures compared to risks predicted at higher exposures, which is contradicted by the well-understood mode of action of EO in experimental animals and humans

as described in the EO IRIS Assessment. Thus, the EO IRIS Assessment relies on human cancer risk estimates based on spline-model dose-response extrapolations that are internally inconsistent with its own evaluation of the mode of action of EO. The mean air concentration equivalent to the endogenous concentration in non-smoking humans with no known EO exposures is 1.9 ppb (range 0.13-6.9 ppb; continuous), which is 19,000 times greater than the EO IRIS RSC of 0.1 ppt.[26] An alternative LEC (1/million) of 0.5-1.2 ppb is a more pragmatic, science-based approach for EO risk assessment.

12. The statistical, epidemiological and biological evidence does not support the selection of supralinear spline models to fit the NIOSH study data in the EO IRIS Assessment. A more scientifically sound conservative alternative is to use the Valdez-Flores et al. (2010) approach, which incorporates all the available data from the two strongest human studies (NIOSH and UCC). This approach has been adopted by the European Commission's Scientific Committee on Occupational Exposure Limits.[27]

IV. Because the 2014 NATA Relies Upon the EO IRIS Assessment to Determine the Risk Value for EO, the 2014 NATA Is Not Based on the Best Available Science.

1. The EO IRIS Assessment incorrectly describes the NIOSH exposure model as a "state-of-the-art" validated regression model to estimate historical exposures prior to 1978. In fact, this "state-of-the-art" validated model was tested with post-1978 data only and arbitrarily altered for years prior to 1978. Specifically, a variable considered to be a major predictor of exposure after 1978 was not allowed in the model to impact exposures prior to 1978. The reliability, validation and likelihood of exposure misclassification prior to 1978 were not objectively evaluated.

The EO IRIS Assessment's evaluation of the cancer potency of EO is dependent on an analysis of commercial sterilization worker exposure conducted by NIOSH. The NIOSH EO data for the sterilization work cohort were nearly all collected between 1978 and 1986 at 20 different facilities, but included just seven mean values based on 23 exposure measurements for the period 1976-77.[28] Ultimately, of the 20 facilities, 16 facilities were eliminated from the

[26] Kirman CR, Hays SM. 2017. Derivation of endogenous equivalent values to support risk assessment and risk management decisions for an endogenous carcinogen: Ethylene oxide. Regul Toxicol Pharmacol, 91: 165-72.

[27] *See* Recommendation from the Scientific Committee on Occupational Exposure Limits for ethylene oxide, SCOEL/SUM/160 (June 2012).

[28] Hornung et al. (1994).

exposure assessment for lack of personal sampling, documentation of sampling, or links of sampling to job categories.

Based on the available worker data, the workers included in the NIOSH study cohort were employed in the sterilization industry as early as the 1930s. Noting that "there were no measurement data prior to 1976," Hornung et al. (1994) describe the statistical model[29] developed to estimate NIOSH EO-cohort worker exposures based on data collected after 1978. That model was applied to estimate worker exposures over a large timespan (1935-1975) during which not a single observed measurement was available to validate the application of that model extrapolation procedure.

Although the NIOSH statistical regression model estimated exposure measurements after 1977 with reasonable reliability, Hornung et al. (1994) highlighted that post-1978 regulatory standards and consequent progressively stringent operational EO-exposure controls accounted for the pronounced decreasing trend in measured NIOSH-cohort EO exposures that occurred after 1978. Prior to 1978, these EO standards and controls were largely or entirely absent. Thus, they were irrelevant to most of the 1935-1975 timespan, during which time the NIOSH statistical model was applied to estimate historical worker exposures without any empirical physical-modeling basis for direct validation.

The final statistical model selected to predict the natural logarithm (ln) of EO exposure included two nonlinearly modeled variables which were determined to be the two most EO-predictive variables identified: Calendar Year ("Year") and Sterilizer Volume ("Cubic Feet"). These two variables were each modeled to have an inverted parabolic relationship to predicted ln(EO) levels, resulting in predicted peak EO exposures to occur during 1978 as a function of Year. Hornung et al. (1994) note that their final statistical model arbitrarily set the value of Year to be 1978 for all years prior to 1978, explaining that:

> Since we felt that the decrease in ETO levels after 1978 (independent of engineering controls) was explained by improved work practices after ETO was identified as a potential carcinogen, we set each predicted ETO level prior to 1978 equal to the predicted level in 1978. Variation in exposure levels prior to 1978 were modeled as a function of the remaining terms in the model with the calendar year effect fixed at 1978. Therefore, there was no extrapolation by calendar year prior to 1978.

[29] Steenland NK, Stayner LC, Griefe AL. 1987. Assessing the feasibility of retrospective cohort studies. Am J Ind Med, 12: 419-30; Greife AL, Hornung RW, Stayner LG, Steenland KN. 1988. Development of a model for use in estimating exposure to ethylene oxide in a retrospective cohort mortality study. Scand J Work Environ Health, 14(Suppl 1): 29-30.

Thus, the "validated" model was arbitrarily and selectively altered for years prior to 1978 by fixing the calendar year value to 1978. Nonetheless, for the same period prior to 1978, the model still predicts that lower EO sterilizer volumes were associated with lower occupational EO exposures—a prediction made without any independent, pre-1978 measurement-based or physical-modeling-based evidence supporting such an association during that period. The IRIS Program should have questioned the reliability and validation of the model prior to 1978, and objectively considered the likelihood of exposure misclassification during this period.

2. **The results of NIOSH's statistical model for exposures prior to 1978 were not provided in the 2014 Draft EO IRIS Assessment or in the cited NIOSH publications. In the appendices of the final EO IRIS Assessment, two new figures (Figures D-22 and D-33) present new information on estimated exposures by worker, but no explanation or critical evaluation was added. There is a lack of transparency in the EO IRIS Assessment of these influential data used to derive the EO cancer slope factor.**

A basic standard quality expectation for a peer-reviewed publication of a statistical model for exposure is that the results section should include summary of the output of the model; in other words, the estimated exposures resulting from the model. Neither the NIOSH exposure modeling publications nor the NIOSH epidemiology studies that rely on this model provide any descriptive summary of exposures estimated by the model prior to the late 1970s. The IRIS Program should have independently evaluated the exposure data, especially after ACC provided the summary of NIOSH exposures by job (reprinted below as Figure 1).

Figures D22 and D23 in the EO IRIS Assessment are graphs of estimated annual exposures for the entire cohort by worker, but not by job. However, there is no discussion or analysis of these graphs in either Appendix D or the main report. These figures are less informative in understanding how the NIOSH exposure model estimated exposure by job because these figures are based on each worker who could have different job assignments. Nevertheless, the 95th percentile of annual exposures of the NIOSH cases in Figure D-23 has a very similar pattern of exposures as the job with the maximum exposure in Figure 1 below.

As described below, neither Hornung et al. (1994) nor the IRIS Program offer any realistic explanation for the counterintuitive trend backward in time from the late 1970s that is predicted by the NIOSH statistical regression model, other than such a trend just happens to be what that statistical model predicts. Thus, there is a lack of transparency and independent critical evaluation of the exposure estimates of the NIOSH exposure model in the EO IRIS Assessment.

Moreover, the derivation of the NIOSH statistical regression model can no longer be reproduced, because the raw data on which it was based no longer exist.[30]

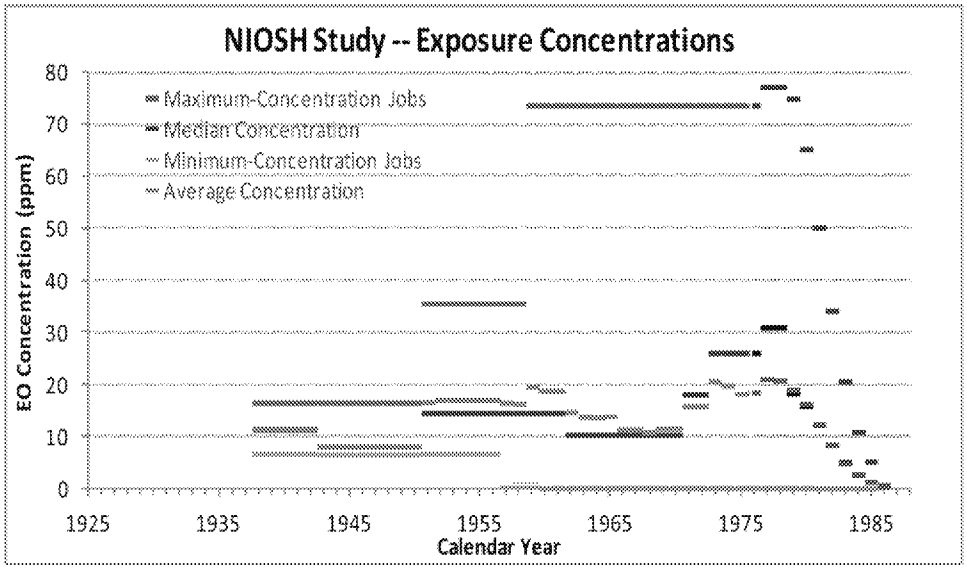

Figure 1. NIOSH statistical regression model predictions of 8-hour time-weighted average exposure to EO by job in each calendar year. This summary data for each job was provided by NIOSH and was used to estimate exposures for participants in the NIOSH cohort based on job code. This figure appeared on page 173 of Appendix M ("Comments on NIOSH Exposure Papers: Greife et al. (1988) and Hornung et al. (1994)") of Comments on the Revised External Review Draft Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Docket ID No. EPA-HQ-ORD-2006-0756 submitted to EPA by ACC on October 11, 2013, but did not appear either in Hornung et al. (1994) or any of the draft EO IRIS Assessments reviewed by SAB.

[30] Appendix H (Summary of 2007 External Peer Review and Public Comments And Disposition) of the EO IRIS Assessment states, "[i]n response to the panel's suggestion that the Hornung analysis represents an 'invaluable opportunity' for further analysis of the impact of possible errors in exposure estimation, the EPA investigated the possible use of the 'errors in variables' approach (page 27 of the panel report). Steenland visited the NIOSH offices in Cincinnati in order to review the data and assess whether it would support an errors-in-variables analysis. Unfortunately, the electronic data files used in the [NIOSH] exposure analysis were no longer available, so that analysis based on the errors-in-variables approach was not possible." *Id.* at H-28. Thus, the raw data on which NIOSH relied to derive its statistical regression model used to extrapolate historical NIOSH-cohort exposures to EO prior to the late-1970s, when measures of workplace EO first began to be made, no longer exist—implying that there is no longer any way to validate the claim by Hornung et al. (1994) that their model was able to predict the 85% of the variation in log values of EO concentrations measured starting in the late-1970s. Even if that claim were true, it has no logical bearing on the ability of that model to generate accurate extrapolations of occupational exposure to EO back in time prior to the late 1970s when, as emphasized by Hornung et al. (1994), occupational conditions were quite different because none or virtually none of many sterilization technology changes and sterilization workplace practices, which only began to be adopted starting in the late 1970s to greatly reduce EO exposures (as reflected by NIOSH-cohort exposure measures made starting in the late 1970s to which the NIOSH statistical regression model was fit), were in place prior to that time.

The pattern shown in Figure 1 indicates generally lower exposures for earlier time periods when the crudest technology was used under the least stringent worker protection standards. The SAB considered this pattern to be "surprising," as discussed in greater detail in Section 4, below. Indeed, the pattern of the NIOSH exposure data by job in Figure 1 is the reverse of patterns of historical exposure levels from published studies of exposures to volatile chemicals through time with improvements in technology and increased worker protection requirements[31] as illustrated in two relevant examples (Figures 2 and 3).

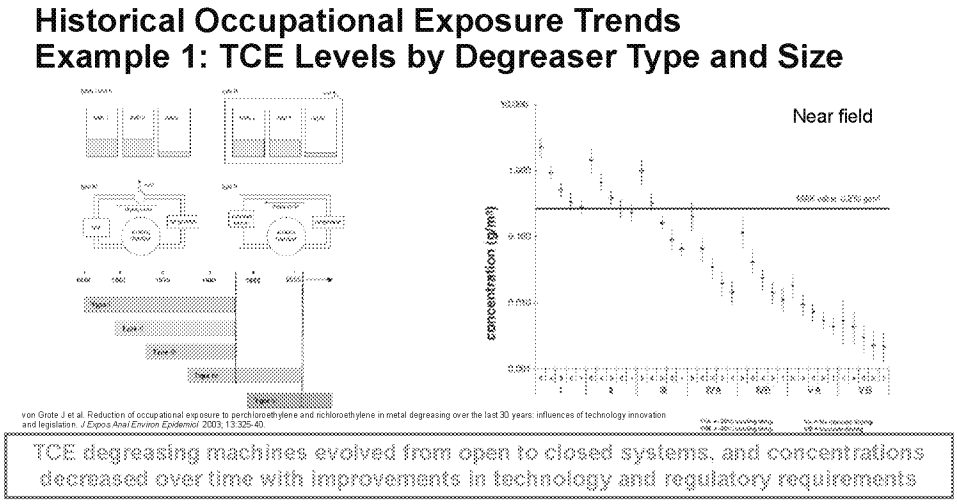

Figure 2. Historical occupational exposure trends, Example 1: TCE levels by degreaser type and size. Source: von Grote et al. (2003b).

[31] *E.g.*, von Grote JHM. 2003a. Occupational Exposure Assessment in Metal Degreasing and Dry Cleaning – Influences of Technology Innovation and Legislation. Doctoral Dissertation, Swiss Federal Institute of Technology, Zürich. Available at: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.628.1123&rep=rep1&type=pdf; von Grote J, Hürlimann C, Scheringer M, Hungerbühler K. 2003b. Reduction of occupational exposure to perchloroethylene and trichloroethylene in metal degreasing over the last 30 years: influences of technology innovation and legislation. J Expo Anal Environ Epidemiol, 13: 325-40; von Grote J, Hürlimann C, Scheringer M, Hunger K. 2006. Assessing occupational exposure to perchloroethylene in dry cleaning. J Occup Envir Hyg, 3: 606-19.

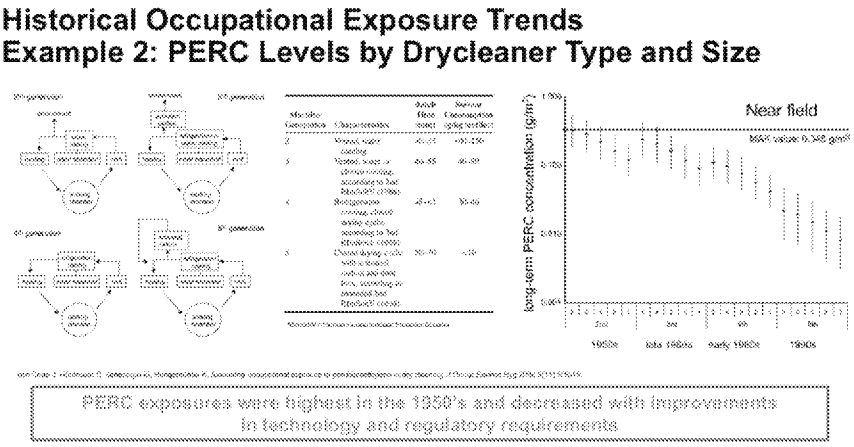

Figure 3. Historical occupational exposure trends, Example 2: PERC levels by dry cleaner type and size. Source: von Grote et al. (2006).

3. The EO IRIS Assessment repeatedly asserts that the NIOSH exposure estimates were well-validated using a state-of-the art model, when in fact there was no validation of exposure estimates prior to 1978. These assertions regarding verification procedures are incorrect for the late 1930s to 1978.

Assertions made in the EO IRIS Assessment about independent evaluation of model estimates are inaccurate. Table 1 lists the statements in the EO IRIS Assessment related to the UCC and NIOSH exposure assessments.

Table 1: List of EO IRIS Assessment statements regarding UCC or NIOSH exposure assessment

Page Number	Description of UCC exposure	Description of NIOSH exposure
1-1		Had a well-defined exposure assessment for individuals
1-2		"high-quality" study based on several attributes, including availability of individual worker exposure estimates from a high-quality exposure assessment
1-4		Retrospective exposure estimation is an inevitable source of uncertainty in this type of epidemiology study; however, the NIOSH investigators put extensive effort into addressing this issue by developing a state-of-the-art regression model to estimate unknown historical exposure levels using

Page Number	Description of UCC exposure	Description of NIOSH exposure
		variables, such as sterilizer size, for which historical data were available.
3-5	Crude exposure assessment, with a high potential for exposure misclassification	
3-6		… the exposure model and verification procedures are described in Greife et al. (1988) and Hornung et al. (1994). Briefly, a regression model was developed to allow estimation of exposure levels for time periods, facilities, and operations for which industrial hygiene data were unavailable. The data for the model consisted of 2,700 individual time-weighted exposure values for workers' personal breathing zones, acquired from 18 facilities between 1976 and 1985. The data were divided into two sets, one for developing the regression model and the second for testing it. Seven out of 23 independent variables tested for inclusion in the regression model were found to be significant predictors of EtO exposure and were included in the final model. This model predicted 85% of the variation in average EtO exposure levels.
3-7		Good-quality estimates of individual exposure
3-8	"cruder" especially for highest exposure	Based on a validated regression model
4-3 and 4-4	Exposure assessment is much less extensive than that used for the NIOSH cohort, with greater likelihood for exposure misclassification, especially in the earlier time periods when no measurements were available (1925-1973). Exposure estimation for the individual workers was based on a relatively crude exposure matrix that cross-classified three levels of exposure intensity with four time periods. The exposure estimates for 1974-1988 were based on measurements from air sampling at the West Virginia plants since 1976. The exposure	This is in contrast to the NIOSH exposure assessment in which exposure estimates were based on extensive sampling data and regression modeling. In addition, the sterilization processes used by the NIOSH cohort workers were fairly constant historically, unlike chemical production processes, which likely involved much higher and more variable exposure levels in the past.

Page Number	Description of UCC exposure	Description of NIOSH exposure
	estimates for 1957-1973 were based on measurements in a similar plant in Texas. The exposure estimates for 1940-1956 were based loosely on a "rough" estimate reported for chlorohydrin-based EtO production in a Swedish facility in the 1940s (Hogstedt et al., 1979). The exposure estimates for 1925-1939 were further conjectures based on the Swedish 1940s estimate. Thus, for the two earliest time periods (19251939 and 19401956) at least, the exposure estimates are highly uncertain. (See Section A.2.20 of Appendix A for a more detailed discussion of the exposure assessment for the UCC cohort.)	
4-5		It was judged to be substantially superior to the UCC study with respect to a number of key considerations in particular, in order of importance: (1) quality of the exposure estimates …
4-60	largely uninformative in terms of assessing the unit risk estimates derived from the NIOSH study because of the crude exposure assessment used in the UCC study	

The EO IRIS Assessment does not critically evaluate the uncertainties of the NIOSH linear regression model, and does not clarify that the NIOSH model was not validated with any data prior to 1978. In the appendices, similar deficiencies pertain to assertions concerning measures applied purportedly to validate the NIOSH statistical regression model,[32] purported empirical and unbiased bases for the NIOSH statistical regression model,[33] and purportedly unlikely inaccurate characterization of exposure by the NIOSH statistical regression model and its purported validation despite nonexistence of original data upon which it was derived.[34]

NIOSH historical extrapolations of occupational EO exposures prior to the late-1970s, were, as described by Hornung et al. (1994), "derived from a regression model based on

[32] *See* EO IRIS Assessment, Appendix A, at A-14.

[33] *See id.*, Appendix D, at D-75.

[34] *See id.*, Appendix H, at H-27 – H-28.

observed measurements." This regression model was applied to extrapolate worker exposures over a large timespan (1935-1975), during which not a single observed measurement was available to validate the application of that extrapolation procedure, and only a small subset of measures was available during 1976-77. Although the NIOSH statistical regression model reliably estimated exposure measurements made after 1977, Hornung et al. (1994) highlighted that post-1977 regulatory standards and consequent progressively stringent operational EO-exposure controls accounted for the pronounced decreasing trend in measured NIOSH-cohort EO exposures that occurred starting in 1978. Prior to 1978, EO standards and controls were largely or entirely absent. Thus, they were irrelevant to most of the 1935-1975 timespan.

4. **In response to public and SAB comments questioning the lower than expected exposures in earlier years predicted by the statistical regression model, the IRIS Program states that the decrease is related to the sterilizer volume. In other words, the model predicts that smaller sterilizer volume results in lower exposures. This response essentially uses the output of the model to answer a question about whether the model assumptions are correct, instead of independently verifying the validity of these assumptions. This circular reasoning does not address the underlying concern of whether the model assumption that Sterilizer Volume has an inverted parabolic (that is, an upside-down U-shaped) relationship with predicted EO exposure is correct. It also does not address whether other factors that might result in increased exposure during early years were properly accounted for in the model.**

During the review of the 2014 draft EO IRIS Assessment, the SAB questioned the general pattern of historical exposures that were lower in some or all years prior to 1975. The SAB had specifically requested EPA to address this issue in a substantive manner (i.e., using historical, physicochemical, and/or engineering facts or models independent of the NIOSH statistical regression model itself). The SAB noted:

> The SAB is also concerned that public commenters had exposure data from the NIOSH cohort that the EPA did not have. For instance, a few selected graphs were presented in **public comments to the Augmented CAAC that indicated exposure predictions for** four jobs in two of the fourteen plants **showed lower exposures in some or all years prior to 1975. The SAB was provided only a few carefully selected examples, and thus was unable to assess the extent of these surprising data.** This is an uncertainty that can easily be ruled out. **Upon reviewing the model equation in Hornung et al. (1994), <u>the SAB finds the surprising historical behavior to be unlikely</u>** and could be explained by changes

> in processes in specific plants, rather than some failure of the model to capture historically larger exposures. The EPA should ensure that they obtain all relevant data released from NIOSH to members of the public.[35]

Figure 1 above shows that the "surprising historical behavior" characterized by the SAB as "unlikely" does not pertain only to a few specific jobs in different plants, but is a general pattern going back in time prior to the late-1970s. EPA's response to the SAB's concern was:

> contrary to public comments made at the SAB meeting, the NIOSH EtO exposure patterns are not anomalous, but rather reflect the underlying changes in variables predicting exposure over time. One of the principal drivers of the NIOSH exposure levels was the cubic feet of the sterilizers used [see Table III, Hornung et al. (1994)]. It was not uncommon in these plants for sterilizer volume to have increased over time as the demand for EtO-sterilized products increased. **Increased sterilizer volume generally resulted in higher predicted average exposures until the late 1970s, when increased controls were used after it became known that EtO might be dangerous**.[36]

The IRIS Program provided quantitative examples illustrating the point emphasized in the quote above for two different plants, in effect illustrating that the response is consistent with the NIOSH statistical regression model defined in Tables III and VI of Hornung et al. (1994). However, the response is circular and, thus, nonresponsive to the SAB concern, because it relies on the same statistical regression model to attempt to validate its assertion that "increased sterilizer volume generally resulted in higher predicted average exposures until the late 1970s."

The NIOSH regression model predicts that EO exposure levels are proportional to an inverted parabolic (upside-down U-shaped) function of sterilizer volume. This function reaches a maximum predicted EO exposure level at a sterilizer volume value of approximately 4,000 ft^3. This regression function is estimated entirely from measurement data obtained nearly exclusively after 1977. However, NIOSH does not explain a plausible physical basis for this complex exposure/volume relationship observed nearly exclusively after 1977. Although this relationship explains a statistically significant amount of variation in the available EO measures, NIOSH offers no convincing evidence that such a relationship must also reliably apply to periods prior to 1978. Hornung et al. (1994) point out that regulatory constraints, sterilization operation, and

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[35] Science Advisory Board Review of the EPA's Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Revised External Review Draft - August 2014) (Aug. 7, 2015), EPA-SAB-15-012 (2015 SAB Review), at 18 (emphasis added).

[36] EO IRIS Assessment, Appendix I, at I-26 – I-27 (emphasis added).

sterilization technology all differed greatly from prior to 1978 vs. in/after 1978; they emphasize that in 1978, efforts to control EO exposure began to be implemented on an accelerated basis.

None of the three methods applied by Hornung et al. (1994) to validate their statistical regression model[37] is capable of providing any direct form of validation or verification of historical EO exposures actually incurred by the NIOSH cohort. The NIOSH regression model makes that prediction, based on its statistical regression fit to historical EO measurements that only began in the late 1970s, without any other empirical, physical-modeling, or engineering rationale upon which to establish even the plausibility of that model prediction (e.g., based on independent published literature, historical data, physical/compartmental modeling, or any type of reasoning whatsoever bearing on whether sterilizer chamber volume per se is or is not expected to have correlated with or determined historical EO exposure levels prior to the late-1970s).

Hornung et al. (1994) note that pounds of EO used each year served as a surrogate measure of potential EO exposure, but that since such EO utilization data "were not available for all plants in the study, the size of the sterilizer units (in cubic feet of capacity) was substituted after we determined that there was a high degree of correlation between these two variables." However, in order to achieve sterilization efficacy, EO concentrations used in sterilization chambers have remained approximately constant over time—*regardless* of the volume of sterilization chambers used—except insofar as EO concentrations used are well known (and were reported by experienced EO industry workers in interviews discussed below) to have *increased* going backwards in time from the late 1970s, because higher concentrations of EO were used in earlier decades during the evolution of sterilization operations and technology.

Likewise, because utilization of internal sterilization chamber volume has remained fairly constant over time, independent of reduced chamber volume going back in time from the late 1970s, opening of each chamber door and storage of off-gassing sterilized materials resulted in similar immediate concentrations of EO exposure to nearby workers. Reduced chamber volumes going back in time implied that greater numbers of such smaller chambers had to be used to process approximately the same load of sterilized material per plant. To the extent that smaller amounts of sterilized material were processed by plants earlier in time, then those

[37] Hornung et al. (1994) explain that, in the absence of historical exposure data to perform such verification, they applied a three-phase evaluation procedure consisting of 1) a statistical cross-validation procedure applied to a subset of post-1978 empirical measures of EO, 2) comparison of predictions made a by "a panel of 11 industrial hygienists familiar with ethylene oxide levels in the sterilization industry" to the latter subset of empirical data gathered subsequent to 1978, and 3) an evaluation of the ability of the statistical model to explain the empirical variance exhibited by the entire set of empirical measures of (as noted above, nearly all post-1977) EO exposures available for the NIOSH cohort.

processes are certain to have occurred in smaller facilities, implying that going back in time since the late-1970s there was either an increase (as noted above) or no substantial change in the mass-of-EO-used to workspace-volume ratio that determined the time-weighted average EO concentration to which sterilization workers were exposed throughout that period (particularly for the most heavily exposed workers).

Of greater significance, EPA's response does not take into account critical variables, such as level of EO residue in sterilized materials based on the number of air washes used, the length of time sterilized materials were stored prior to return to customers, and where they were stored relative to chamber operations—variables that changed substantially over the decades of EO sterilization prior to the late 1970s. Historical (pre-late-1970s) estimates of NIOSH cohort EO exposure rely on historical extrapolations made only by the NIOSH statistical regression model that were driven primarily by a correlation primarily between chamber volume and post-late-1970s measures of EO exposure. Operational changes that could have influenced EO exposure concentrations prior to 1976/78 were not investigated.

Even the NIOSH study expected higher historical exposures that would be influenced by the absence of engineering and regulatory controls: "Exposure levels are likely to have been higher [than "the late 1970s"], however, before the installation of engineering controls, when the OSHA standard was 50 ppm instead of the present 1 ppm."[38] Moreover, in the 1940s and 1950s, the MAC-TWA and TLV-TWA were 100 ppm.[39] In 1978, the U.S. Food and Drug Administration (FDA) published proposed "maximum residue limits" of 5-250 ppm for medical devices for human use that are sterilized with EO. Prior to 1978, there were no regulatory standards to reduce residues on medical devices, so the residues were around 10–30,000 ppm depending on the type of material.[40] But the IRIS Program failed to take this information into account when modeling the data.

5. **The EO IRIS Assessment makes the unsubstantiated claim that "the sterilization processes used by the NIOSH cohort workers were fairly constant historically, unlike chemical production processes, which likely involved much higher and more variable exposure levels in the past."[41] In**

[38] Steenland K, Stayner L, Greife A, Halperin W, Hayes R, Hornung R, Nowlin S. 1991. Mortality among workers exposed to ethylene oxide. N Engl J Med, 324(20): 1402-07, at 1406.

[39] ACGIH. 2001. Ethylene Oxide: TLV® Chemical Substances 7th Edition Documentation.

[40] Ernst RR and Whitbourne JE. 1971. Toxic residuals. In the Study of the requirements, preliminary concepts, and feasibility of a new system to process medical/surgical supplies in the field, pp. 46-57, Appendix pp. 1-2, Contract No. DADA17-70-C-0072. U.S. Army Medical R&D Command, Washington, D.C. (Defense Documentation Center Accession No. AD890320 and AD890321).

[41] EO IRIS Assessment, at 4-4.

fact, there was an evolution in technology and practices associated with the sterilization processes between the late 1930s and early 1970s. Data and information from industrial sterilization operators and the literature refute this claim.

Interviews conducted by Exponent, Inc. with three former sterilization operators who began work in the mid-1960s and early to mid-1970s (one was a member of the NIOSH cohort) confirmed operational differences in the sterilization operations in the 1960s and 1970s, and in earlier decades, relative to operations post-1978. This new interview information is supported by information and data in the technical literature on sterilization operations in early decades, including high EO residue levels in and rates of EO off-gassing from EO-sterilized medical materials,[42] and by current quantitative measures of in-chamber EO concentration during sterilization operations after single and multiple air washes that were transmitted to Exponent, Inc. by an industrial sterilization company. These data indicate that the EO IRIS Assessment's assumption that the sterilization processes were fairly constant between the late 1930s and early 1970s is incorrect.

These data also indicate that the variables in the NIOSH model that predicted exposures after the mid-1970s do not capture important potential sources of exposures to sterilizer operators prior to the 1970s:

a. Technology improvements for worker protection such as back venting and use of aeration processing rooms to degas sterilized materials were implemented post 1978. Thus, the presence or absence of back venting or ventilated aeration rooms may help discriminate exposures after 1978, but not between the late 1930s and 1977.

b. Pre-1978 commercial sterilization operations typically included at most only a single post sterilization air wash (relative to numerous washes used typically in later decades); in a current sterilization unit using 100% EO, an EO concentration

[42] Perkins JJ. 1969. Principles and Methods of Sterilization in Health Sciences, 2nd ed. Charles C. Thomas, Springfield, IL; Bruch CW. 1972. Toxicity of ethylene oxide residues. In: Phillips GB, Miller WS, eds. Industrial sterilization, Duke University Press, Durham, NC, at 119-23; Bruch CW. 1981. Ethylene Oxide sterilization—technology and regulation. Industrial ethylene oxide sterilization of medical devices: process design, validation, routine sterilization, AAMI Technological Assessment. Report No. 1-81. Arlington, VA: Association for the Advancement of Medical Instrumentation, at 3-5; Roberts RB, Rendell-Baker L. 1972. Aeration after ethylene oxide sterilisation. Failure of repeated vacuum cycles to influence aeration time after ethylene oxide sterilisation. Anesthesiol, 27(3): 278-82; Stetson JB, Whitbourne JE, Eastman C. 1976. Ethylene oxide degassing of rubber and plastic materials. Anesthesiol, 44(2): 174-80; White JD. 1977. Standard aeration for gas-sterilized plastics. J Hyg Camb, 79: 225-32.

of 17,200 ppm was measured in chamber air after a single wash cycle. Fewer wash cycles result in much higher peak exposures when opening the chamber doors, as well as higher residue levels remaining on the pallets of sterilized material. These higher residue levels contribute to higher exposure levels to those working in areas where pallets are stored.

c. Most 1960s and 1970s operations had evolved to storing the sterilized materials during degassing in a separate room from chamber operations, while operations in earlier decades had chamber operations and sterilized material stored in the same workspace. In the 1950s and 1960s, sterilizer operators would be expected to have higher exposures than in the 1970s because there was one (or no) air washes and the sterilized pallets with high residue levels were often stored in the same room as the chambers.

d. Systematic application of forced and efficient ventilation where sterilizers were operating and where treated pallets were stored was rare or absent prior to the mid-1970s.

e. The period of degassing of sterilized materials was generally about 7 days during the mid-1960s and 1970s, but was ≤1 day in earlier decades. This indicates that the levels of residues in the sterilized materials and, hence, exposures were consistently high in earlier decades.

f. Although with increasing time prior to the mid-1970s sterilization operations involved smaller sterilizers (i.e., having smaller sterilizer chamber volumes), sterilizer operations involved less mechanized or non-mechanized processes, less- or non-ventilated chamber and storage operations, more leaky EO containment during sterilization, and more direct operator exposure to EO vapor (e.g., during change of filters contacting liquid EO and manual connection/disconnection of EO tanks)—factors that likely acted jointly to generate EO exposures to sterilizer operators and other related workers that were greater prior to the late 1970s than during later periods.

g. According to interviewed operators with decades of experience in the EO sterilization industry, concentrations of EO applied in sterilizers currently and since the late 1970s (400–600 mg/L) have been lower by a factor of roughly 1.5 than those applied during earlier decades, and resulting chamber concentrations of EO upon opening of sterilizer chamber doors (which at that time were not actively

ventilated) thus are likely to have been equal to or (with increasing likelihood going back further in time) greater than those that occurred during 1978.

Each of these factors taken alone or in combination indicate that, compared to the sterilization worker environment starting in 1978, when technology improvements and regulatory controls were introduced with increasing frequency and stringency, it is highly probable that greater EO concentrations occurred in the sterilization worker environment from the mid-1960s to the late 1970s. Moreover, it is virtually certain that even greater EO concentrations occurred in the sterilization worker environment prior to the mid-1960s, contrary to trends in occupational exposures during those times that were extrapolated using the NIOSH statistical regression model.

The new information summarized above confirms that the SAB's concern was not effectively addressed by the IRIS Program, and therefore all assessments of EO cancer risk derived using NIOSH epidemiological study data are potentially confounded by greater magnitudes of uncertainty than are stated in the EO IRIS Assessment. These assessments are based on historical extrapolations of occupational exposures prior to the late-1970s produced by the NIOSH regression model and thus necessarily depend on the accuracy and reliability of those extrapolations. This major source of uncertainty in the EO IRIS Assessment is a key defect.

6. **Comparisons of relative reliability made between the NIOSH and UCC studies are inaccurate. These comparisons were a key basis upon which the IRIS Program rejected the UCC Study as a source of epidemiology study data for cancer risk assessment. The EO IRIS Assessment does not acknowledge and appropriately consider limitations of the NIOSH exposure assessment posed by low extrapolations of NIOSH cohort exposures to EO prior to the late 1970s without any corroborating data or any supporting engineering/process considerations derived from or directly relevant to that period of time**.

The EO IRIS Assessment argues inaccurately that the UCC exposure assessment was "too crude" to be used for exposure-response analysis (see Table 1). To the contrary, Greenberg et al. (1990) describe their categorization of departments into "high," "medium," and "low" categories based on a detailed reconstruction of processes using records and interviews of older employees.[43] The categorization was validated using frequencies of visits to the medical department for acute over exposures. The UCC exposure assessment was expanded to include

[43] Greenberg HL, Ott MG, Shore RE. 1990. Men assigned to ethylene oxide production or other ethylene oxide related chemical manufacturing: A mortality study. Br J Ind Med, 47: 221-30.

individual exposure estimates, as described in detail by Swaen et al. (2009).[44] All such efforts associated with epidemiology studies require assumptions and involve uncertainties.

The UCC study, however, includes actual UCC data based on monitoring data from the UCC Texas plant with very similar operations from as early as 1957. Estimates for the 1940-1956 period are based on the published literature for companies using a similar process for EO production. The greatest uncertainty is for 1925-39; however, only 4.8% of the cohort worked during that period. In contrast, **approximately 70% of the NIOSH cohort had workplace exposures prior to 1978, the period of unverified exposure estimates.**

The EO IRIS Assessment's criticism of the UCC approach, i.e., it includes data from a comparable plant that was not part of the cohort, is biased because NIOSH also used exposure data from plants that were not included in the cohort. The fact that UCC-cohort exposures estimated between 1957-1973 are based on contemporary actual exposure measurements obtained from a very similar plant is a major advantage (and certainly not a deficiency) of the UCC approach relative to the NIOSH study.

In contrast, critical limitations and uncertainties associated with NIOSH's statistical regression modeling for the period prior to the late 1970s (based entirely on a fit obtained to data gathered only starting in the late 1970s, since no actual measurements of EO exposure were available for the NIOSH cohort prior to that time) are not accurately characterized or even meaningfully acknowledged in the EO IRIS Assessment or in related NIOSH publications. For example, Hornung et al. (1994) did not reveal that their approach resulted in lower, rather than higher, exposures over the entire period addressed prior to the late 1970s, with no exposures prior to 1978 exceeding those that occurred in and also were reliably estimated for 1978. As noted above, the pattern predicted by the NIOSH statistical regression model conflicts with what is known about early processes in the sterilant industry, and was characterized as "surprising" and "unrealistic" by the SAB.

The EO IRIS Assessment is highly misleading because what it refers to as NIOSH statistical regression model "validation" was done only for its post-late-1970s predictions, since no earlier EO-measurement data were available. Model extrapolations of historical EO exposure prior to the late 1970s were conjectural, relying entirely on putative explanatory power of a regression model fit to EO-measurement data that, as acknowledged by Hornung et al. (1994), exhibited a steeply declining pattern of EO exposures over time post-1977 due to regulatory concerns and EO-control measures that simply did not exist previously. New information

[44] Swaen GM, Burns C, Teta JM, Bodner K, Keenan D, Bodnar CM. 2009. Mortality study update of ethylene oxide workers in chemical manufacturing: a 15 year update. J Occup Environ Med, 51(6): 714-23.

described above confirms that the NIOSH exposure estimates for periods prior to the late 1970s are substantially and unrealistically low, and therefore are likely to have biased all assessments of EO cancer risk that relied only on NIOSH cohort study data. Moreover, the IRIS Program has failed to investigate whether such bias may render assessments of EO cancer risk unreliable.

7. **The EO IRIS Assessment relies solely on the NIOSH study of sterilant workers and fails to incorporate the important findings from the UCC study of workers in EO producing and using operations. The IRIS Program considered and characterized three factors in its selection of the NIOSH study: cohort size, exposure data, and confounding. Based on these factors, the IRIS Program dismissed the UCC study as a basis for EO cancer risk estimation. In considering cohort size, the IRIS Program ignored the most important comparison—the number of lymphohematopoietic tissue cancers, not the total cohort size.**

As discussed in detail in the other sections, the NIOSH study does not have superior exposure data compared to the UCC study, so both studies have comparable applicability to risk assessment.

Cohort size is only one factor in assessing study informativeness. The most important factor is the number of events of interest, which for a mortality study is dependent on length of follow up and percent deceased. The most recent published study of the UCC cohort reports a sizeable number of deaths due to leukemia and lymphomas, comparable to the events among males in the NIOSH study that would make a meaningful contribution to the number of events for an exposure-response analysis.[45] Despite the smaller number of male workers in the UCC study, they have been followed for a longer period of time (37 yr on average compared to 25 yr for the NIOSH study) and include 51% deceased compared to 19% of the much younger NIOSH sterilant population. The EO IRIS Assessment criticizes the sample size in the UCC cohort, noting (erroneously) "only" 27 LHC cancers and 12 leukemias; the correct number of leukemias is 11 (EPA interchanged the numbers of leukemia and NHL deaths). However, the EO IRIS Assessment does not also note the male population of the NIOSH study had 37 LHC cancers and only 10 leukemias. Furthermore, no substantive criticisms of the NIOSH study appear in the EO IRIS Assessment, when in fact there are major uncertainties with respect to the NIOSH exposure estimates as described in detail above.

The EO IRIS Assessment raises concerns about confounding in the UCC study because of the presence of multiple chemicals in the workplace. This source of bias would only be

[45] Swaen et al. (2009).

expected when analyses yield positive findings, i.e., increases that may not be attributed to EO but to other chemicals. This, in fact, was identified by Greenberg et al. (1990), which reported an increase in leukemia and pancreatic cancer that was found to be attributable to exposures to one or more chemicals in the ethylene chlorohydrin production unit that was characterized as a "low" EO department. The 278 workers involved in that department were removed from the cohort and separately analyzed in a companion publication,[46] which verified increased risk observed by Greenberg et al. (1990). The remaining EO workers did not exhibit cancer increases in subsequent updates.[47] The three central reasons cited in the EO IRIS Assessment for excluding the UCC study are not defensible as explained above, and therefore indicate a biased preference for using the NIOSH study as a sole basis for EO cancer risk estimation.

In addition, the EO IRIS Assessment diminishes the value of the most recent UCC cohort study claiming they were followed so long that background rates of lymphoid tumors would be so large as to miss increased risks due to EO. The important factor is to have sufficient time since first exposure (latency). The 37 yr. average follow-up of Swaen et al. (2003) is not excessive in light of the fact that the most recent hires (1988) have 15 yr. follow-up at most. It is desirable to have 20-25 yr. follow-up for a cancer outcome of interest and even longer when exposures are lower as they were post-1976. Furthermore, there were two earlier studies of this cohort (Greenberg et al., 1990 and Teta et al., 1993) when the cohort was younger, which failed to identify EO-related cancer increases. These studies examined the findings by hire date, duration of exposure, time since first exposure and performed comparisons to the non-exposed chemical workers adjusting for age. It is implausible and speculative that the aging of the cohort masked significant EO-related cancer increases.

The UCC study should have been incorporated in both the hazard characterization and the exposure-response analysis. Consequently, the IRIS Program's handling of these key issues—cohort size, exposure estimation, and confounding—is incomplete, inaccurate, and biased.

8. The use of the supralinear spline model for the lymphoid and breast cancers in the final EO IRIS Assessment is based on an invalid statistical analysis. Because the analysis did not correctly calculate degrees of freedom associated with that fitted model, it contains erroneous measures of absolute and relative goodness of fit of that model. When both the p-values and Akaike

[46] Benson LO, Teta MJ. 1993. Mortality due to pancreatic and lymphopoietic cancers in chlorohydrin production workers. Br J Ind Med, 50: 710-16.

[47] Teta MJ, Benson LO, Vitale JN. 1993. Mortality study of ethylene oxide workers in chemical manufacturing: A 10 year update. Br J Ind Med, 50: 704-09; Swaen et al. (2009).

Information Criterion (AIC) values characterizing fit quality are corrected, the supralinear spline model does not fit the NIOSH lymphoid tumor data statistically significantly better than the log-linear Cox model.

The EO IRIS Assessment justifies why it does not account for the degrees of freedom by citing the 2015 SAB Review: "The knot is preselected and is not considered a parameter in these analyses, consistent with the SAB's concept of parsimony (SAB, 2015)."[48] However, the concept of parsimony is a preference for a simpler model with fewer estimated parameters when fitting and evaluating a single model. The SAB did not direct EPA to violate well founded and widely accepted statistical practice by ignoring the fact that a particular parameter (in this case, the knot of a bi-linear spline model) of a spline model was actually estimated when defining the total number of its estimated parameters, when comparing the goodness of fit of that spline model to another model (such as a log-linear model) that involves no estimated knot.[49]

The EO IRIS Assessment indicates to fit particular supralinear spline models, their "knots were obtained by doing a grid search by increments of 100 ppm x days and then interpolating where appropriate."[50] In other words, the knot of the final supralinear spline model selected was indeed an additional estimated (in this case, numerically optimized) parameter, standard statistical model-fitting procedures always require that p-values be evaluated for a goodness-of-fit statistic only after subtracting one degree of freedom ***for each one of the total number of parameters (a number typically denoted as k) that are estimated when fitting a model***, regardless of how such parameters are estimated.

Failure to follow this procedure always results in an erroneously inflated "p-value" for goodness of fit (only a model with a p-value for goodness-of-fit larger than 0.05 is typically considered acceptable), and thus also in an underestimated value of a corresponding AIC used to compare goodness of fit of different models (a model with a smaller AIC value is preferred, and AIC is defined as twice the sum of k [defined above] and a fit-specific positive quantity). If the proper procedure is not followed to define total degrees of freedom (k), the result is a p-value indicating a fit that is better than actually is the case (i.e., a p-value indicating that deviations between a fitted model and the observed/modeled data are more likely to have occurred by chance alone than actually is the case), and consequently also an AIC value that misrepresents a

[48] EO IRIS Assessment, Appendix D, at D-6.

[49] The EO IRIS Assessment quotes the SAB as follows: "in some settings the principle of parsimony may suggest that the most informative analysis will rely upon fixing some parameters rather than estimating them from the data. The impact of the fixed parameter choices can be evaluated in sensitivity analyses. In the draft assessment, fixing the knot when estimating linear spline model fits from relative risk regressions is one such example." Appendix D, at D-6, note 11.

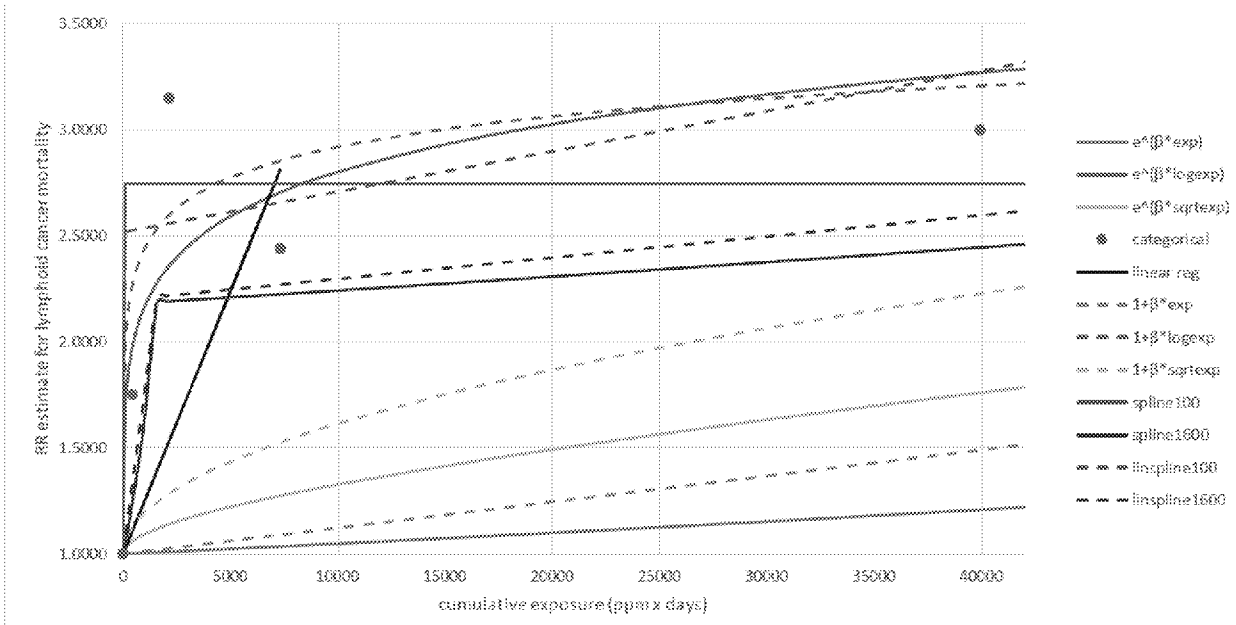
[50] EO IRIS Assessment, Appendix D, Table D-27, note a.

model's goodness of fit relative to that of another model for which degrees of freedom (k) are defined properly.

By ignoring this statistical procedure for its supralinear spline model fit, the EO IRIS Assessment artificially and erroneously inflates the p-value and reduces the AIC value that was used to compare that model to those of other models being compared for which degrees of freedom were defined correctly. **When both the p-values and AIC values are corrected, the selected supralinear spline model does not fit the NIOSH lymphoid tumor data statistically significantly better than the log- linear cumulative model (see Appendix 1).**

9. **The selection of the supralinear spline model for the lymphoid tumors is also based on misleading illustrations of "visual fits" that do not convey either the actual data that were fit or the relative goodness of fit to these data of log-linear and supralinear spline models. Only in a footnote does the IRIS Program acknowledge that the visual comparison misrepresents the log-linear model being compared. Consequently, and erroneously, the fit to the data appears far worse than the supralinear spline model. The data plotted in that figure also were summary data that misrepresent the true magnitude of the scatter of the data that were used for model fitting.**

The EO IRIS Assessment visually represents alternative models considered in relation to data used for model fitting in Figures 4-3 through 4-8, explaining that "to facilitate a visual comparison of the models, select models are replotted against the categorical data in deciles." Figure 4 below reprints Figure 4-3 from the EO IRIS Assessment and illustrates the incorrect basis for the conclusion that the NIOSH exposure-response is supralinear and that only models that are supralinear have good visual fit to the data.



e^(β*exp): RR = $e^{(\beta \times \text{exposure})}$; e^(β*logexp): RR = $e^{(\beta \times \ln(\text{exposure}))}$; e^(β*sqrtexp): RR = $e^{(\beta \times \text{sqrt}(\text{exposure}))}$; categorical: RR = $e^{(\beta \times \text{exposure})}$ with categorical exposures, plotted at the mean cumulative exposure; linear reg: weighted linear regression of categorical results, excluding highest exposure group (see text); 1 + β*exp: RR = 1 + β × exposure; 1 + β*logexp: RR = 1 + β × ln(exposure); 1 + β*sqrtexp: RR = 1 + β × sqrt(exposure); spline100(1,600): Two-piece log-linear spline model with knot at 100 (1,600) ppm × days (see text); linspline100(1,600): Two-piece linear spline model with knot at 100 (1,600) ppm × days (see text). (Note that, with the exception of the categorical results and the linear regression of the categorical results, the different models have different implicitly estimated baseline risks; thus, they are not strictly comparable to each other in terms of RR values, i.e., along the *y*-axis. They are, however, comparable in terms of general shape.)

Source: Steenland reanalyses for males and females combined; see Appendix D (except for linear regression of categorical results, which was done by EPA).

Figure 4-3. Exposure-response models for lymphoid cancer mortality vs. occupational cumulative exposure (with 15-year lag).

Figure 4. Figure 4-3 from the EO IRIS Assessment using categorical data (solid purple points) to compare the visual fits of the different models, including the selected two-piece log-linear-spline model (dashed red curve) and the standard Cox log-linear regression model (solid blue curve).

Figure 4-3 misrepresents the relative quality of true visual fits to the EO IRIS Assessment's preferred supralinear spline model compared to the more parsimonious log-linear Cox regression model in two important ways. First, Figure 4-3 plots data points that represent categorical data aggregated into quartiles (filled purple points in Figure 4, above) instead of the actual individual cases modeled. This comparison was used in earlier drafts of the IRIS Assessment when the 2014 draft EO IRIS Assessment modeled those categorical aggregated or summary data. However, when the final EO IRIS Assessment followed the SAB's recommendation to model individual cases, the data plots were not corrected accordingly to show the true magnitude of data scatter in relation to fitted models.

Second, the IRIS Program acknowledges in a footnote to Figure 4-3 that "the various models have different implicitly estimated baseline risks; thus, they are not strictly comparable to each other in terms of RR values (i.e. along the y-axis). They are, however, comparable in terms of general shape." It is not transparent, however, that these graphs cannot be used at all to compare some of the models shown in a valid way. In particular, the lower log-linear model fit shown (the solid blue "line" that appears to go through the origin of the plot shown in Figure 4-3) appears to provide a very poor fit to the cloud of individual data through which that model passes, because the place where that model is shown to intersect the y-axis was artificially forced (in that figure) to intersect the value of 1 along the y-axis, when in fact that model does actually pass centrally through the cloud of actual raw data to which it was fit. That is, although both the EO IRIS Assessment's preferred model and the log-linear model do more or less centrally pass through the cloud of data to which these models were fit, Figure 4-3 misleads the reader by showing a relatively poor fit of the simpler (i.e., more parsimonious) log-linear model compared to the more complex supralinear spline model that was selected in the EO IRIS Assessment.

Figure 5[51] more accurately compares the supralinear spline model (red dashed curve) and the standard Cox log-linear regression model (solid blue curve). The latter model is the approach used by Valdez-Flores et al. (2010) to fit the NIOSH, UCC, and combined NIOSH+UCC study data for lymphoid tumors. In Figure 5, the baseline (zero-exposure) value of hazard rate (HR) to which the log-linear model was fit is set equal to the same baseline HR as that estimated using the supralinear spline model. Therefore, Figure 5 shows more accurately than Figure 4 that the supralinear spline model fits the data no better than standard Cox log-linear regression model.

[51] Figure 5 improves comparison along the y-axis by dividing model-estimated values of hazard rate (HR) ratio by the baseline HR of the individual categorical cases (thus making an apples-to-apples comparison), and uses a logarithmic scale to improve comparison of the linear difference between the fitted models and observed values of relative risk measured as hazard rate ratio (RR). In Figure 4, RR values greater than one appear disproportionally more distant from 1 than RR values less than one, because of the linear RR scale used in that figure. RR values greater than one can be as large as infinity, but RR values less than one cannot be less than 0. In contrast, values of Ln(RR)—i.e., values of RR plotted on a logarithmic scale—as shown in Figure 5 can be as large as infinity and as small as minus infinity (see Appendix 1).

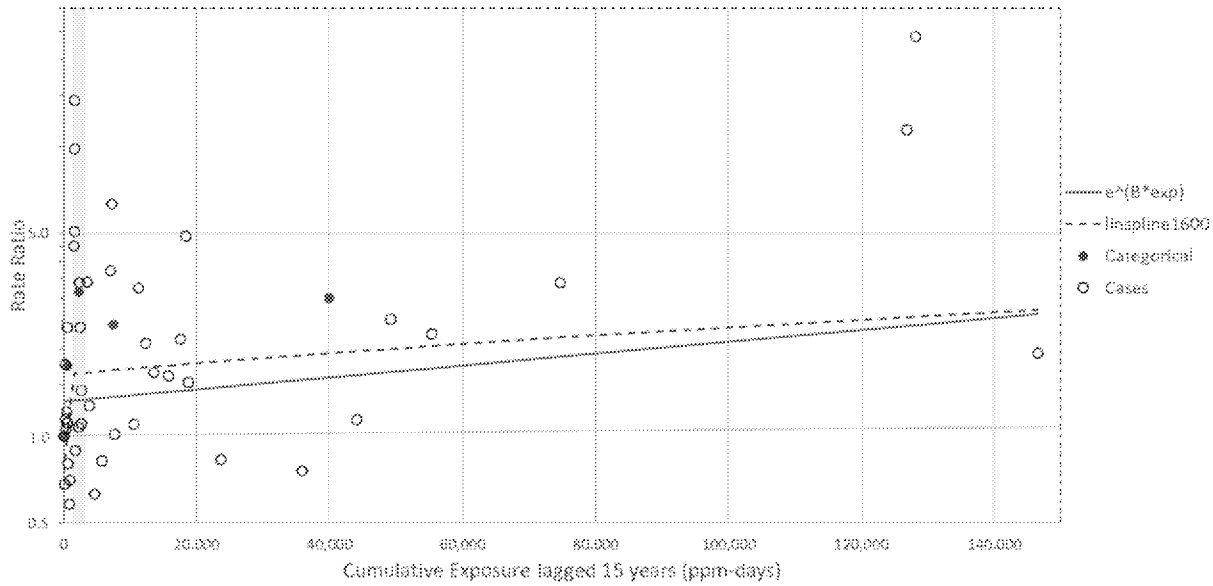


Figure 5. Apples-to-apples comparison of the EO IRIS Assessment's preferred supralinear spline model (red dashed curve) and the log-linear Cox proportional hazards model (solid blue curve), plotted in relation to categorical data (solid purple points) from Figure 4 together with corresponding actual (raw/individual-level) data to which these models were fit (open points).

The misleading plots of categorical data in the EO IRIS Assessment were a key justification for its rejection of the standard Cox log-linear proportional hazards model in favor of a supralinear exposure-response relationship, as indicated in Table 4-14 of the EO IRIS Assessment.

10. The selection of a spline model as the preferred model for EO cancer risk estimation assumes a supralinear increase in tumor response in the low-dose exposure region with a subsequent plateauing of response at higher exposures. The body of cancer epidemiologic studies, including the NIOSH studies, does not support such a pattern of risk. While certain NIOSH sub-analyses suggest increases in male lymphoid tumors and female breast cancers, the findings are limited to the highest cumulative exposure groups, not the lowest.

Steenland et al. (2003) state, "Exposure-response data do suggest an increased risk … for those with higher cumulative exposures to ETO."[52] The authors also say, "The dip in the spline

[52] Steenland K, Whelan E, Deddens J, Stayner L, Ward E. 2003. Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States). Cancer Causes Control, 14: 531-39.

curve in the region of higher exposures suggested an inconsistent or non-monotonic risk with increasing exposure." The default expectation for a genotoxic carcinogen would be this pattern of monotonically increasing risk in relation to exposure, which is why the authors call it "inconsistent." The EO IRIS Assessment notes that it is not unexpected to have fluctuations in exposure-response curves due to random variation, yet in the exposure-response section the IRIS Program models such plausibly random fluctuation using a supralinear response model.

The EO IRIS Assessment cites Mikoczy et al. (2011)[53] to support the use of the supralinear spline model for breast cancer: "Although the reason for the observed supralinear exposure-response relationship is unknown, it is worth noting that the results of the Swedish sterilizer worker study reported by Mikoczy et al. 2011, …support the general supralinear exposure-response relationship observed in the NIOSH study."[54] However, Mikoczy et al. (2011) studied a low-exposure population that exhibited a significant increase in breast cancer incidence only when analyzed using an internal analysis comparing more-highly exposed to low-exposed workers, and exhibited no such significant increase in a corresponding external analysis involving comparison to matching members of a general population. The explanation for this anomaly lies in the dramatic and (as indicated by Mikoczy et al., 2011) statistically significant deficit of breast cancers in the low exposure group of the internal comparison; because in the internal comparison that low-exposed group was used as the referent group, the two higher exposure groups being compared showed significantly higher rates breast cancer relative to that lower-exposed group.

It might be argued that the non-representative and significantly low rate of breast cancer incidence exhibited by the low-exposure group used for internal comparison simply reflects a Healthy Worker Effect (HWE). However, the breast cancer rate for that group was remarkably low (only about half that of the reference population group of age-matched Swedish women used), and there is no HWE specific to breast (or to any other type of) cancer in Swedish female workers.[55] Thus, the EO IRIS Assessment does not accurately acknowledge and address the problematic nature of the internal-comparison reference group that served as the basis for results of internal comparisons of breast cancer incidence reported by Mikoczy et al. (2011).

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[53] Mikoczy Z, Tinnerberg H, Jonas Björk J, Albin M. 2011. Cancer incidence and mortality in Swedish sterilant workers exposed to ethylene oxide: updated cohort study findings 1972–2006. Int J Environ Res Public Health, 8: 2009-19.

[54] EO IRIS Assessment, at 4-71.

[55] Gridley G, Nyren O, Dosemeci M, Moradi T, Adami HO, Carroll L, Zahm SH. 1999. Is there a healthy worker effect for cancer incidence among women in Sweden? Am J Ind Med, 36(1): 193-99.

The EO IRIS Assessment's extra risk estimate suggests a highly potent carcinogen. This is contrary to epidemiology findings which show overall weak positive findings (see Appendix 2). While interest has centered on leukemia, other blood related malignancies, and recently on breast cancer, there are numerous inconsistencies among the studies; elevated risks above background, in isolated studies, are of small magnitude; and there is an absence of a clear exposure-response for any specific cancer type. The most informative studies are the NIOSH (Steenland et al. 2003, 2004) and UCC studies (Swaen et al. 2009), which are studies of comparable utility for risk assessment purposes. These epidemiology studies do not support supralinearity (high risk at low exposures). Certain NIOSH subanalyses showed increase for males only (lymphoid tumors) in the highest (not the lowest) cumulative exposure groups. Extended follow up of chemical workers, UCC and others, and sterilant workers show little, if any, increases. The epidemiological evidence does not support the RSC of 0.1 ppt, which suggests a highly potent carcinogen.

11. The use of a supralinear spline model for cancer risk estimation is inconsistent with the assumed mode-of-action of EO toxicity and tumorigenicity. Such a model predicts higher risk at low exposures compared to risks predicted at higher exposures, which is contradicted by the well-understood mode of action of EO in experimental animals and humans as described in the EO IRIS Assessment. Thus, the EO IRIS Assessment relies on human cancer risk estimates based on spline-model dose-response extrapolations that are internally inconsistent with its own evaluation of the mode of action of EO. The mean air concentration equivalent to the endogenous concentration in non-smoking humans with no known EO exposures is 1.9 ppb (range 0.13-6.9 ppb; continuous), which is 19,000 times greater than the EO IRIS RSC of 0.1 ppt. An alternative LEC (1/million) of 0.5-1.2 ppb is a more pragmatic, science-based approach for EO risk assessment.

As a direct acting DNA- and protein-reactive toxicant, the high-level toxicological and cancer mode of action of EO importantly predicts a *sublinear* increase in dose-response at low exposures and an associated dose-disproportionate *increase* in toxicity at higher EO doses.[56] This expected dose-response pattern is due to attenuation of low-dose EO toxicity mediated by intervention of key detoxification pathways (EO conjugation with glutathione and enzymatic hydrolysis to oxidized metabolites; repair of EO-induced DNA adducts), and an associated dose-disproportionate (supralinear) increase in toxicity at higher doses due to saturation of those same pathway(s) as the EO dose increases, as summarized below in Figure 6.

[56] Kirman and Hays (2017).

The EO IRIS Assessment describes and supports this projected EO mode of action and its implications for the shape of the cancer dose response in the low- to high-dose regions as follows:

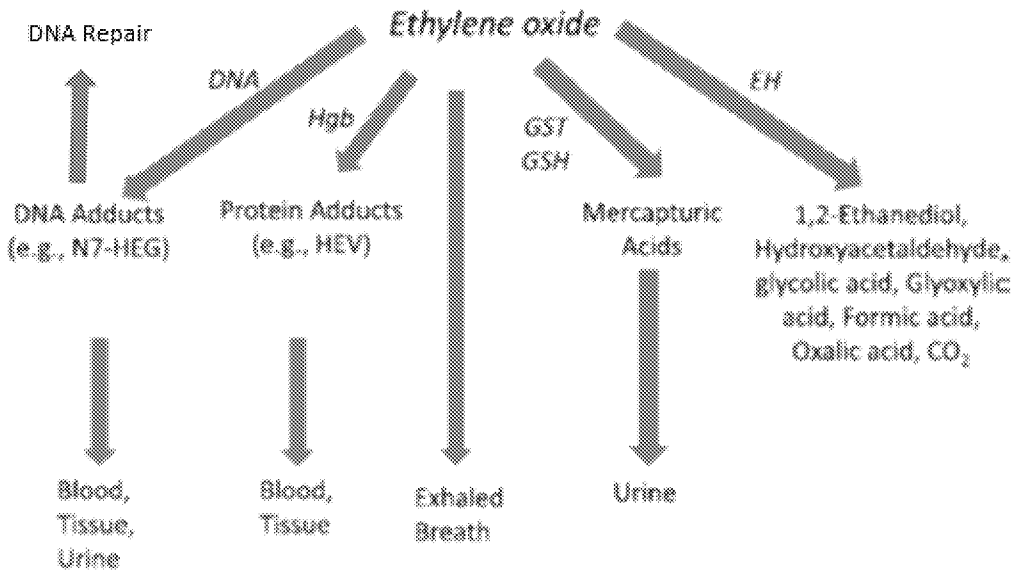
> [E]PA considers it *highly plausible that the dose-response relationship over the endogenous range is sublinear* (e.g., that the baseline levels of DNA repair enzymes and other protective systems evolved to deal with endogenous DNA damage would work more effectively for lower levels of endogenous adducts), that is, that the *slope of the dose-response relationship for risk per adduct would increase* as the level of endogenous adducts increases.[57]

The EO IRIS Assessment's analysis of the EO mode of action emphasizes that the dose-response is highly likely ("highly plausible") to be *sublinear* "over the endogenous range" of internal EO doses that result from well-characterized endogenous production of EO secondary to metabolism of ethylene originating from normal biological processes.

Exploiting the well-defined linear relationship between exogenous EO exposure and systemic hemoglobin adducts in humans, Kirman and Hays (2017) estimate that the contribution of endogenously generated EO exposures to the overall systemic dose of EO is substantially greater than the 0.1 ppt exogenous EO exposure projected by the EO IRIS Assessment as resulting in a 1×10^{-6} cancer risk in humans. A meta-analysis of 661 non-smoking individuals not exposed to external EO indicated that endogenous background EO exposures are equivalent to a mean external exogenous EO exposure of 1.9 ppb (range 0.13-6.9 ppb). This "endogenous equivalent" contribution to the overall systemic EO dose is 19,000 times greater than the 0.1 ppt exogenous EO one-in-a-million risk dose estimated by the EO IRIS Assessment.

It is clear that even a 1000-fold increase in exogenous EO exposures above 0.1 ppt would only approach the low end of the total systemic EO dose contributed by endogenous EO generation. Any contributions of exogenous EO to cancer risk below this low-end endogenous dose would not be detectable within the likely day-by-day intra- and inter-individual variability (0.13-6.9 ppb) associated with normal endogenous EO exposure loads.

[57] EO IRIS Assessment, at 4-95 (emphasis added).



Modified from Kirman & Hays, Reg Toxicol Pharmacol 91: 165-172, 2017

Figure 6. EO metabolism (adapted from Kirman and Hays, 2017).

Kirman and Hays (2017) also recognize that increased EO hemoglobin adducts associated with smoking provided an opportunity to further check the EO IRIS Assessment's supralinear model predictions that moderately low external EO exposures realistically contribute to increased cancer risks. A meta-analysis of 379 smokers not otherwise exposed to EO found that smoking increased EO exposures approximately 10-fold above the endogenous equivalent dose for background (non-EO exposed) individuals (mean background endogenous equivalent exposure = 1.9 ppb; mean smoker exposure = 18.8 ppb). The spline-model relied on by the EO IRIS Assessment predicts that the moderate increase in EO exposure associated with smoking would result in a detectable increase in lymphohematopoietic and breast cancers. However, this expectation is not met despite the very large smoking cohort.

Kirman and Hays (2017) note that smoking has been causally associated only with one subtype of lymphohematopoietic cancer, acute myeloid leukemia (AML). Not only is this cancer not increased in the NIOSH occupational cohort specifically exposed to higher doses of EO than those resulting from smoking, but Valdez-Flores et al. (2010), using a non-spline-based risk model, also demonstrate a statistically significant negative slope between cumulative exposure to EO and AML in that same NIOSH cohort. Kirman and Hays (2017) also observe that evidence

of a causal relationship between smoking and breast cancer is considered only as suggestive and not sufficient. Thus, projections of low-dose elevations in specific EO-associated cancer risks based on spline model extrapolations from relatively high occupationally-exposed individuals are not consistent with cancer outcomes in the much larger smoking cohort experiencing moderately elevated EO exposures.

Kirman and Hays (2017) also address the concern that any additional exogenous EO exposures above background, regardless of how small, represent a plausible contribution to increased cancer risks. They conclude that the approximate four order of magnitude disparity between EO endogenous exposures (mean = 1.9 ppb) and EPA projected increased risk at exposures greater than 0.1 ppt "creates a signal-to-noise issue [in the biological plausibility of tumor outcomes] when exogenous exposures fall well below those consistent with endogenous exposures. In such cases, small exogenous exposures may not contribute to total exposure or to potential effects in a biologically meaningful way."

Recently, Calabrese (2018)[58] offers additional insight into the lack of plausibility of additivity to background of risks associated with low (and particularly less than background) exposures to EO. Calabrese reports that the mutational spectra of K-ras in EO-induced lung and Harderian gland tumors, and H-ras and p53 in mouse mammary tumors, were not at all similar to mutational spectra of these same tumors in control mice from the EO studies. These molecular-level data indicate that the mode of action of generation of control (background) tumors differs substantively from those originating from exogenous EO-exposed animals, even though control animals experience significant endogenous EO exposures. Thus, these data stand in contrast to the assumption of additivity to background that presumes that chemically-induced elevation of background tumors that are otherwise pathologically similar to chemically-induced tumors must share common mode(s) of action reviewed by Calabrese (2018).

The potential for additivity to background also is not supported by a comparison of total endogenous EO-specific DNA adducts in spleen, liver and stomach of rats relative to adducts in these same tissues resulting from a thousand-fold range of EO intraperitoneal doses (0.0001, 0.0005, 0.001, 0.005, 0.01, 0.05 and 0.1 mg/kg/day; 0.1 mg/kg/day approximately equivalent to a 1 ppm 6 hr/day EO inhalation exposure).[59] Importantly, Marsden et al. (2009) also emphasize that the increase in adducts associated with exogenous EO were not statistically significant at any

[58] Calabrese EJ. 2018. The additive to background assumption in cancer risk assessment: A reappraisal. Envir Res, 16: 175-204.

[59] Marsden DA, Jones DJ, Britton RG, Ognibene T, Ubick E, Johnson GE, Farmer PB, Brown K. 2009. Dose-response relationships for N7-(2-hydroxyethyl)guanine induced by low-dose [^{14}C]ethylene oxide: evidence for a novel mechanism of endogenous adduct formation. Cancer Res, 69(7): 3052-59.

dose with the exception of adducts in liver in rats administered 0.05 mg/kg/day, suggesting that exogenous adducts may not present any additional risk over endogenous adducts over this range of EO doses (i.e., additivity to background). Interestingly, endogenous DNA adducts were statistically increased in spleen and liver at the 0.05 and 0.1 mg/kg/day EO, indicating that higher EO doses alter internal biological processes leading to increased potential for endogenous EO formation.

Further investigations demonstrated that the high-dose-specific in endogenous-only adducts may have been secondary to increased oxidative stress. Both the high level of background endogenous adducts and high-dose specific increases in endogenous-only EO adducts further supports the authors' conclusion that "if the compound [EO] is produced endogenously, low doses of exogenous exposure may be overwhelmed by the background levels, leading to no detectable statistically significant increase in risk due to the external exposure." This conclusion (see Figure 6) is entirely consistent with the analyses developed by Kirman and Hays (2017) in which endogenous EO equivalent exposures in humans (mean = 1.9 ppb) are estimated as being 19,000 times higher than the exogenous EO dose of 0.1 ppt presenting a one-in-a-million cancer risk from spline-model low-dose extrapolation.

An alternative LEC (1/million) of 0.5-1.2 ppb is within the range of endogenous EO levels. Taking into account the biological mode of action and the endogenous EO equivalent exposures in humans, this approach is more plausible and science-based than the EO IRIS assessment.

12. The statistical, epidemiological and biological evidence does not support the selection of supralinear spline models to fit the NIOSH study data in the EO IRIS Assessment. A more scientifically sound conservative alternative is to use the Valdez-Flores et al. (2010) approach, which incorporates all the available data from the two strongest human studies (NIOSH and UCC). This approach has been adopted by the Scientific Committee on Occupational Exposure Limits.

As described in previous sections, the selection of the supralinear spline model is based on incorrect statistical analysis and biased evaluation of the NIOSH exposure modeling relative to the UCC exposure estimates. Furthermore, the epidemiological evidence and biological mode of action do not support the supralinear spline model. A more scientifically supportable approach is that published by Valdez-Flores et al. (2010), who make full use of the available data from both the NIOSH and UCC cohorts. The effect was modeled as a standard Cox proportional log-linear hazards model (i.e., exponentiated linear) function of cumulative EO exposure (ppm-days) treated as a continuous variable.

The EO IRIS Assessment focuses the cancer risk assessment on lymphoid tumors (defined by NIOSH as including non-Hodgkin's lymphoma, lymphocytic leukemia and multiple myeloma) and breast cancer incidence. The weight of evidence does not support breast cancer as an endpoint for risk assessment (see Appendix 2). Therefore, our analysis focuses on the mortality data for lymphohematopoietic (LH) tissue cancers including leukemia (and specific myeloid and lymphocytic leukemia), non Hodgkin's lymphoma (NHL), multiple myeloma (MM) and "lymphoid" cancers (a grouping developed in Steenland et al. (2004) that included NHL, MM, and lymphocytic leukemia).

Valdez-Flores et al. (2010) propose a range of 1-3 ppb based on the Maximum Likelihood Estimate (MLE) of the Effective Concentrations (ECs) associated with an extra risk of one-in-a-million [EC(1/million)] (see Table 2).[60] The authors select the MLE as the most reliable data for point of departure because the Lowest Effective Concentrations LECs), the 95% lower bound on the ECs, are insensitive to the magnitude of the best estimated slope, which can be negative, yet have a positive 95% upper confidence limit resulting in a finite LEC as occurred for multiple myeloma.

Table 2: Maximum Likelihood Estimate (MLE) of the EC (1/million) and Lowest Effective Concentration (LEC)

EO type of cancer (mortality)	MLE UCC & NIOSH (ppb)	LEC UCC & NIOSH (ppb)	LEC NIOSH only (ppb)
Lymphoid	1.5	0.5	0.2
Non-Hodgkin's lymphoma	2.3	0.9	0.8
Multiple Myeloma	Negative slope, value not calculated	1.2	0.8
Leukemia	9.2	0.9	0.9
Lymphocytic Leukemia	2.4	0.9	0.9
Breast cancer	0.7	0.1	0.1

[60] NIOSH only provided ACC with the breast cancer mortality and not the incidence data, despite multiple requests for the incidence data. The results from the breast cancer mortality are included in Table 2 for completeness.

EO type of cancer (mortality)	MLE UCC & NIOSH (ppb)	LEC UCC & NIOSH (ppb)	LEC NIOSH only (ppb)
Range for LHC	1.5-9.2	0.5-1.2	0.4-0.9
Range for LHC and breast cancer	0.7-9.2	0.1-1.2	0.1-0.9

The MLE and LEC values reported in Table 2 are conservative values because (a) extra risk was calculated despite no statistically significant slope in the exposure-response analyses; (b) the NIOSH data was included without adjustment for likelihood of underestimation of exposures; and (c) the limited evidence of cancer risk based on the entire body of epidemiologic evidence (summarized in Appendix 2).

The EO IRIS Assessment and Valdez-Flores et al. (2010) identify several differences between the two approaches in deriving their recommended 1/million exposure levels to use as points of departure (see Table 3).[61]

Table 3: Approximate sources of differences between Valdez-Flores et al. (2010) and EO IRIS Assessment approaches

Valdez-Flores et al (2010) compared to EO IRIS Assessment	Reference	Factor
Extra risk at age 70 instead of 85 years	Valdez-Flores et al. (2010), p. 319	2.3
Different approaches to implementing age-adjusted adjustment factor (ADAF)	Valdez-Flores et al. (2010), p. 319 used an approach that adjusted the slope; EPA's cancer risk assessment guidelines (2005) use 1.66	1.66
Use of incidence background rates compared to mortality background rates in lymphoid tumor unit risk estimation (incidence/mortality ratio, $R_{i/m}$).	$R_{i/m}$ = 5.26/1.99 The EO IRIS Assessment unit risk using background lymphoid cancer incidence rates with model for lymphoid mortality data = 5.26/ppm, and unit risk using background	2.64

[61] *See* EO IRIS Assessment, Appendix A, at A-33 – A-35.

	mortality rates with model for lymphoid mortality data is 1.99/ppm; see Table 4-7, page 4-23; whereas Valdez-Flores et al. (2010) unit risk using background lymphoid mortality rates with model for lymphoid mortality data	

Valdez-Flores et al (2010) used well-accepted statistical principles to guide decisions about whether to include a lag period, how to calculate the degrees of freedom, and whether the MLE for the EC (1/million) can be interpolated within the lower region of the experimental data set. For example, because there was no significance between the models with and without a lag period and no clear biological plausibility for selection of a specific lag period, the more parsimonious model (no lag) was selected. In contrast, the IRIS Program tested different lag periods and knots but did not fully account for the higher degrees of freedom typically considered when different ranges of values are tested.

Valdez-Flores et al. (2010) also modeled down to 10^{-6} risk, whereas the IRIS Program modeled to 10^{-2} risk and used the LEC01 as a point of departure (POD) for linear low-dose extrapolation. Valdez-Flores et al. (2010) suggest that PODs should be within the range of observed exposures, and chose a 10^{-6} risk level because the corresponding exposure level was in the range of the observed occupational exposures (converted to equivalent environmental exposures). Thus, Valdez-Flores et al. (2010) fully used the experimental data to derive a 10^{-6} risk level.

An additional difference that is not captured in Table 3 is the EO IRIS Assessment estimates risk for both lymphoid and breast cancer, whereas Valdez-Flores et al. (2010) estimates risk for lymphoid tumors alone. As discussed above and in greater detail in Appendix 2, breast cancer is not a target of EO. The EO IRIS Assessment recognizes that magnitudes of increased risks for breast cancer were not large and implies that the evidence is weaker than that for lymphoid tumors. Despite these issues, the EO IRIS Assessment introduces breast cancer as a target organ and inappropriately develops a risk value. Uncertainties described by Steenland et al. (2003) related to the breast cancer incidence study are dismissed as unimportant. It is notable that the ratio between risk for lymphoid plus breast cancer incidence (6.06 per ppm)[62] divided by the risk for lymphoid tumor incidence alone (5.26 per ppm)[63] is only 1.15.

[62] EO IRIS Assessment, at 4-58.

[63] *Id.* at 4-31.

As discussed above, the NIOSH exposure assessment was not validated prior to the late 1970s and likely underestimated exposures. In contrast, the UCC exposure estimation from the 1940s to 1970s was based on actual data from similar operations during the same time period.[64] The greatest uncertainty is between 1925-1939, but only 4.8% of the UCC cohort had work history before 1940.[65] These uncertainties are no greater than the NIOSH study uncertainties and do not justify study rejection for exposure-response analysis. Both studies are well-conducted epidemiology studies with comparable power in terms of number of events for males and of comparable utility in terms of individual exposure estimates. In fact, the UCC study was originally a NIOSH study, in that it was nested within a NIOSH/UCC collaborative study of 29,000 UCC workers in the Kanawha Valley of West Virginia.[66]

The EO IRIS Assessment also criticizes Valdez-Flores et al. (2010) for not using any log cumulative exposure models which were found to be statistically significant in analyses by Steenland et al. (2004), consistent with the apparent supralinearity of the NIOSH exposure-response data. Yet, the EO IRIS Assessment also considers the log cumulative exposure model to be "problematic because this model, which is intended to fit the full range of occupational exposures in the study, is inherently supralinear …, with the slope approaching infinity as exposures decrease towards zero, and results can be unstable for low exposures."[67]

Similarly, the IRIS Program rejected other statistically significant models due to unstable results for low exposures. As noted above, the assumption of supralinearity is based on a flawed statistical analysis of its preferred-model fit and on a misleading visual comparison of invalidly overlaid models plotted in relation to categorical data grouped in quartiles instead of considering the pattern of RR for individual cases, which more realistically reveals a very noisy data cloud through which the simpler and traditionally accepted Cox proportional model fits as well as the supralinear spline model.

Crump (2005) noted that:

> Because of these potential distortions of the exposure-response shape, one should be cautious in drawing conclusions about the shape of the exposure response from epidemiological data. Since even random, unbiased errors in exposure measurement will convert a linear exposure response, and can convert sub-linear

[64] Swaen et al. (2009).

[65] *Id.*

[66] Rinsky RA, Ott G, Ward E, Greenberg H, Halperin W, Leet T. 1988. Study of mortality among chemical workers in the Kanawha Valley of West Virginia. Am J Ind Med, 13: 429-38.

[67] EO IRIS Assessment, at 4-10.

> response, into a seemingly supralinear shape, one should be particular[ly] cautious about concluding an exposure-response is truly supralinear. In particular, it could be inadvisable to extrapolate an observed supralinear exposure response to low exposures to predict human risk.[68]

Crump's caution is especially relevant to the NIOSH data in light of the high potential for exposure misclassification in the earlier years of the NIOSH study when there was no data to validate the NIOSH exposure model, as described above. EPA's cancer risk assessment guidelines echo this caution: "a steep slope [i.e., supralinear] also indicates that errors in an exposure assessment can lead to large errors in estimating risk."[69]

D. Conclusion

The 2014 NATA fails to meet the requirements of the IQA and the OMB and EPA Guidelines because its use of the EO IRIS Assessment is not the best available science. Therefore, the 2014 NATA risk estimates for EO should be withdrawn and corrected to reflect scientifically-supportable risk values and EPA should not use the EO IRIS Assessment's inhalation RSC of 0.1 ppt to calculate EO risk in its ongoing CAA Section 112 RTR rulemakings and other regulatory actions. As discussed above, a more reasonable and scientifically supportable approach to an exposure response analysis yields ranges for the MLE (1.5-9.2 ppb) and LEC (0.5-1.2 ppb) that are more than three orders of magnitude greater than the EO IRIS Assessment's environmental concentration associated with one-in-a-million risk.

Sincerely,

William Gulledge

William P. Gulledge
Senior Director
Chemical Products & Technology Division

Enclosures:

Appendix 1 – Statistical Issues with EPA's Calculation of p-values and AIC's for Spline Models and Linear Models in the EO IRIS 2016
Appendix 2 – Brief Summary of Epidemiological Data for EO

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[68] Crump KS. 2005. The effect of random error in exposure measurement upon the shape of the exposure response. Dose-Response, 3: 456-64.

[69] EPA, Guidelines for Carcinogen Risk Assessment, at 3-19.

Appendix 1

Statistical Issues with EPA's Calculation of p-values and AIC's for Spline Models and Linear Models in the EO IRIS 2016

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Introduction

The document "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS), December 2016" (EO IRIS 2016) has several statistical inaccuracies that play an important role in model selection and, ultimately, in the risk assessment of EtO. The exposure-response modeling of lymphoid mortality for the NIOSH study is reviewed here, and statistical pitfalls are highlighted. EPA's statistical numbers are corrected herein and new results are derived. These corrected results question conclusions drawn by EPA about model selection. Although EPA's conclusions for the other endpoints are not analyzed herein, similar statistical pitfalls must have been incurred, as the statistical pitfalls are related to the methodology that was used for all endpoints analyzed by EPA.

Table 1 reproduces Table 4-6 of EO IRIS 2016. In this table EPA to summarizes how the linear spline model with knot at 1600 ppm × days was selected to describe the relationship between lymphoid mortality rate ratio and cumulative exposures to EO. The summary in the table indicates that the model was selected because: a) adequate statistical fit; b) adequate visual fit; c) including local fit (visual) to low-exposure range; linear fit; and d) AIC within two units of lowest AIC models considered.

It can also be shown (using the likelihood ratio test -- analyses not presented here) that EPA's selected linear spline model does not fit the NIOSH lymphoid mortality data statistically significantly better (at the 5% significance level) than the nested linear model. Similarly, log-linear spline model with knot at 1600 ppm-days does not fit the NIOSH lymphoid mortality data statistically significantly better (at the 5% significance level) than the nested log-linear model. Thus, according to the following SAB recommendation on page 12, the log-linear and the linear models should be preferred over the log-linear spline and linear spline models, respectively:

> Third, the principle of parsimony (the desire to explain phenomena using fewer parameters) should be considered. Attention to this principle becomes even more important as the information in the analysis dataset becomes even more limited.

Appendix 1

Thus, models with very few estimated parameters should be favored in cases where there are only a few events in the dataset.

Table 1. The following table has been extracted from EO IRIS 2016 Table 4-6

Table 4–6. Models considered for modeling the exposure-response data for lymphoid cancer mortality in both sexes in the National Institute for Occupational Safety and Health cohort for the derivation of unit risk estimates

Model[a]	*p-value*[b]	AIC[c]	Comments
Two-piece spline models			
Linear spline model with knot at 1,600 ppm × days	0.07	462.1	**SELECTED.** Adequate statistical and visual fit, including local fit to low-exposure range; linear model; AIC within two units of lowest AIC of models considered.
Linear spline model with knot at 100 ppm × days	0.046	461.4	Good overall statistical fit and lowest AIC of two-piece spline models, but poor local fit to the low-exposure region, with no cases below the knot.
Log-linear spline model with knot at 1,600 ppm × days	0.07	462.6	Linear model preferred to log-linear (see text above).
Log-linear spline model with knot at 100 ppm × days	0.047	461.8	Good overall statistical fit and tied for lowest AIC[c] of two-piece spline models, but poor local fit to the low-exposure region, with no cases below the knot.
Linear (ERR) models (RR = 1 + β × exposure)			
Linear model	0.13	463.2	Not statistically significant overall fit and poor visual fit.
Linear model with log cumulative exposure	0.02	460.2	Good overall statistical fit, but poor local fit to the low-exposure region.
Linear model with square-root transformation of cumulative exposure	0.053	461.8	Borderline statistical fit, but poor local fit to the low-exposure region.
Log-linear (Cox regression) models (RR = $e^{\beta \times \text{exposure}}$)			
Log-linear model (standard Cox regression model)	0.22	464.4	Not statistically significant overall fit and poor visual fit.
Log-linear model with log cumulative exposure	0.02	460.4	Good overall statistical fit; lowest AIC[c] of models considered; low-exposure slope becomes increasingly steep as exposures decrease, and large unit risk estimates can result; preference given to the two-piece spline models because they have a better ability to provide a good local fit to the low-exposure range.
Log-linear model with square-root transformation of cumulative exposure	0.08	462.8	Not statistically significant overall fit and poor visual fit.

[a]All with cumulative exposure as the exposure variable, except where noted, and with a 15-yr lag.

[b]*p*-values from likelihood ratio test, except for linear regression of categorical results, where Wald *p*-values are reported. $p < 0.05$ considered "good" statistical fit; $0.05 < p < 0.10$ considered "adequate" statistical fit if significant exposure-response relationships have already been established with similar models.

Appendix 1

[c]AICs for linear models are directly comparable and AICs for log-linear models are directly comparable. However, for the lymphoid cancer data, SAS proc NLP consistently yielded −2LLs and AICs about 0.4 units lower than proc PHREG for the same models, including the null model, presumably for computational processing reasons, and proc NLP was used for the linear RR models. Thus, AICs for linear models are equivalent to AICs about 0.4 units higher for log-linear models. No AIC was calculated for the linear regression of categorical results.

EPA's Misinterpretation of SAB Comments about the Knot of Spline Models

EPA justifies the p-values and AIC values for the linear spline and log-linear spline models in their Table 4-6 misquoting SAB's comments. In section D.3.2 of the appendices (reference), EPA states (emphasis added) "Table D-27 also presents the AIC values for the same models to facilitate comparison with the two-piece spline models, which include an extra parameter. [The knot is preselected and is not considered a parameter in these analyses, consistent with the SAB's concept of parsimony (SAB, 2015)].[14]" Their footnote 14 in the same sections states "[14] in some settings the principle of parsimony may suggest that the most informative analysis will rely upon fixing some parameters rather than estimating them from the data. The impact of the fixed parameter choices can be evaluated in sensitivity analyses. In the draft assessment, fixing the knot when estimating linear spline model fits from relative risk regressions is one such example" [page 12 of SAB (2015)]."

Although the SAB quote is accurate, the quote just a fragment of a response and is taken out of context. The full question and SAB response are as follows (emphasis added):

> *2b: For the (low-exposure) unit risk estimates, EPA presents an estimate from the preferred model as well as a range of estimates from models considered "reasonable" for that purpose (Sections 4.1.2.3 and 4.5 and Chapter 1). Please comment on whether the rationale provided for defining the "reasonable models" is clearly and transparently described and scientifically appropriate.*
>
> The SAB understands that the EPA considered four "reasonable" models for providing unit risk estimates; these all have unit risk estimates reported in Table 4-13. A few additional models are described in Tables 4-12 and 4-13, some of which could also be considered reasonable. The presentation of "reasonable" models considers model fit and some a priori (but not clearly articulated) notion about the acceptable shape of the dose-response function in the low-dose region. Because the data do not appear to conform to the a priori notion, the draft assessment also considers models based on an untransformed continuous exposure term or a linear regression of the categorical results as reasonable. However, these models do a poorer job reflecting the patterns in the data. Although much of the approach is scientifically appropriate, the SAB does not agree with all of the judgments. In order to strengthen the assessment and presentation, some modifications are suggested to the approach for comparing models and choosing which models are reasonable. The SAB recommends that

the discussion be revised to provide more clarity and transparency as well as making the disposition easier to follow. In general, discussion of statistical significance should occur in a more nuanced fashion so that important perspective about the results is not lost in the tendency to turn the statistical evidence into a binary categorization of significant vs. not significant. (This can mislead readers into interpreting a pair of results as inconsistent when their p-values, effect estimates, and 95% confidence intervals are very similar, but the two p-values happen to be on opposite sides of 0.05.) Consideration of reasonable models should address the quality of fit in the region of interest for risk assessment. Prioritizing sufficiently flexible exposure parameterizations (e.g., not linear) and exposure functions with more local behavior (e.g., splines, linear and cubic) reduces the impact of highly exposed individuals on the risk estimates for lower exposures. Discarding a model because the fitted curve is "too steep" needs scientific justification. Furthermore, follow-up by the EPA is needed to clearly articulate the criteria for determining that models are reasonable as well as providing transparent definitions for frequently used terms such as "too steep," "unstable," "problematic," and "credible" (p. 4-38). The SAB recommends assigning weight to certain types of models based on a modified combination of biologic plausibility and statistical considerations, and using somewhat different considerations for comparing AICs than those currently employed in the draft assessment.

Regarding statistical considerations about various models, the SAB recommends a different set of emphases in the priorities for the most reasonable models and gives guidance on the preference for their ordering. First, priority should be given to regression models that directly use individual-level exposure data. Because the NIOSH cohort has rich individual-level exposure data, linear regression of the categorical results should be de-emphasized in favor of models that directly fit individual-level exposure data. Second, among models fit to individual-level exposure data, models that are more tuned to local behavior in the data should be relied on more heavily. Thus, spline models should be given higher priority over transformations of the exposure. Third, the principle of parsimony (the desire to explain phenomena using fewer parameters) should be considered. Attention to this principle becomes even more important as the information in the analysis dataset becomes even more limited. Thus, models with very few estimated parameters should be favored in cases where there are only a few events in the dataset. To elaborate further, in some settings the principle of parsimony may suggest that the most informative analysis will rely upon fixing some parameters rather than estimating them from the data. The impact of the fixed parameter choices can be evaluated in sensitivity analyses. In the draft assessment, fixing the knot when estimating linear spline model fits from relative risk regressions is one

such example. Use of AIC can assist with adhering to this principle of parsimony, but its application cannot be used naïvely and without also including scientific considerations. (See further discussion below.) Beyond these recommendations for choosing among models, one advantage of fitting and examining a wide range of models is to get a better understanding of the behavior of the data in the exposure regions of interest. For instance, the models shown in Table 4-13 and Figures 4-5 and 4-6 can be compared, ideally with one or more of these presentations augmented with a few more model fits, including the square root transformation of cumulative exposure, linear regression of categorical results given more categories, and several additional 2-piece linear spline models with different knots. From the comparisons, it is clear that these data suggest a general pattern of the risk rising very rapidly for low-dose exposures and then continuing to rise much more slowly for higher exposures. It is reassuring to observe that many of the fitted models reflect this pattern even though they have different sensitivity to local data.

Results of statistical analyses do not always conform to an a priori understanding of biologic plausibility. When this is the case, investigators need to reassess whether the data are correct, a different approach to model fitting should be employed, or whether the prevailing notion of biologic plausibility should be re-examined. When sufficient exploration of the fitted models has been conducted and a range of models with different properties all suggest a dose-response relationship that would not have been predicted in advance (as is the case in these NIOSH data analyses), then the remaining two considerations should be reviewed. The response to Charge Question 4 further discusses uncertainty in the exposure data. The SAB also encourages finding opportunities to use other evidence from the literature to support the observed dose-response relationship. Specifically, the SAB encourages a discussion of the Swedish sterilization workers study results using the internal comparison group.

The application of AIC for selecting models is acceptable within some constraints as outlined in the following discussion. Burnham and Anderson (2004) is an additional reference that discusses the use of AIC for model selection. (The following discussion is intended to be fairly comprehensive and thus covers points that the SAB did not identify as problematic in the draft assessment.) AIC is an appropriate tool to use for model selection for both nested and non-nested models, provided these models use the same likelihood formulation and the same data. AIC is not the preferred way to characterize model fit. For model selection, (1) AIC is not an appropriate tool for comparing across different models that are fit using different measures, such as comparing a Poisson vs. least squares fit to count data; (2) one should not use AICs to compare models using different

transformations of the outcome variable; and (3) comparing AICs from models estimated using different software tools, including different implementations within the same statistical package can be challenging because many calculations of AIC remove constants in the likelihood from the estimated AIC. These AIC features require that users interested in comparing AICs across different software routines (even those within one statistical package) understand exactly what likelihood is being maximized and how the AIC is calculated. AIC can be used to compare the same regression model with the same outcome variable and different predictors whether or not these models are nested. This gives a consistent estimate of the mean-squared prediction error (MSPE), which is one criterion for choosing a model. Finally, the theory behind this MSPE criterion can break down with a large number of models. Thus, naïve applications of AIC for model selection can be problematic (but are not necessarily so in any particular application). In particular, differences in AICs could be an artifact of how the calculation was done. This is a possible difference between the linear and exponential relative risk models applied to the breast cancer incidence data. Although the EPA provided some clarification about its approach in its February 19, 2015 memo to the SAB, the SAB still does not have sufficient information to determine whether or not this is the case.

In conclusion, although the SAB concurs with the EPA's selected model, it believes that aspects of EPA's approach to model selection can be refined and that more transparency in the presentation is needed.

Summary of recommendations:

- Revise the discussion to provide more clarity and transparency as well as making the disposition easier to follow.
- Discarding a model because the fitted curve is "too steep" is only acceptable when there is scientific justification.
- Clearly articulate the criteria for determining that models are reasonable as well as providing transparent definitions for frequently used terms such as "too steep," "unstable," "problematic," and "credible".
- Assign weight to various models based on a modified combination of biological plausibility and statistical considerations; use somewhat different considerations for comparing AICs than those currently employed in the draft assessment.
- Use a different set of emphases in the priorities for the most reasonable models; detailed suggestions are provided by the SAB in this response.

Appendix 1

2c: For analyses using a two-piece spline model, please comment on whether the method used to identify knots (Section 4.1.2.3 and Appendix D) is transparently described and scientifically appropriate.

The method used to identify the knots involves a sequential search over a range of plausible knots to identify the value at which the likelihood is maximized. This is scientifically appropriate and a practical solution that is transparently described.

The quote from EPA states "[The knot is preselected and is not considered a parameter in these analyses, consistent with the SAB's concept of parsimony (SAB, 2015)]." However, EPA also states on footnote a to Table D-27 "knots were obtained by doing a grid search by increments of 100 ppm x days and then interpolating where appropriate" and foot note b states "For models with very low knots, alternate knots were obtained from local maximum likelihoods because of the small number of cases informing the slope of the low-exposure spline for low knots (see Figure D-14)." EPA further states on page D-41 (emphasis added) "For the two-piece log-linear model, the single knot was chosen at 100 ppm-days based on a comparison of likelihoods assessed every 100 ppm-day from 100 to 15,000. The best likelihood was at 100 ppm-days. Figure D-15 below shows the likelihood versus the knots. Figure D-15 also suggests a local maximum likelihood near 1,600 ppm-days."

In summary, EPA's description of how the knots for the linear spline and log-linear spline models were found clearly indicate that the knots were not fixed parameters, but rather were optimized numerically and in this way were estimated from the data that were fit. That is, the knots used by EPA for the linear and log-linear spline models were determined using the NIOSH data, so that the knot maximized the likelihood of the spline model. The knots, therefore, were not fixed parameters independent of the NIOSH data, as would be the case in SAB discussion of an example. EPA contradicts itself when it states "[The knot is preselected and is not considered a parameter in these analyses, consistent with the SAB's concept of parsimony (SAB, 2015)].[14]" The latter EPA statement is simply false, because each knot value derived by EPA was in fact optimized (i.e., estimated) by EPA to best fit a corresponding model to a specific set of data. This fact has no relevance at all to the concept of parsimony in model selection, which refers to preference for selecting among different models the one(s) that has (have) the fewest total number (k) of estimated parameters. The parsimony concept is also expressed in the definition of the Akaike Information Criterion (AIC), which is proportional to the value of k, insofar as superior models are identified as those with smaller associated values of AIC. Likewise, a p-value for goodness of model fit is typically evaluated in relation to a corresponding value of the total number of degrees of freedom (DF) associated with that fit, and the latter number is always defined as the total number (n) of data points modeled minus the total number (k) of estimated model parameters, i.e., DF = n–k. An invalid reduction in k (e.g., by improperly considering a parameter "fixed" when in fact it was estimated to get a best fit for that model), therefore always improperly inflates the value of DF, which results in an erroneously high p-value for goodness-

of-fit that falsely magnifies the likelihood that deviations between data and a model fit to those data are due only to chance (i.e., due only to sampling error).

Misinterpretation of Degrees of Freedom Results in Miscalculated p-values, AIC and Incorrect Model Selection

The "log-linear spline model with knot at 1,600 ppm-days" has three parameters that each were estimated: slope below the knot, slope above the knot, and the knot itself. However, when EPA calculated a corresponding p-value associated with its reported chi-square test for improved fit relative to an associated null model, EPA used only two degrees of freedom for this calculation. This resulted in artificially and erroneously inflating the measure of improved fit used to compare the linear spline model to other models for which p-values were calculated using degrees of freedom that accurately reflected the total number of estimated parameters associated with other model fits being compared. Specifically, EPA did not include the degree of freedom associated with the separate procedure EPA applied to numerically and graphically maximize the log likelihood of each linear spline model for which an optimum knot value was also estimated. By failing to account for the degree of freedom associated with knot-estimation, the p-value EPA reported for each such linear spline model was miscalculated to yield a lower p-value (indicating an unrealistically improved fit) than would be produced had the correct number of degrees of freedom been used by EPA for each such calculation.

In using the approach EPA took in this regard, EPA may have misinterpreted comments of the EPA (2015) Science Advisory Board (SAB) review of the EPA (2014) draft IRIS document, which on pages 12–14 state that:

> the principle of parsimony (the desire to explain phenomena using fewer parameters) should be considered. Attention to this principle becomes even more important as the information in the analysis dataset becomes even more limited. Thus, models with very few estimated parameters should be favored in cases where there are only a few events in the dataset. To elaborate further, in some settings the principle of parsimony may suggest that the most informative analysis will rely upon fixing some parameters rather than estimating them from the data. The impact of the fixed parameter choices can be evaluated in sensitivity analyses. In the draft assessment, **fixing the knot when estimating linear spline model fits from relative risk regressions is one such example**. … differences in AICs could be an artifact of how the calculation was done.

Importantly (as shown above), although the SAB indicated that fixing a knot value can be done as part of a practical approach to knot-value estimation, it also stated that "differences in AICs could be an artifact of how the calculation was done." The SAB unfortunately failed to emphasize (but must be assumed to agree with the fact) that **differences in p-values from chi-square tests of improved fit relative to the null model can also reflect non-meaningful**

artifacts if associated p-value calculations are not done correctly. Specifically, it is not meaningful to compare (as EPA did) a p-value from a Cox linear-regression model of Log(RR) on ppm-days of exposure (defined to be associated with one degrees of freedom for each of the estimated slope of the line) to a p-value from EPA's linear spline model fit (assumed to be associated with only two degrees of freedom corresponding to its two estimated slopes) conditional on a knot value that EPA estimated by minimizing log likelihood in relation to the knot value. EPA incorrectly assumed its optimized knot-value estimate is not associated with one additional degree of freedom. Thus, EPA erroneously deflated the total degrees of freedom associated with their three-parameter linear model by evaluating it as if it had only two degrees of freedom (parameters) associated with it. Consequently, EPA miscalculated the p-value for its spline model resulting in an erroneously low p-values of ~0.07 (see Table 2), when (as explained in more detail in the next section) the correctly calculated p-value is ~2-fold greater (i.e., 0.14 to 0.15) and do not differ meaningfully from p-values associated with the more parsimonious linear Cox regression model (see corrected Table 4-6 discussed in the next section).

Table 2. SAS results given for this model in Table D-33 in Appendix D of EO IRIS 2016

Table D-33. Results of two-piece log-linear spline model for lymphoid cancer mortality, men and women combined, knot at 1,600 ppm-days

Model fit statistics						
Criterion	**Without covariates**	**With covariates**				
-2 LOG L	463.912	**458.640**				
AIC	463.912	**462.640**				
SBC	463.912	466.581				
Testing global null hypothesis: BETA = 0						
Criterion	**Without covariates**	**With covariates**				
Likelihood ratio	5.2722	**2**	**0.0716**			
Score	5.2666	2	0.0718			
Wald	5.1436	2	0.0764			
Analysis of maximum likelihood estimates						
Parameter	**DF**	**Parameter estimate**	**Standard error**	**χ2**	**Pr > ChiSq**	**Hazard ratio**
LIN_0	1	0.0004893	0.0002554	3.6713	0.0554	1.000
LIN_1	1	0.0004864	0.0002563	3.6014	0.0577	1.000

Miscalculated p-values: Example using the log-linear spline model with knot at 1,600 ppm-days"

The likelihood ratio test is used to test whether a fitted model significantly improves the fit of the data by estimating parameters instead of just assuming a baseline (null) model for the data. The likelihood ratio test is evaluated by comparing the likelihood of the model with the estimated parameters and the likelihood of the null model. If the likelihood of the model with the estimated parameters is equal to the likelihood of the null model, then the natural logarithm of the ratio of

these likelihoods multiplied by two follow a Chi-Square distribution with as many degrees of freedom as the number of parameters estimated for the fitted model. Thus, if the fit of the baseline (null) model and the model with estimated parameters are not different,

$$Chi - Square(k) = \chi_k^2 = -2\ln\left(\frac{likelihood\ for\ null\ model}{likelihood\ for\ fitted\ model}\right)$$

This can also be written as follows,

$$\chi_k^2 = -2LogL(null\ model) - 2LogL(fitted\ model)$$

Here k is the number of degrees of freedom (k is the number of parameters that were estimated in excess of the parameters estimated for the null model).

For the model in Table 2 (Table D-33 in EO IRIS 2016) the χ_k^2 value was equal to 5.2722 and k was set to 2. This resulted in a p-value of 0.0716. That is, the fitted model was assumed to have two parameters; namely, the slope below the knot and the slope above the knot. The results in Table 2 are from a SAS output for the model specified. The model specified included a knot. This knot was determined so that the likelihood of the spline model was maximized. That is, the knot is another parameter that was searched for outside SAS. Because the estimation of the "knot" was done outside SAS, the SAS program did not count the knot as a parameter and, consequently, the Chi-Square test SAS reported does not reflect the fact that the knot was also estimated. The correct Chi-Square that accounts for the fact that the knot was estimated outside SAS should then be 5.2722, but k (the degrees of freedom) should be 3. This corrected calculation would result in a p-value of 0.1529. That is, the corrected p-value indicates that the likelihood of the "log-linear spline model with knot at 1,600 ppm × days" is not different from the likelihood of the null model. In plain words, there is not enough evidence indicating that the fitted log-linear spline model explains the variability in the data any better than the null model.

Miscalculated AICs: Example using the log-linear spline model with knot at 1,600 ppm-days

The Akaike Information Criterion (AIC) is equal to $2k$ - $2LogL$ where k is the number of parameters estimated for the model and LogL is the logarithm of the likelihood. Here, Table 2 (Table D-33 in EO IRIS 2016) lists the -2LogL as 458.640 and the AIC as 462.640. That is;

$$462.640 = 2k + 458.640$$

The AIC and –2LogL implies that k equals 2. That is, the spline model was assumed to have estimated two parameters; namely, the slope below the knot and the slope above the knot. The results in the Table 2 consist of SAS output for the spline model specified. The model specified included a knot. This knot was pre-assigned (i.e., previously estimated using a separate optimization procedure outside the SAS run), so the likelihood of the model was maximized only

conditional on the estimated knot-value used for that calculation. Consequently, the knot must be treated as an additional parameter that was estimated outside SAS. Because the estimation of the "knot" was done outside SAS, the SAS run performed by EPA did not count the knot as a model parameter and, consequently, the resulting AIC value it obtained does not reflect that the knot was in fact estimated. EPA could have requested SAS to account properly for the extra degree of freedom properly associated with its estimated knot value, but EPA evidently elected not to make this request of SAS.

The correct AIC, which accounts for the fact that the knot was estimated outside SAS, should instead be

$$AIC = 464.640 = 2\times3 + 458.640$$

These differences are summarized in corrected Table 3 below.

Model selection with correct AIC and p-values

EPA selects the "linear spline model with knot at 1,600 ppm × days" for lymphoid for the following reasons:

a) Adequate statistical fit. EPA's uses the erroneous p-value of 0.07 (Table 1) to select the model arguing that it is close to 0.05. However, the corrected p-value is 0.14 (Table 3) once the fact that the knot was also estimated is accounted for by adding one more degree of freedom to the chi-square distribution. The corrected p-value is now in the range of the p-values for the log-linear and linear models; in fact, it is larger than the p-value (0.13) for the linear model.

b) Adequate visual fit. EPA's visual fit is dismissed in the footnote of Figure 4-3 of the EO IRIS 2016 report. The footnote reads "(Note that, with the exception of the categorical results and the linear regression of the categorical results, the different models have different implicitly estimated baseline risks; thus, they are not strictly comparable to each other in terms of RR values, i.e., along the y-axis. They are, however, comparable in terms of general shape.)" In addition to the visual-fit caveat listed by EPA in the IRIS report, they failed to indicate that the models are **not** fit to the five nonparametric rate ratios shown in the figure, but rather to the individual cases that includes nine cases of lag-15 EO unexposed workers and 44 cases with lag-15 EO cumulative exposure. That is, the graph shown in Figure 4-3 of the EO IRIS 2016 report does not show all the variability in the full data and visual comparisons can be misleading. Furthermore, the categorical rate ratios are not "the data", but rather, non-parametric estimate of the rate ratios.

c) Including local fit (visual) **to low-exposure range; linear model.** When the models are plotted against the non-parametric rate ratios of the 44 exposed cases, all models seem to fit the

non-parametric models about the same; which is consistent with the calculated p-values and AIC values.

d) AIC within two units of lowest AIC of models considered. EPA's uses the erroneous AIC value of 462.1 to select the model arguing that it is within two units from the lowest AIC (460.2 for the "linear model with log cumulative exposure"). However, the corrected AIC is 464.5 once the fact that the knot was also estimated is accounted for by adding one more parameter in the calculation of the AIC. The corrected AIC for the "linear spline model with knot at 1,600 ppm-days" is now larger than the AIC values for the linear model (463.6) and for the log-linear model (464.4).

Once the errors indicated above concerning calculating p-values, calculating AIC values, and associated adjustments for different calculations of likelihood values are all corrected, EPA's best model for lymphoid should be reconsidered. Using the criteria EPA EO IRIS uses to select a model, the best models for the lymphoid data are the "linear model" followed by the "log-linear model."

Table 3. The following table has been extracted from EO IRIS 2016 Table 4-6 and the p-values and AIC values have been corrected to reflect the degree of freedom for the knot in the spline models and to reflect the likelihood difference between SAS procedures used for linear and log-linear models

Table 4–6. Models considered for modeling the exposure-response data for lymphoid cancer mortality in both sexes in the National Institute for Occupational Safety and Health cohort for the derivation of unit risk estimates

Model[a]	*p-value*[b]	AIC[c]	Comments
Two-piece spline models			
Linear spline model with knot at 1,600 ppm × days	0.14	464.5	**SELECTED.** Adequate statistical and visual fit, including local fit to low-exposure range; linear model; AIC within two units of lowest AIC of models considered.
Linear spline model with knot at 100 ppm × days	0.11	463.8	Good overall statistical fit and lowest AIC of two-piece spline models, but poor local fit to the low-exposure region, with no cases below the knot.
Log-linear spline model with knot at 1,600 ppm × days	0.15	464.6	Linear model preferred to log-linear (see text above).
Log-linear spline model with knot at 100 ppm × days	0.11	463.8	Good overall statistical fit and tied for lowest AIC_c of two-piece spline models, but poor local fit to the low-exposure region, with no cases below the knot.
Linear (ERR) models (RR = 1 + β × exposure)			
Linear model	0.13	463.6	Not statistically significant overall fit and poor visual fit.
Linear model with log cumulative exposure	0.02	460.6	Good overall statistical fit, but poor local fit to the low-exposure region.

Appendix 1

Model[a]	*p-value*[b]	AIC[c]	Comments
Linear model with square-root transformation of cumulative exposure	0.053	462.2	Borderline statistical fit, but poor local fit to the low-exposure region.
Log-linear (Cox regression) models (RR = $e^{\beta \times \text{exposure}}$)			
Log-linear model (standard Cox regression model)	0.22	464.4	Not statistically significant overall fit and poor visual fit.
Log-linear model with log cumulative exposure	0.02	460.4	Good overall statistical fit; lowest AIC[c] of models considered; low-exposure slope becomes increasingly steep as exposures decrease, and large unit risk estimates can result; preference given to the two-piece spline models because they have a better ability to provide a good local fit to the low-exposure range.
Log-linear model with square-root transformation of cumulative exposure	0.08	462.8	Not statistically significant overall fit and poor visual fit.

[a]All with cumulative exposure as the exposure variable, except where noted, and with a 15-yr lag.

[b]*p*-values from likelihood ratio test, except for linear regression of categorical results, where Wald *p*-values are reported. $p < 0.05$ considered "good" statistical fit; $0.05 < p < 0.10$ considered "adequate" statistical fit if significant exposure-response relationships have already been established with similar models.

[c]AICs for linear models are directly comparable and AICs for log-linear models are directly comparable. However, for the lymphoid cancer data, SAS proc NLP (where NLP = nonlinear programming) consistently yielded −2LLs and AICs about 0.4 units lower than proc PHREG for the same models, including the null model, presumably for computational processing reasons, and proc NLP was used for the linear RR models. Thus, AICs for linear models are equivalent to AICs about 0.4 units higher for log-linear models. No AIC was calculated for the linear regression of categorical results.

Note: In order to make the AICs comparable for different models, the AIC's for the linear models have been increased by 0.4 to reflect the discrepancy in the -2LogL values reported by the SAS proc NLP and by SAS PHREG (as indicated in green in this table).

Figures 1 to 4 are versions of EPA's Figure 4-3. A model (TrueLogL – dotted light blue line in the graphs) was added to relieve the caveat posed by EPA in the footnote to Figure 4-3 about the visual comparability of fitted models. The TrueLogl model is an approximation to the correct visual representation of the log-linear (standard Proportional Hazards Model fit to the NIOSH full data set) after adjusting for the difference in baseline risks between the rate ratios and the loglinear model. In Figures 1 to 4, all the individual RR (categorical) in the light blue box of the figure are summarized by the red dot in the light blue box (EPA's 5 RRs for the last quartile). Similarly, all the individual RR (categorical) in the light yellow box of the figure are summarized by the red dot in the light yellow box (EPA's 5 RRs for the third quartile). In the same way, all the individual RR (categorical) in the light green box of the figure are summarized by the red dot in the light green box (EPA's 5 RRs for the second quartile). Finally, all the individual RR (categorical) in the clear box, next to the vertical axis of the figure, are summarized by the red dot in the clear box (EPA's 5 RRs for the first quartile).

Appendix 1

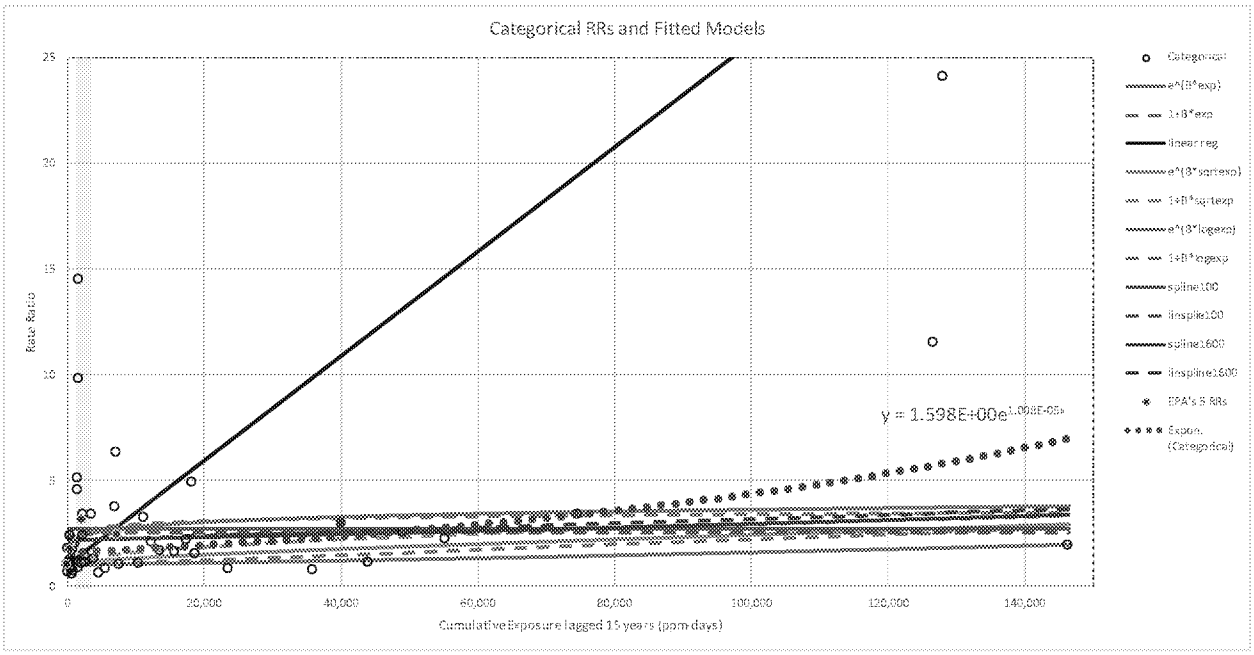
Figure 1 shows all EPA models plotted versus the individual nonparametric rate ratios (categorical) and grouped rate ratios (EPA's 5 RRs). The range of cumulative exposures when the rate ratios for all cases are plotted is much bigger than the range of cumulative exposures when the rate ratios are averaged over several cases (EPA's 5 RRs). The variability of the rate ratios for the individual cases (categorical) is much larger than the variability of the rate ratios averaged over several cases (EPA's 5 RRs). Except for the unacceptable linear model fit to four rate ratios (linear reg), all models fit approximately the same in Figure 1. The model Expon. (Categorical) is a plot of the approximate log-linear model (e^(B*exp)) adjusted by dividing the model for the hazard rate by the baseline hazard rate of the nonparametric estimates.

Figure 2 shows an expansion of the low-left corner of Figure 1. These are all EPA models plotted versus the nonparametric rate ratios with values between 0 and 3.5 and cumulative exposures between 0 and 40,000 ppm-days. This graph resembles Figure 4-3 of the EO IRIS 2016 report with the exception that rate ratios based on individual cases (categorical) that are in the range of the graph are plotted in addition to the aggregated four points used by EPA (EPA's 5 RRs).

Figure 3 is the same as Figure 1 except that the vertical scale is shown using a logarithmic scale of the rate ratios to visualize the linear difference between the fitted models and the rate ratios.

Figure 4 is the same as Figure 2 except that the vertical scale is shown using a logarithmic scale of the rate ratios to visualize the linear difference between the fitted models and the rate ratios.

Figure 1. EPA models plotted against all lymphoid rate ratios in the NIOSH data



Appendix 1

Figure 2. EPA models plotted against all lymphoid rate ratios in the NIOSH data in the low exposure concentration range and with the rate ratio truncated to the same range of EPA's Figure 4-3.

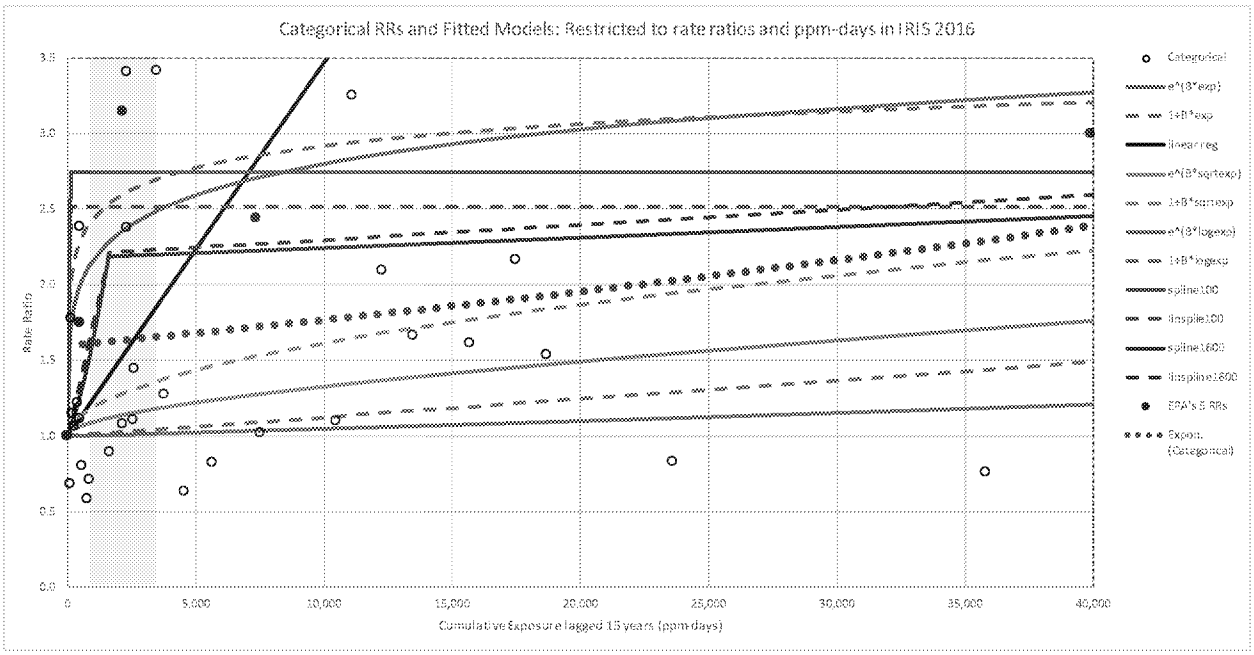
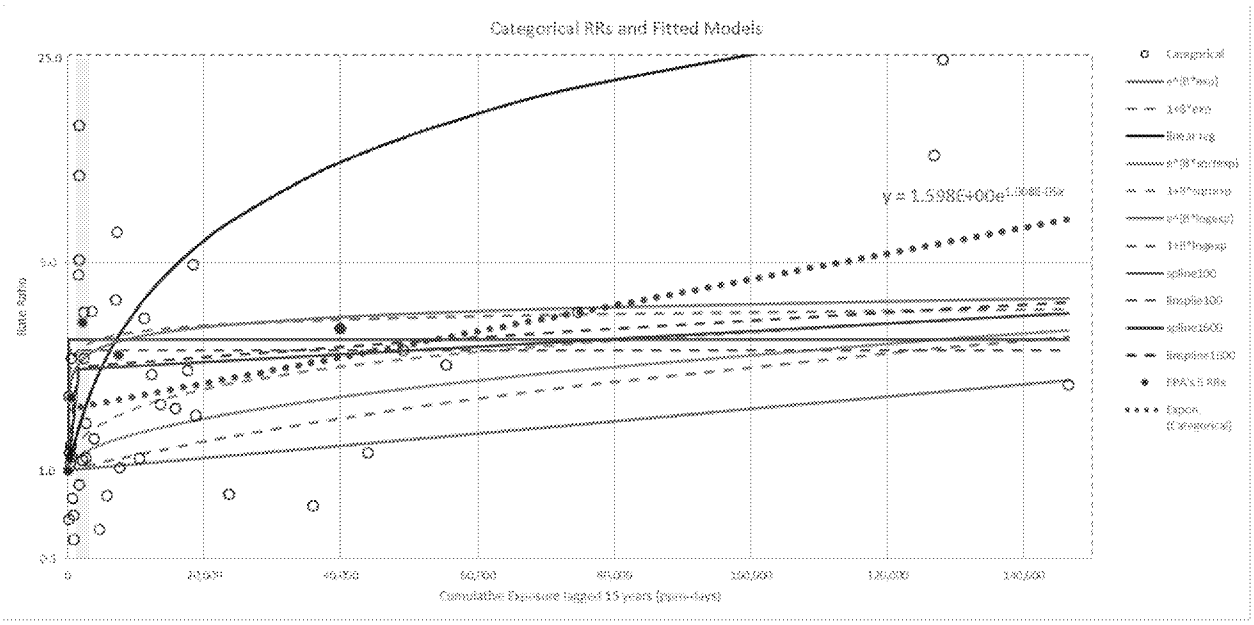
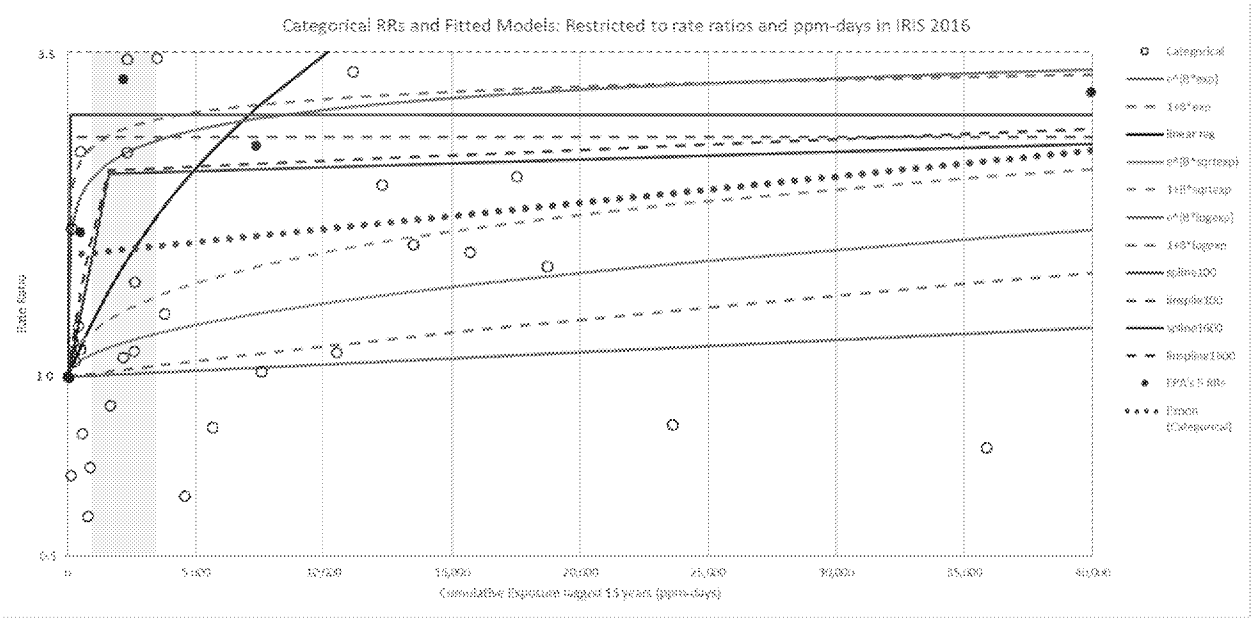


Figure 3. EPA models plotted against the logarithm of all lymphoid rate ratios in the NIOSH data



Appendix 1

Figure 4. EPA models plotted against the logarithm all lymphoid rate ratios in the NIOSH data in the low exposure concentration range and with the rate ratio truncated to the same range of EPA's Figure 4-3.



Appendix 2

Brief Summary of Epidemiological Data for EO

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The relevant epidemiology, despite the large number of studies published over a forty-year period, are not supportive of a determination that EO is a human carcinogen. While interest has centered on leukemia, other blood related malignancies, and recently breast cancer: (1) there are numerous inconsistencies across the studies, (2) elevated risks above background are found in isolated studies and the effect size is of small magnitude, and (3) there is an absence of a clear exposure-response relation for any specific cancer type.

Examination of the specific cancer subtypes (leukemia, non-Hodgkin's lymphoma [NHL], Hodgkin's disease [HD], multiple myeloma [MM] and lymphohematopoietic cancers [LH] overall) illustrates the absence of clear evidence of carcinogenicity and no clear choice for a target organ should a dose-response be attempted. Table 1 summarizes the individual and overall findings from the EO studies for leukemia. Taking the ratio of the total observed cases and the total expected number of cases yields a summary risk estimate. The total number of deaths due to leukemia is 64 with 56.86 expected for an SMR /SIR of 1.13 (95% CI: 0.87-1.44). It is noteworthy that Hogstedt's increase was mainly attributable to myeloid leukemias, while Steenland focused on lymphocytic leukemia in the lymphoid category. As shown by Shore and Teta in their meta-analyses, Hogstedt is an outlier that is statistically different in findings from the other studies, i.e., a cause of heterogeneity. Furthermore, it is incorrect to include a cluster which gave rise to the hypothesis in a summary risk estimate. Excluding Hogstedt, yields 57 observed leukemias and 56.06 expected for an SMR/SIR of 1.02 (95% CI: 0.77, 1.32). Clearly Hogstedt's hypothesis of EO as a cause of leukemia has not been confirmed.

Appendix 2

Table 1. Leukemia in Epidemiology Studies of Ethylene Oxide

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	7	0.80	9.21* (3.70, 19.0)
Lymphocyctic	2	---	---
Myeloid	3	---	---
NOS	2	---	---
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	5	3.58	1.40 (0.45, 3.26)
Thiess 1981/Kiesselbach 1990	2	2.35	0.85 (0.10, 3.07)
Morgan 1981/Divine 1990	0	0.60	0.00 (0.00, 6.57)
Greenberg 1990/Teta 1993/ Swaen 2009	11	11.8	0.93 (0.47, 1.67)
Steenland 1991/Stayner 1993/ Steenland 2004	29	29.3	0.99 (0.71, 1.36)
Bisanti 1993	2	0.30	6.50 (0.79, 23.5)
Gardner 1989/Coggon 2004	5	4.60	1.08 (0.35, 2.51)
Olsen 1997	2	3.00	0.67 (0.08, 2.40)
Norman 1995	1	0.54	1.85 (0.05, 10.3)
Summary	64	56.9	1.13 (0.87, 1.44)
Summary (-Hogstedt)	57	56.1	1.02 (0.77, 1.32)

For HD there were 17 observed compared to 10.84 expected (1.57; 95% CI: 0.91-2.51) (Table 2). The Swaen case-control study was included and an expected number was derived to combine these results with those of the cohort studies. (The proportion of controls exposed, 5%, was applied to the case group of 10 cases yielding an expected exposed of 0.5). Relying only on the two strongest studies (Swaen 2009 and Steenland 2004) yields for HD, 6 vs. 6.54 (0.92; 95% CI: 0.34, 2.0). The Swaen 2009 UCC cohort had no deaths due to HD.

Appendix 2

Table 2. Hodgkin Disease in Epidemiology Studies of Ethylene Oxide

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	0	---	---
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	1	1.31	0.76 (0.02, 4.25)
Thiess 1981/Kiesselbach 1990	---	---	---
Morgan 1981/Divine 1990	3	0.40	8.34* (1.68, 24.4)
Greenberg 1990/Teta 1993/ Swaen 2009	0	1.70	0.00* (0.00, 0.22)
Steenland 1991/Stayner 1993/ Steenland 2004	6	4.84	1.24 (0.53, 2.43)
Bisanti 1993	---	---	---
Gardner 1989/Coggon 2004	2	1.05	1.91 (0.23, 6.89)
Olsen 1997	2	0.70	2.86 (0.35, 10.3)
Norman 1995	0	0.34	0.00 (0.00, 10.9)
Swaen 1996	3	0.50	8.50* (1.40, 39.9)
Summary	17	10.8	1.57 (0.91, 2.51)

Two studies provided no data for MM (Kiesselbach 1990 and Bisanti 1993) and four others failed to provide expected values (Hogstedt 1988, Divine 1990, Olsen 1997, and Swaen 2009) (Table 3). Upon contacting Dow, we were able to obtain the expected number of 5.1 for MM. Based on the studies with complete information, there are 22 observed and 24.0 expected for a summary estimate of 0.92 (Table 3). This result is heavily weighted by the largest study, Steenland et al. 2004, who reported 13 cases vs. 14.13 expected (SMR= 0.92). This summary risk estimate does not indicate an association with MM.

Appendix 2

Table 3. Multiple Myeloma in Epidemiology Studies of Ethylene Oxide

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	0	---	---
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	2	2.08	0.96 (0.12, 3.47)
Thiess 1981/Kiesselbach 1990	---	---	---
Morgan 1981/Divine 1990	0	---	---
Greenberg 1990/Teta 1993/ Swaen 2009	3	5.10	0.59 (0.12, 1.72)
Steenland 1991/Stayner 1993/ Steenland 2004	13	14.1	0.92 (0.49, 1.57)
Bisanti 1993	---	---	---
Gardner 1989/Coggon 2004	3	2.50	1.20 (0.25, 3.49)
Olsen 1997	1	NR	NR
Norman 1995	1	0.23	4.34 (0.11, 24.2)
Summary	22	24.0	0.92 (0.57, 1.39)

Using the same method of pooling the observed and expected values of NHL across the different studies results in a meta-SMR/SIR estimate of 1.12 based on 62 observed and 55.4 expected, a small, non-statistically significant increase (Table 4).

Table 4. Non-Hodgkins Lymphoma in Epidemiology Studies of Ethylene Oxide

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	2	---	---
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	9	6.25	1.44 (0.66, 2.73)
Thiess 1981/Kiesselbach 1990	---	---	---
Morgan 1981/Divine 1990	0	0.90	0.00 (0.00, 4.04)
Greenberg 1990/Teta 1993/ Swaen 2009	12	11.5	1.05 (0.54, 1.83)
Steenland 1991/Stayner 1993/ Steenland 2004	31	31.0	1.00 (0.72, 1.35)
Bisanti 1993	3	0.20	16.9* (3.49, 49.5)
Gardner 1989/Coggon 2004	7	4.80	1.46 (0.59, 3.02)
Olsen 1997	5	NR	NR
Norman 1995	0	0.76	0.00 (0.00, 4.85)
Summary	62	55.4	1.12 (0.86, 1.43)

Examination across the ten studies of all LH cancers yields a non-statistically significant increase based on 175 observed vs. 156.97 expected (Meta-SMR/SIR = 1.11; 95% CI: 0.96, 1.29) (Table 5). Exclusion of Hogstedt would result in a weak excess (1.07) and narrow confidence interval (95% CI: 0.91, 1.25).

Appendix 2

Table 5. All Lymphopoietic and Hematopoietic Cancers in Epidemiology Studies of Ethylene Oxide

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	9	2.00	4.59* (2.10, 8.70)
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	18	14.4	1.25 (0.74, 1.98)
Thiess 1981/Kiesselbach 1990	5	4.99	1.00 (0.32, 2.34)
Morgan 1981/Divine 1990	3	3.00	1.01 (0.20, 2.96)
Greenberg 1990/Teta 1993/ Swaen 2009	27	30.4	0.89 (0.59, 1.29)
Steenland 1991/Stayner 1993/ Steenland 2004	79	79.0	1.00 (0.79, 1.24)
Bisanti 1993	5	0.70	7.00* (2.27, 16.4)
Gardner 1989/Coggon 2004	17	12.9	1.30 (0.77, 2.10)
Olsen 1997	10	7.70	1.29 (0.62, 2.38)
Norman 1995	2	1.88	1.06 (0.13, 3.84)
Summary	175	157.0	1.11 (0.96, 1.29)
Summary (-Hogstedt)	166	155.0	1.07 (0.91, 1.25)

As discussed above, Steenland et al. (2004) grouped three LHC cancers into the "lymphoid" category and reported some positive findings for men only. This category included lymphocytic leukemias only. The original cluster reported by Hogstedt in 1979 consisted of myeloid leukemias (Table 2). The results from the only other study to examine the lymphoid category as defined by NIOSH (UCC cohort) are inconsistent with the NIOSH results (Swaen 2009). From an internal analysis using Cox proportional hazard model, no evidence of an exposure–related response was observed by Swaen et al. using the UCC EO cohort. In fact, the females in the NIOSH study are also inconsistent with the male findings for lymphohematopoietic and "lymphoid" tumors (Steenland 2004).

Steenland et al. also examined both incidence and mortality from breast cancer for the sterilizer cohort (Steenland 2003, 2004). Among the overall results for this disease endpoint among other studies, only Norman et al. (1995) reported an increase (Table 6). Hogstedt enumerated all the cancers from his numerous cohorts and updates. No breast cancer cases were identified. Similarly, there was no excess among the hospital workers studies by Coggon et al. (2004), even among those with "continual" exposure (5 observed, 7.2 expected). The data related to breast cancer derived predominately from the NIOSH studies of sterilant workers with 102 deaths and 103 expected for an SMR of 0.99 (95% CI: 0.81-1.20) (Steenland 2004) and 319 incident cases with 367 expected for a statistically significant deficit of 0.87 (95% CI: 0.77-0.97) (Steenland 2003) due to underascertainment of cases. When examined in various exposure subgroup analyses, however, NIOSH concluded there was some evidence of an increase for breast cancer.

Appendix 2

Table 6. Ethylene Oxide Epidemiology Studies of Female Breast Cancer

Study	Observed	Expected	Obs./Exp. (95% CI)
Coggon et al. 2004	11	13.1	0.84 (0.42, 1.51)
Steenland et al. 2004	102	103.0	0.99 (0.81, 1.20)
Steenland et al. 2003	319	367.0	0.87* (0.77, 0.97)
Mikoczy et al. 2011	41	50.9	0.81 (0.58, 1.09)
Norman et al. 1995	12	7.0	1.72 (0.93, 2.93)
Hogstedt et al. 1986	0	---	---
Summary (incident cases only)	372	424.9	0.88* (0.79, 0.97)
Summary (mortality cases only)	113	116.1	0.97 (0.80, 1.17)

EPA recognizes that magnitudes of increased risks for breast cancer were not large and implies that the evidence is weaker than that for lymphoid tumors. Despite these issues, EPA proceeds to introduce breast cancer as a target organ in the IRIS Assessment and inappropriately develops a risk value. Uncertainties described by Steenland et al. (2003) related to the breast cancer incidence study are dismissed as unimportant by EPA. EPA agrees with Steenland that the breast cancer incidence findings are not conclusive, due to inconsistencies in the exposure-response and an incomplete cancer ascertainment. Using these data, the slopes of EPA's attempted exposure-response analyses were non-statistically significant or biologically uninterpretable, leading them to employ novel approaches for quantitative risk assessment. The modeling challenges could be anticipated given Steenland's statement of uncertainty with respect to breast cancer, "The dip in the spline curve in the region of higher exposures suggested an inconsistent or non-monotonic risk with increasing exposure."

The Agency downplays the potential for selection bias based on the consistency in the incidence study between results from full cohort and those from the subgroup interviewed (68% of study subjects). Selection bias (referred to by Steenland as "possible biases due to patterns of non-response") remains a concern, however, with duration reported as a stronger risk factor than cumulative exposure in both analyses. Those who work longer stay in the area longer and are more likely to get picked up in the state tumor registries and be found for interview, therefore with the potential to impact the results of both analyses. Shorter duration workers with lower exposures are more likely to leave the area and not be captured in the overall analyses and less likely to be interviewed. Their diagnoses get missed, creating a possible biased positive exposure-response. Steenland recognized this limitation and admitted he was unable to fully address it and listed it as one of his uncertainties:

> A second possible bias was the preferential ascertainment of breast cancer among women with stable residence in states with cancer registries; women with stable residency might be expected to have longer duration of employment in companies

under study, and hence greater cumulative exposure. Unfortunately, we did not have residential history, limiting our ability to explore this possibility.

The more recent study by Mikoczy et al. (2011) has been cited as supportive of an association with breast cancer, in spite of an overall deficit (SIR=0.81; 95% CI: 0.58-1.09) based on 41 cases observed. With 15-year latency it is 0.86, also suggesting no increase. Similar to NIOSH, however, the two higher cumulative exposure groups (of three total group) had statistically significant elevated rates of breast cancer (2.76; 95% CI: 1.20-6.33 and 3.55; 95% CI: 1.58-7.93) in an *internal* Poisson analysis, due, however, to a substantial and statistically significant deficit of breast cancer in the low dose reference group (SIR=0.52; 95% CI: 0.25-0.96). There are clearly advantages to comparing workers to workers in epidemiology studies to overcome possible biases in external comparisons to the general population. However, there may also be disadvantages to using an internal comparison group that are not recognized. One danger is selecting a referent group that has an unusual excess or deficit of the disease of interest as illustrated in this study. This illustrates the problem that can arise from internal comparisons and should not always to be preferred despite what EPA contends.

In addition to LH cancers, EPA uses breast cancer as a target endpoint. We conclude that the choice of breast cancer as a target organ for EO dose-response assessment is not justified for several reasons: (1) EPA agrees that the evidence for breast cancer is even weaker than the evidence for the lymphoid category, (2) the NIOSH findings suffer from potential selection biases, show a non-monotonic increase in risk with increasing exposure, and neither mortality nor incidence rates overall exceed background rates in the general population, and (3) the breast cancer findings from the other epidemiology studies are equivocal.

There is no obvious target organ for an EO exposure-response assessment for a quantitative risk assessment. Given the weak epidemiology evidence for carcinogenicity, the lack of consistency or a clear exposure-response, the selection of a specific target organ is problematic. Using cumulative exposure as the exposure metric and the standard proportional hazard modeling, none of the slopes for the endpoints of interest are statistically significant (Valdez-Flores, Sielken, and Teta 2010). Despite the absence of a clear exposure-response for any one of the combinations, the authors proceeded to use EPA's standard procedure for unit risk estimation and estimation of exposure associated with a one-in-a-million risk. This approach was adopted by Scientific Committee on Occupational Exposure Limits (SCOEL) for the European Union in 2012 for occupational standard setting.

References

1. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Revised External Review Draft): United States Environmental Protection Agency: Office of Research and Development August 2014.

Appendix 2

2. Bisanti L, Maggini M, Raschetti R, Alegiani SS, Ippolito FM, Caffari B, et al. Cancer mortality in ethylene oxide workers. Br J Ind Med 1993;50(4):317-24.

3. Coggon D, Harris EC, Poole J, Palmer KT. Mortality of workers exposed to ethylene oxide: extended follow up of a British cohort. Occup Environ Med 2004;61(4):358-62.

4. Divine BJ. Update of Texas Morgan Study. Presentation at the American Conference of Occupational Medicine Meeting (unpublished). In. Houston, Texas; 1990.

5. Gardner MJ, Coggon D, Pannett B, Harris EC. Workers exposed to ethylene oxide: a follow up study. Br J Ind Med 1989;46(12):860-5.

6. Greenberg HL, Ott MG, Shore RE. Men assigned to ethylene oxide production or other ethylene oxide related chemical manufacturing: a mortality study. Br J Ind Med 1990;47(4):221-30.

7. Hagmar L, Mikoczy Z, Welinder H. Cancer incidence in Swedish sterilant workers exposed to ethylene oxide. Occup Environ Med 1995;52(3):154-6.

8. Hagmar L, Welinder H, Linden K, Attewell R, Osterman-Golkar S, Tornqvist M. An epidemiological study of cancer risk among workers exposed to ethylene oxide using hemoglobin adducts to validate environmental exposure assessments. Int Arch Occup Environ Health 1991;63(4):271-7.

9. Hogstedt C, Aringer L, Gustavsson A. Epidemiologic support for ethylene oxide as a cancer-causing agent. JAMA 1986;255(12):1575-8.

10. Hogstedt C, Rohlen O, Berndtsson BS, Axelson O, Ehrenberg L. A cohort study of mortality and cancer incidence in ethylene oxide production workers. Br J Ind Med 1979;36(4):276-80.

11. Hogstedt LC. Epidemiological studies on ethylene oxide and cancer: an updating. IARC Sci Publ 1988(89):265-70.

12. Kiesselbach N, Ulm K, Lange HJ, Korallus U. A multicentre mortality study of workers exposed to ethylene oxide. Br J Ind Med 1990;47(3):182-8.

13. Mikoczy Z, Tinnerberg H, Bjork J, Albin M. Cancer incidence and mortality in Swedish sterilant workers exposed to ethylene oxide: updated cohort study findings 1972-2006. Int J Environ Res Public Health 2011;8(6):2009-19.

14. Morgan RW, Claxton KW, Divine BJ, Kaplan SD, Harris VB. Mortality among ethylene oxide workers. J Occup Med 1981;23(11):767-70.

15. Norman SA, Berlin JA, Soper KA, Middendorf BF, Stolley PD. Cancer incidence in a group of workers potentially exposed to ethylene oxide. Int J Epidemiol 1995;24(2):276-84.

16. Olsen GW, Lacy SE, Bodner KM, Chau M, Arceneaux TG, Cartmill JB, et al. Mortality from pancreatic and lymphopoietic cancer among workers in ethylene and propylene chlorohydrin production. Occup Environ Med 1997;54(8):592-8.

17. Shore RE, Gardner MJ, Pannett B. Ethylene oxide: an assessment of the epidemiological evidence on carcinogenicity. Br J Ind Med 1993;50(11):971-97.

18. Stayner L, Steenland K, Greife A, Hornung R, Hayes RB, Nowlin S, et al. Exposure-response analysis of cancer mortality in a cohort of workers exposed to ethylene oxide. Am J Epidemiol 1993;138(10):787-98.

19. Steenland K, Stayner L, Deddens J. Mortality analyses in a cohort of 18 235 ethylene oxide exposed workers: follow up extended from 1987 to 1998. Occup Environ Med 2004;61(1):2-7.

20. Steenland K, Stayner L, Greife A, Halperin W, Hayes R, Hornung R, et al. Mortality among workers exposed to ethylene oxide. N Engl J Med 1991;324(20):1402-7.

21. Steenland K, Whelan E, Deddens J, Stayner L, Ward E. Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States). Cancer Causes Control 2003;14(6):531-9.

22. Swaen GM, Burns C, Teta JM, Bodner K, Keenan D, Bodnar CM. Mortality study update of ethylene oxide workers in chemical manufacturing: a 15 year update. J Occup Environ Med 2009;51(6):714-23.

23. Swaen GM, Slangen JM, Ott MG, Kusters E, Van Den Langenbergh G, Arends JW, et al. Investigation of a cluster of ten cases of Hodgkin's disease in an occupational setting. Int Arch Occup Environ Health 1996;68(4):224-8.

24. Teta MJ, Benson LO, Vitale JN. Mortality study of ethylene oxide workers in chemical manufacturing: a 10 year update. Br J Ind Med 1993;50(8):704-9.

25. Teta MJ, Sielken RL, Jr., Valdez-Flores C. Ethylene oxide cancer risk assessment based on epidemiological data: application of revised regulatory guidelines. Risk Anal 1999;19(6):1135-55.

26. Thiess AM, Schwegler H, Fleig I, Stocker WG. Mutagenicity study of workers exposed to alkylene oxides (ethylene oxide/propylene oxide) and derivatives. J Occup Med 1981;23(5):343-7.

27. Valdez-Flores C, Sielken RL, Jr., Teta MJ. Quantitative cancer risk assessment based on NIOSH and UCC epidemiological data for workers exposed to ethylene oxide. Regul Toxicol Pharmacol 2010;56(3):312-20.

Message

From: Kathryn E. Liziewski [kliziewski@healtheffects.org]
on behalf of Donna Vorhees [DVorhees@healtheffects.org]
Sent: 9/6/2018 9:07:30 PM
Subject: HEI Energy Research Program-Agenda and Materials for September 12-13, 2018 Workshop
Attachments: HEI Energy Research Program September Workshop Participant Packet.pdf; HEI Bibliography 6 September 2018.pdf

Good afternoon,

In preparation for HEI's Exposure Workshop being held September 12-13, 2018 in Austin, Texas, please find the agenda and other preparatory materials attached. We look forward to seeing you in Austin.

Thank you,

Donna Vorhees

Donna J. Vorhees, ScD
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INTRODUCTION TO THE BIBLIOGRAPHY

LITERATURE TO UNDERSTAND POPULATION-LEVEL EXPOSURES RELATED TO DEVELOPMENT OF OIL AND NATURAL GAS FROM UNCONVENTIONAL RESOURCES

Introduction:

This bibliography contains a preliminary list of exposure characterization and health peer-reviewed studies and non-peer-reviewed reports collected by the HEI Energy Research Committee to date. This body of literature includes research conducted in the United States, and that characterize potential agents of exposure to human populations on the regional and local scales. This bibliography is not finalized; please send suggestions of papers that the Committee should review.

Organization:

This bibliography is organized by topics relevant to potential human exposures related to development of oil and natural gas from unconventional resources (UOGD). Publications may be listed in duplicate if they are relevant to more than one topic area.

Topic Area Descriptions:

- **Identification and Properties:** Literature that characterizes chemicals used in UOGD processes, found in wastewater, or detected in air.
- **Fate and Transport:** Literature that characterizes how chemicals released into air and water travel and degrade in the environment.
- **Air Quality:** Literature that assesses air quality through monitoring, modelling, emissions inventories, or a combination of methods. This section is organized by both the primary agent of focus within a given study and by the location of the study.
- **Water Quality and Use:** Literature that assesses surface, ground and drinking water quality through monitoring, modelling, emissions inventories, or a combination of methods. This section is organized by the location of the study and whether the study focuses on surface, drinking or ground quality. This section also includes a sub-section on water use and water resource management.
- **Sediment and Soil Quality:** Literature that characterizes chemicals found in soil or sediment.
- **Noise and Light:** Literature that characterizes noise and light from UOGD operations.
- **Waste Management:** Literature that characterizes chemicals found in wastewater and that assess waste management practices, including transport, storage, disposal and reuse.
- **Toxicity:** Toxicological studies and toxicity reviews of agents associated with UOGD, including chemicals found in drilling fluids, fracturing fluids, wastewater and air.
- **Human Exposure:** Literature focused on estimating potential exposures to human populations, including personal exposure and biomonitoring studies. This section also includes reviews of potential human exposure pathways.
- **Public Health:** Literature that quantifies or qualitatively assesses potential impacts of UOGD on human health. These include human health risk assessments, analytical and descriptive epidemiology studies, community-engaged research, and health reviews.
- **Oil and Gas Worker Health:** Literature focusing on occupational exposure to agents associated with UOGD, including epidemiology studies, modeling studies and reviews.
- **Individual and Community Well-Being:** Literature that assesses public perception, potential community change and economic impacts of UOGD.

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~ We welcome your suggestions of papers that should be included.
Please send to dvorhees@healtheffects.org ~

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STRESSOR IDENTIFICATION AND PROPERTIES

Drilling and Completion Fluid Composition

Bain PA, Kumar A. 2018. In vitro nuclear receptor inhibition and cytotoxicity of hydraulic fracturing chemicals and their binary mixtures. Chemosphere 198:565-573.

Barbati AC, Desroches J, Robisson A, McKinley GH. 2015. Complex Fluids and Hydraulic Fracturing. Ann Rev Chem Biomolecular Eng 7, 415-453.

Bomgardner MM. 2015. Better chemistry flows to the oil and gas industry. Chem Eng News 93:13–17.

Broni-Bediako E, Amorin R. 2010. Effects of drilling fluid exposure to oil and gas workers presented with major areas of exposure and exposure indicators. Research Journal of Applied Sciences, Engineering and Technology 2:710–719.

Caenn R, Darley HCH, Gray GR. 2016. Composition and Properties of Drilling and Completion Fluids, Seventh Edition. Gulf Professional Publishing, Houston, TX.

Chen H, Carter KE. 2017. Characterization of the chemicals used in hydraulic fracturing fluids for wells located in the Marcellus Shale Play. J Environ Manage 200:312-324.

Dieterich M, Kutchko B, Goodman A. 2016. Characterization of Marcellus Shale and Huntersville Chert before and after exposure to hydraulic fracturing fluid via feature relocation using field-emission scanning electron microscopy. Fuel 182:227-235.

Elliott EG, Ettinger AS, Leaderer BP, Bracken MB, Deziel NC. 2016. A systematic evaluation of chemicals in hydraulic-fracturing fluids and wastewater for reproductive and developmental toxicity. J Expos Sci Environ Epidemiol:1–10.

Elsner M, Hoelzer K. 2016. Quantitative survey and structural classification of hydraulic fracturing chemicals reported in unconventional gas production. Environ Sci Technol 50:3290–3314.

Ferrer I, Thurman EM. 2015. Analysis of hydraulic fracturing additives by LC/Q-TOF-MS. Anal Bioanal Chem 407:6417–6428.

Ferrer I, Thurman EM. 2015. Chemical constituents and analytical approaches for hydraulic fracturing waters. Trends in Environmental Analytical Chemistry 5:18–25.

Fisher CA, Jack RF. 2015. Analysis of Ions in Hydraulic Fracturing Wastewaters Using Ion Chromatography. In: Hydraulic Fracturing: Environmental Issues:American Chemical Society, 135–150. Available: http://dx.doi.org/10.1021/bk-2015-1216.ch006.

Gallegos TJ, Varela BA. 2015. Trends in Hydraulic Fracturing Distributions and Treatment Fluids, Additives, Proppants, and Water Volumes Applied to Wells Drilled in the United States from 1947 through 2010—Data Analysis and Comparison to the Literature. Scientific Investigations Report 2014–5131.U.S. Geological Survey.

Gordalla BC, Ewers U, Frimmel FH. 2013. Hydraulic fracturing: a toxicological threat for groundwater and drinking-water? Environ Earth Sci 70:3875–3893.

Hellman JR, Scheetz BE, Luscher WG, Hartwich DG, Kosesk RP. 2014. Proppants for shale gas and oil recovery:

engineering ceramics for stimulation of unconventional energy resources. American Ceramic Society Bulletin Vol 93, No 1.

Hu G, Liu T, Hager J, Hewage K, Sadiq R. 2018. Hazard assessment of hydraulic fracturing chemicals using an indexing method. Science of The Total Environment 619-620:281-290.

Jung H, Carroll K, Kabilan S, Heldebrant D, Hoyt D, Zhong L, et al. 2015. Stimuli-responsive/rheoreversible hydraulic fracturing fluids as a greener alternative to support geothermal and fossil energy production. Green Chem 17:2799–2812.

Kahrilas GA, Blotevogel J, Corrin ER, Borch T. 2016. Downhole Transformation of the Hydraulic Fracturing Fluid Biocide Glutaraldehyde: Implications for Flowback and Produced Water Quality. Environmental science & technology 50:11414-11423.

Kahrilas GA, Blotevogel J, Stewart PS, Borch T. 2015. Biocides in hydraulic fracturing fluids: a critical review of their usage, mobility, degradation, and toxicity. Environ Sci Technol 49:16–32.

Kassotis CD, Vu DC, Vo PH, Lin CH, Cornelius-Green JN, Patton S, Nagel SC. 2018. Endocrine-Disrupting Activities and Organic Contaminants Associated with Oil and Gas Operations in Wyoming Groundwater. Arch Environ Contam Toxicol.

Kassotis CD, Tillitt DE, Lin CH, McElroy JA, Nagel SC. 2016. Endocrine-disrupting chemicals and oil and natural gas operations: potential environmental contamination and recommendations to assess complex environmental mixtures. Environ Health Perspect 124:256–264.

Kassotis CD, Klemp KC, Vu DC, Lin C-H, Meng C-X, Besch-Williford CL, et al. 2015. Endocrine-disrupting activity of hydraulic fracturing chemicals and adverse health outcomes after prenatal exposure in male mice. Endocrinology; doi: 101210/en2015-1375 [Online 14 Oct 2015].

Kassotis CD, Tillitt DE, Davis JW, Hormann AM, Nagel SC. 2013. Estrogen and androgen receptor activities of hydraulic fracturing chemicals and surface and ground water in a drilling-dense region. Endocrinology 155:897–907.

Kassotis CD, Bromfield JJ, Klemp KC, Meng CX, Wolfe A, Zoeller RT, Balise VD, Isiguzo CJ, Tillitt DE, Nagel SC. 2016. Adverse Reproductive and Developmental Health Outcomes Following Prenatal Exposure to a Hydraulic Fracturing Chemical Mixture in Female C57Bl/6 Mice. Endocrinology 157:3469-3481.

Kekacs D, Drollette B, Brooker M, Plata D, Mouser P. 2015. Aerobic biodegradation of organic compounds in hydraulic fracturing fluids. Biodegradation 26:271–287.

Luek JL, Gonsior M. 2017. Organic compounds in hydraulic fracturing fluids and wastewaters: A review. Water Research 123:536-548.

Linkov AM. 2014. On comparison of thinning fluids used for hydraulic fracturing. Int J Eng Sci 77:14–23.

Marcon V, Joseph C, Carter KE, Hedges SW, Lopano CL, Guthrie GD, Hakala JA. 2017. Experimental insights into geochemical changes in hydraulically fractured Marcellus Shale. Applied Geochemistry 76:36-50.

Maule AL, Makey CM, Benson EB, Burrows IJ, Scammell MK. 2013. Disclosure of hydraulic fracturing fluid chemical additives: analysis of regulations. New Solut 23:167–187.

Middleton RS, Carey JW, Currier RP, Hyman JD, Kang Q, Karra S, et al. 2015. Shale gas and non-aqueous fracturing fluids: opportunities and challenges for supercritical CO2. Appl Energy 147:500–509.

Mumford AC, Akob DM, Klinges JG, Cozzarelli IM. 2018. Common Hydraulic Fracturing Fluid Additives Alter the Structure and Function of Anaerobic Microbial Communities. Appl Environ Microbiol 84.

Pirzadeh P, Lesage KL, Marriott RA. 2014. Hydraulic fracturing additives and the delayed onset of hydrogen sulfide in shale gas. Energy Fuels 28:4993–5001.

Rogers JD, Ferrer I, Tummings SS, Bielefeldt AR, Ryan JN. 2017. Inhibition of Biodegradation of Hydraulic Fracturing Compounds by Glutaraldehyde: Groundwater Column and Microcosm Experiments. Environmental Science & Technology 51:10251-10261.

Stringfellow WT, Camarillo MK, Domen JK, Sandelin WL, Varadharajan C, Jordan PD, Reagan MT, Cooley H, Heberger MG, Birkholzer JT. 2017. Identifying chemicals of concern in hydraulic fracturing fluids used for oil production. Environmental Pollution 220:413-420.

Stringfellow WT, Camarillo MK, Domen JK, Sandelin WL, Varadharajan C, Jordan PD, Reagan MT, Cooley H, Heberger MG, Birkholzer JT. 2016. Identifying chemicals of concern in hydraulic fracturing fluids used for oil production. Environmental Pollution.

Stringfellow WT, Domen JK, Camarillo MK, Sandelin WL, Borglin S. 2014. Physical, chemical, and biological characteristics of compounds used in hydraulic fracturing. J Hazard Mater 275:37–54.

Sumner AJ, Plata DL. 2018. Halogenation Chemistry of Hydraulic Fracturing Additives under Highly Saline Simulated Subsurface Conditions. Environmental science & technology 52:9097-9107.

Sutra E, Spada M, Burgherr P. 2017. Chemicals usage in stimulation processes for shale gas and deep geothermal systems: A comprehensive review and comparison. Renew Sust Energ Rev 77:1-11.

Szymczak S, Shen D, Higgins R, Gupta DVS. 2014. Minimizing environmental and economic risks with a proppant-sized solid-scale-inhibitor additive in the Bakken formation. SPE Production & Operations 29:14–20.

Taylor M, Elliott HA, Navitsky LO. 2018. Relationship between total dissolved solids and electrical conductivity in Marcellus hydraulic fracturing fluids. Water science and technology : a journal of the International Association on Water Pollution Research 77:1998-2004.

U.S. Environmental Protection Agency. 2015. Analysis of Hydraulic Fracturing Fluid Data from the FracFocus Chemical Disclosure Registry 1.0. EPA/601/R-14/003. Washington, DC:U.S. EPA.

Vengosh A, Kondash A, Harkness J, Lauer N, Warner N, Darrah TH. 2017. The geochemistry of hydraulic fracturing fluids. In: 15th Water-Rock Interaction International Symposium, Wri-15. (Marques JM, Chambel A, eds.), pp. 21-24.

Xie G, Deng MY, Su JL, Pu LC. 2014. Study on shale gas drilling fluids technology. In: Exploration and Processing of Mineral Resources (Pan W, Xu QJ, Li H, eds.). Advanced Materials Research 868, 651-656.

Yoxtheimer D, Blumsack S, Murphy T. 2012. The decision to use acidic coal-mine drainage for hydraulic fracturing of unconventional shale-gas wells. Environ Pract 14:301–307.

Wastewater Composition

Abualfaraj N, Gurian PL, Olson MS. 2014. Characterization of Marcellus Shale flowback water. Environ Eng Sci 31:514–524.

Akob DM, Cozzarelli IM, Dunlap DS, Rowan EL, Lorah MM. 2015. Organic and inorganic composition and microbiology of produced waters from Pennsylvania shale gas wells. Appl Geochem 60:116–125.

Almond S, Clancy SA, Davies RJ, Worrall F. 2014. The flux of radionuclides in flowback fluid from shale gas exploitation. Environ Sci Pollut Res 21:12316–12324.

Argonne National Laboratory, Veil JA, Puder MG, Elcock D, Robert J. Redweik J. 2004. A White Paper Describing Produced Water from Production of Crude Oil, Natural Gas, and Coal Bed Methane. U.S. Department of Energy, National Energy Technology Laboratory. Available: http://www.netl.doe.gov/KMD/cds/disk23/D-Water%20Management%20Projects/Produced%20Water/W-31-109-ENG-38/pw%20white%20paper.pdf.

Balaba RS, Smart RB. 2012. Total arsenic and selenium analysis in Marcellus shale, high-salinity water, and hydrofracture flowback wastewater. Chemosphere 89:1437–1442.

Balashov VN, Engelder T, Gu X, Fantle MS, Brantley SL. 2015. A model describing flowback chemistry changes with time after Marcellus Shale hydraulic fracturing. AAPG Bulletin 99(1):143–154.

Barbot E, Vidic NS, Gregory KB, Vidic RD. 2013. Methane spatial and temporal correlation of water quality parameters of produced waters from Devonian-age shale following hydraulic fracturing. Environ Sci Technol 47:2562–2569.

Bean JK, Bhandari S, Bilotto A, Hildebrandt Ruiz L. 2018. Formation of particulate matter from the oxidation of evaporated hydraulic fracturing wastewater. Environmental science & technology 52:4960-4968.

Bibby KJ, Brantley SL, Reible DD, Linden KG, Mouser PJ, Gregory KB, et al. 2013. Suggested reporting parameters for investigations of wastewater from unconventional shale gas extraction. Environ Sci Technol 47:13220–13221.

Brown VJ. 2014. Radionuclides in fracking wastewater: managing a toxic blend. Environ Health Perspect 122:A50–A55.

Butkovskyi A, Bruning H, Kools SAE, Rijnaarts HHM, Van Wezel AP. 2017. Organic Pollutants in Shale Gas Flowback and Produced Waters: Identification, Potential Ecological Impact, and Implications for Treatment Strategies. Environmental science & technology 51:4740-4754.

Capo RC, Stewart BW, Rowan EL, Kolesar Kohl CA, Wall AJ, Chapman EC, et al. 2014. The strontium isotopic evolution of Marcellus Formation produced waters, southwestern Pennsylvania. Int J Coal Geol 126:57–63.

Chapman EC, Capo RC, Stewart BW, Kirby CS, Hammack RW, Schroeder KT, et al. 2012. Geochemical and strontium isotope characterization of produced waters from Marcellus shale natural gas extraction. Environ Sci Technol 46:3545–3553.

Chen R, Sharma S, Bank T, Soeder D, Eastman H. 2015. Comparison of isotopic and geochemical characteristics of sediments from a gas- and liquids-prone wells in Marcellus Shale from Appalachian Basin, West Virginia. Appl Geochem 60:59–71.

Chittick EA, Srebotnjak T. 2017. An analysis of chemicals and other constituents found in produced water from hydraulically fractured wells in California and the challenges for wastewater management. J Environ Manage 204:502-509.

Cluff MA, Hartsock A, MacRae JD, Carter K, Mouser PJ. 2014. Temporal changes in microbial ecology and geochemistry in produced water from hydraulically fractured Marcellus shale gas wells. Environ Sci Technol 48:6508–6517.

Crosby LM, Tatu CA, Varonka M, Charles KM, Orem WH. 2018. Toxicological and chemical studies of wastewater from hydraulic fracture and conventional shale gas wells. Environmental Toxicology and Chemistry 37:2098-2111.

Dunne E. 2016. Flowback and Produced Waters: Opportunities and Challenges for Innovation-Proceedings of a Workshop. The National Academies Press, Washington, DC.

Engle MA, Rowan EL. 2014. Geochemical evolution of produced waters from hydraulic fracturing of the Marcellus Shale, northern Appalachian Basin: a multivariate compositional data analysis approach. Int J Coal Geol 126:45–56.

Environment Agency. 2011. Shale Gas: North West — Monitoring of Flowback Water. Available: http://webarchive.nationalarchives.gov.uk/20140328084622/http:/www.environment-agency.gov.uk/static/documents/Business/6th_Dec_-_Shale_gas_-_North_West_-_Monitoring_of_flowback_water_-_update_%283%29.pdf.

Fisher CA, Jack RF. 2015. Analysis of Ions in Hydraulic Fracturing Wastewaters Using Ion Chromatography. In: Hydraulic Fracturing: Environmental Issues: American Chemical Society, 135–150. Available: http://dx.doi.org/10.1021/bk-2015-1216.ch006.

Fisher JC, Belden JB, Bidwell JR. 2010. Can site-specific heuristic toxicity models predict the toxicity of produced

water? Chemosphere 80:542–547.

Fucik K. 1992. Toxicity identification and characteristics of produced water discharges from Colorado and Wyoming. In: Produced Water (Ray J, Engelhardt F, eds). New York:Springer, 187-198.

Haluszczak LO, Rose AW, Kump LR. 2013. Geochemical evaluation of flowback brine from Marcellus gas wells in Pennsylvania, USA. Appl Geochem 28:55–61.

Harkness JS, Dwyer GS, Warner NR, Parker KM, Mitch WA, Vengosh A. 2015. Iodide, bromide, and ammonium in hydraulic fracturing and oil and gas wastewaters: environmental implications. Environ Sci Technol 49:1955–1963.

He Y, Sun C, Zhang Y, Folkerts EJ, Martin JW, Goss GG. 2018. Developmental toxicity of the organic fraction from hydraulic fracturing flowback and produced waters to early life stages of zebrafish (danio rerio). Environmental Science & Technology 52:3820-3830.

He Y, Flynn SL, Folkerts EJ, Zhang Y, Ruan D, Alessi DS, Martin JW, Goss GG. 2017. Chemical and toxicological characterizations of hydraulic fracturing flowback and produced water. Water Research 114:78-87.

He C, Li M, Liu W, Barbot E, Vidic R. 2014. Kinetics and Equilibrium of Barium and Strontium Sulfate Formation in Marcellus Shale Flowback Water. Journal of Environmental Engineering 140:B4014001.

Hoelzer K, Sumner AJ, Karatum O, Nelson RK, Drollette BD, O'Connor MP, D'Arnbro EL, Getzinger GJ, Ferguson PL, Reddy CM, Elsner M, Plata DL. 2016. Indications of Transformation Products from Hydraulic Fracturing Additives in Shale-Gas Wastewater. Environmental science & technology 50:8036-8048.

Khan NA, Engle M, Dungan B, Holguin FO, Xu P, Carroll KC. 2016. Volatile-organic molecular characterization of shale-oil produced water from the Permian Basin. Chemosphere 148:126–136.

Kondash AJ, Albright E, Vengosh A. 2017. Quantity of flowback and produced waters from unconventional oil and gas exploration. Science of The Total Environment 574:314-321.

Konkel L. 2016. Salting the Earth: The Environmental Impact of Oil and Gas Wastewater Spills. Environmental health perspectives 124:A230-A235.

Kujawska J, Cel W, Wasag H. 2016. Leachability of heavy metals from shale gas drilling waste. Rocznik Ochrona Srodowiska 18:909-919.

Liu HH, Sang SX, Xu HJ, Liu SQ. 2013. Variational characteristics of water quality of produced formation water in coalbed methane production area. In: Advances in Environmental Technologies, Pts 1-6 (Zhao J, Iranpour R, Li X, Jin B, eds). Advanced Materials Research 726-731, 1560-1565. Available: <Go to ISI>://WOS:000333767500314.

Luek JL, Harir M, Schmitt-Kopplin P, Mouser PJ, Gonsior M. 2018. Temporal dynamics of halogenated organic compounds in Marcellus Shale flowback. Water Res 136:200-206.

Luek JL, Schmitt-Kopplin P, Mouser PJ, Petty WT, Richardson SD, Gonsior M. 2017. Halogenated Organic Compounds Identified in Hydraulic Fracturing Wastewaters Using Ultrahigh Resolution Mass Spectrometry. Environmental Science & Technology 51:5377-5385.

Luek JL, Gonsior M. 2017. Organic compounds in hydraulic fracturing fluids and wastewaters: A review. Water Research 123:536-548.

Luek JL, Schmitt-Kopplin P, Mouser PJ, Petty WT, Richardson SD, Gonsior M. 2017. Halogenated organic compounds identified in hydraulic fracturing wastewaters using ultrahigh resolution mass spectrometry. Environmental Science & Technology.

Lyman SN, Mansfield ML. 2018. Organic compound emissions from a landfarm used for oil and gas solid waste disposal. Journal of the Air & Waste Management Association 68:637-642.

Lyman SN, Mansfield ML, Tran HNQ, Evans JD, Jones C, O'Neil T, Bowers R, Smith A, Keslar C. 2018.

Emissions of organic compounds from produced water ponds I: Characteristics and speciation. Science of the Total Environment 619:896-905.

Maguire-Boyle SJ, Barron AR. 2014. Organic compounds in produced waters from shale gas wells. Environ Sci Process Impacts 16:2237–2248.F

Maloney KO, Baruch-Mordo S, Patterson LA, Nicot JP, Entrekin SA, Fargione JE, Kiesecker JM, Konschnik KE, Ryan JN, Trainor AM, Saiers JE, Wiseman HJ. 2016. Unconventional oil and gas spills: Materials, volumes, and risks to surface waters in four states of the U.S. Sci Total Environ.

Mansfield ML, Tran HNQ, Lyman SN, Bowers RL, Smith AP, Keslar C. 2018. Emissions of organic compounds from produced water ponds III: Mass-transfer coefficients, composition-emission correlations, and contributions to regional emissions. Science of The Total Environment 627:860-868.

Murali Mohan A, Hartsock A, Bibby KJ, Hammack RW, Vidic RD, Gregory KB. 2013. Microbial community changes in hydraulic fracturing fluids and produced water from shale gas extraction. Environ Sci Technol 47:13141–13150.

Murali Mohan A, Hartsock A, Hammack RW, Vidic RD, Gregory KB. 2013. Microbial communities in flowback water impoundments from hydraulic fracturing for recovery of shale gas. FEMS Microbiol Ecol 86:567–580.

National Academies of Sciences, Engineering, and Medicine. 2016. Flowback and Produced Waters: Opportunities and Challenges for Innovation: Proceedings of a Workshop. Proceeding. The National Academies Press, 101.

Nelson AW, May D, Knight AW, Eitrheim ES, Mehrhoff M, Shannon R, et al. 2014. Matrix complications in the determination of radium levels in hydraulic fracturing flowback water from Marcellus shale. Environ Sci Technol Lett 1:204–208.

Oetjen K, Chan KE, Gulmark K, Christensen JH, Blotevogel J, Borch T, et al. 2018. Temporal characterization and statistical analysis of flowback and produced waters and their potential for reuse. Sci Total Environ 619-620:654-664.

Oetjen K, Giddings CGS, McLaughlin M, Nell M, Blotevogel J, Helbling DE, Mueller D, Higgins CP. 2017. Emerging analytical methods for the characterization and quantification of organic contaminants in flowback and produced water. Trends in Environmental Analytical Chemistry 15:12-23.

Oetjen K, Thomas L. 2016. Volatile and semi-volatile organic compound patterns in flowback waters from fracturing sites within the Marcellus Shale. Environ Earth Sci 75:1-10.

Olsson O, Weichgrebe D, Rosenwinkel K-H. 2013. Hydraulic fracturing wastewater in Germany: composition, treatment, concerns. Environ Earth Sci 70:3895–3906.

Orem W, Varonka M, Crosby L, Haase K, Loftin K, Hladik M, Akob DM, Tatu C, Mumford A, Jaeschke J, Bates A, Schell T, Cozzarelli I. 2017. Organic geochemistry and toxicology of a stream impacted by unconventional oil and gas wastewater disposal operations. Applied Geochemistry 80:155-167.

Orem W, Tatu C, Varonka M, Lerch H, Bates A, Engle M, et al. 2014. Organic substances in produced and formation water from unconventional natural gas extraction in coal and shale. Int J Coal Geol 126:20–31.

Osselin F, Nightingale M, Hearn G, Kloppmann W, Gaucher E, Clarkson CR, Mayer B. 2018. Quantifying the extent of flowback of hydraulic fracturing fluids using chemical and isotopic tracer approaches. Applied Geochemistry 93:20-29.

Phan TT, Capo RC, Stewart BW, Macpherson GL, Rowan EL, Hammack RW. 2016. Factors controlling Li concentration and isotopic composition in formation waters and host rocks of Marcellus Shale, Appalachian Basin. Chem Geol 420:162–179.

Phan TT, Capo RC, Stewart BW, Graney JR, Johnson JD, Sharma S, et al. 2015. Trace metal distribution and mobility in drill cuttings and produced waters from Marcellus Shale gas extraction: uranium, arsenic, barium. Appl

Geochem 60:89–103.

Piotrowski PK, Weggler BA, Barth-Naftilan E, Kelly CN, Zimmermann R, Saiers JE, Dorman FL. 2018. Non-Targeted chemical characterization of a Marcellus shale gas well through GC x GC with scripting algorithms and high-resolution time-of-flight mass spectrometry. Fuel 215:363-369.

Piotrowski PK, Weggler BA, Yoxtheimer DA, Kelly CN, Barth-Naftilan E, Saiers JE, Dorman FL. 2018. Elucidating Environmental Fingerprinting Mechanisms of Unconventional Gas Development through Hydrocarbon Analysis. Analytical chemistry 90:5466-5473.

Regnery J, Coday BD, Riley SM, Cath TY. 2016. Solid-phase extraction followed by gas chromatography-mass spectrometry for the quantitative analysis of semi-volatile hydrocarbons in hydraulic fracturing wastewaters. Anal Methods 8:2058–2068.

Robbins SJ, Evans PN, Parks DH, Golding SD, Tyson GW. 2016. Genome-Centric Analysis of Microbial Populations Enriched by Hydraulic Fracture Fluid Additives in a Coal Bed Methane Production Well. Front Microbiol 7:15.

Rowan E, Engle M, Kirby C, Kraemer T. 2011. Radium content of oil-and gas-field produced waters in the Northern Appalachian basin (USA)—Summary and discussion of data. Scientific Investigations Report 2011–5135. Reston, VA:U.S. Geological Survey.

Rowan EL, Engle MA, Kraemer TF, Schroeder KT, Hammack RW, Doughten MW. 2015. Geochemical and isotopic evolution of water produced from Middle Devonian Marcellus Shale gas wells, Appalachian Basin, Pennsylvania. AAPG Bulletin 99(2):181–206.

Schwab MD, Cammarota MC. 2018. Composition and treatment of effluent from shale gas production. Clean Technol Environ Policy 20:1245-1257.

Seales MB, Dilmore R, Ertekin T, Wang JY. 2016. Numerical analysis of the source of excessive Na+ and Cl– species in flowback water from hydraulically fractured shale formations. Society of Petroleum Engineers; doi: 102118/180911-PA.

Shih J-S, Saiers JE, Anisfeld SC, Chu Z, Muehlenbachs LA, Olmstead SM. 2015. Characterization and analysis of liquid waste from Marcellus Shale gas development. Environ Sci Technol 49:9557–9565.

Shonkoff SB, Stringfellow WT, Domen JK. 2016. Hazard Assessment of Chemical Additives Used in Oil Fields that Reuse Produced Water for Agricultural Irrigation, Livestock Watering, and Groundwater Recharge in The San Joaquin Valley of California: Preliminary Results. PSE Healthy Energy, Inc. Oakland, CA. Available from http://psehealthyenergy.org/site/view/1306.

Sitterley K, Linden K, Ferrer I, Thurman E. 2018. Discovery of proprietary amino ethoxylates in hydraulic fracturing wastewater using LC/Q-TOF/MS with solid phase extraction. Abstr Pap Am Chem Soc 255:1.

Spellacy MD. 2013. Hydraulic Fracturing Bulk Characteristics Determination and Analysis. Columbus, OH:Ohio State University. Available: http://kb.osu.edu/dspace/handle/1811/54511.

Sun C, Zhang YF, Martin J, Alessi D. 2018. Non-target mass spectrometry profiling of organic compounds in hydraulic fracturing flowback water. Abstr Pap Am Chem Soc 255:1.

Thurman EM, Ferrer I, Rosenblum J, Linden K, Ryan JN. 2017. Identification of polypropylene glycols and polyethylene glycol carboxylates in flowback and produced water from hydraulic fracturing. Journal of Hazardous Materials 323:11-17.

Thurman EM, Ferrer I, Blotevogel J, Borch T. 2014. Analysis of hydraulic fracturing flowback and produced waters using accurate mass: identification of ethoxylated surfactants. Anal Chem 86:9653–9661.

Thyne G, Brady P. 2016. Evaluation of formation water chemistry and scale prediction: Bakken Shale. Applied Geochemistry 75:107-113.

Tran HNQ, Lyman SN, Mansfield ML, O'Neil T, Bowers RL, Smith AP, Keslar C. 2018. Emissions of organic compounds from produced water ponds II: Evaluation of flux chamber measurements with inverse-modeling techniques. Journal of the Air & Waste Management Association 68:713-724.

Wappes S, Williams S, Tittle S, Nguyen T, Overton B, Steffey D, Wilk M, Omary M, Beatty J. 2018. Wasted fracking water: An examination of components by instrumental methods to assess potential environmental impact. Abstr Pap Am Chem Soc 255:1.

Wilke FDH, Vieth-Hillebrand A, Naumann R, Erzinger J, Horsfield B. 2015. Induced mobility of inorganic and organic solutes from black shales using water extraction: Implications for shale gas exploitation. Appl Geochem 63:158–168.

Wilke FDH, Schettler G, Vieth-Hillebrand A, Kühn M, Rothe H. 2018. Activity concentrations of 238U and 226Ra in two European black shales and their experimentally-derived leachates. Journal of Environmental Radioactivity 190-191:122-129.

Ying L, O'Connor F, Stolz JF. 2015. Scintillation gamma spectrometer for analysis of hydraulic fracturing waste products. J Environ Sci Health A Tox Hazard Subst Environ Eng 50:511–515.

Zhang T, Bain DJ, Hammack RW, Vidic RD. 2015. Analysis of Radium-226 in high salinity wastewater from unconventional gas extraction by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS). Environ Sci Technol 49:2969–2976.

Zhou Q, Dilmore R, Kleit AN, Wang JY. 2015. Evaluating Fracturing Fluid Flowback in Marcellus Using Data Mining Technologies. Presented at SPE Hydraulic Fracturing Technology Conference, 3–5 February 2015, The Woodlands, TX:Society of Petroleum Engineers.

Ziemkiewicz PF, He TY. 2015. Evolution of water chemistry during Marcellus Shale gas development: A case study in West Virginia. Chemosphere 134:224–231.

Solid Waste Composition

Marshall University Center for Environmental Geotechnical and Applied Sciences. 2015. Examination of Leachate, Drill Cuttings and Related Environmental, Economic and Technical Aspects Associated with Solid Waste Facilities in West Virginia. Charleston, WV:West Virginia Department of Environmental Protection.

Phan TT, Capo RC, Stewart BW, Graney JR, Johnson JD, Sharma S, et al. 2015. Trace metal distribution and mobility in drill cuttings and produced waters from Marcellus Shale gas extraction: uranium, arsenic, barium. Appl Geochem 60:89–103.

Naturally Occurring Radioactive Material (NORM)

Allard DJ. 2015. Pennsylvania's technologically enhanced, naturally occurring radioactive material experiences and studies of the oil and gas industry. Health Phys 108:178.

Babcock L, Butalia T, Dutta P, Frazier J, Gannon M, Hall M, et al. 2015. NORM and TENORM: Occurrence, Analysis, Methods, Monitoring, Handling and Disposal — R&D Needs. The NORM Working Group at The Ohio State University. Available: http://efdsystems.org/pdf/NORM_FINAL_4_11_15.pdf.

Doyi I, Essumang DK, Dampare S, Glover ET. 2016. Technologically enhanced naturally occurring radioactive materials (tenorm) in the oil and gas industry: A review. In: Reviews of environmental contamination and toxicology volume 238, (de Voogt P, ed). Cham:Springer International Publishing, 107-119.

Eitrheim ES, May D, Forbes TZ, Nelson AW. 2016. Disequilibrium of Naturally Occurring Radioactive Materials (NORM) in Drill Cuttings from a Horizontal Drilling Operation. Environmental Science & Technology Letters 3:425-429.

Geltman EAG, LeClair N. 2018. Variance in State Protection from Exposure to NORM and TENORM Wastes Generated During Unconventional Oil and Gas Operations: Where We Are and Where We Need to Go. NEW

SOLUTIONS: A Journal of Environmental and Occupational Health Policy 0:240-261.

Hamlat MS, Djeffal S, Kadi H. 2001. Assessment of radiation exposures from naturally occurring radioactive materials in the oil and gas industry. Applied radiation and isotopes : including data, instrumentation and methods for use in agriculture, industry and medicine 55:141-146.

Lopez A. 2013. Radiological Issues Associated with the Recent Boom in Oil and Gas Hydraulic Fracturing. Presented at ASME 15th International Conference on Environmental Remediation and Radioactive Waste Management, Vol 1: Low/Intermediate-Level Radioactive Waste Management; Spent Fuel, Fissile Material, Transuranic and High-Level Radioactive Waste Management, 8–12 September 2013, Brussels, Belgium:American Society of Mechanical Engineers.

Nelson AW, Eitrheim ES, Knight AW, May D, Mehrhoff MA, Shannon R, Litman R, Burnett WC, Forbes TZ, Schultz MK. 2015. Understanding the Radioactive Ingrowth and Decay of Naturally Occurring Radioactive Materials in the Environment: An Analysis of Produced Fluids from the Marcellus Shale. Environ Health Perspect 123:689–696.

Nelson AW, May D, Knight AW, Eitrheim ES, Mehrhoff M, Shannon R, Litman R, Schultz MK. 2014. Matrix complications in the determination of radium levels in hydraulic fracturing flowback water from Marcellus shale. Environ Sci Technol Lett 1:204–208.

Nelson AW, Knight AW, May D, Eitrheim ES, Schultz MK. 2015. Naturally-Occurring Radioactive Materials (NORM) Associated with Unconventional Drilling for Shale Gas. In: Hydraulic Fracturing: Environmental Issues:American Chemical Society, 89–128. Available: http://dx.doi.org/10.1021/bk-2015-1216.ch004.

Pennsylvania Department of Environmental Protection. January 2015. Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) Study Report. Rev. 0. Prepared for PADEP by PermaFix, Beaver, PA.

Rosenblum J, Nelson AW, Ruyle B, Schultz MK, Ryan JN, Linden KG. 2017. Temporal characterization of flowback and produced water quality from a hydraulically fractured oil and gas well. Sci Total Environ 596-597:369-377.

Rowan EL, Kraemer TF. 2012. Radon-222 Content of Natural Gas Samples from Upper and Middle Devonian Sandstone and Shale Reservoirs in Pennsylvania: Preliminary Data. Open-File Report Series 2012-1159. Reston, VA:U.S. Geological Survey. Available: http://pubs.usgs.gov/of/2012/1159.

Air Quality Emission Inventories

Advanced Resources International Inc. for the American Petroleum Institute. 2012. Estimate of Impacts of EPA Proposals to Reduce Air Emissions from Hydraulic Fracturing Operations. Washington, DC:American Petroleum Institute. Available: http://www.api.org/~/media/files/policy/hydraulic_fracturing/nsps-og-ari-impacts-of-epa-air-rules-final-report.pdf.

Alamo Area Council of Governments. 2014. Oil and Gas Emission Inventory, Eagle Ford Shale. 582-11-11219 Amendment Number 5, Task 2, Project II. Alamo, TX:Texas Commission on Environmental Quality. Available: http://www.aacog.com/documentcenter/view/19069.

Hendler A, Nunn J, Lundeen J, McKaskle R. 2006. VOC Emissions from Oil and Condensate Storage Tanks. Prepared for Houston Advanced Research Center. The Woodlands, TX:HARC.

Johnson D, Covington A, Clark N. 2014. Environmental and economic assessment of leak and loss audits at natural gas compressor and storage facilities. Energy Technology 2:1027–1032.

Litovitz A, Curtright A, Abramzon S, Burger N, Samaras C. 2013. Estimation of regional air-quality damages from Marcellus Shale natural gas extraction in Pennsylvania. Environ Res Lett 8:1–8.

Pétron G, Frost G, Miller BR, Hirsch AI, Montzka SA, Karion A, et al. 2012. Hydrocarbon emissions characterization in the Colorado Front Range: A pilot study. J Geophys Res 117; D04304, doi:101029/2011JD016360.

Rodriguez G, Ouyang C. 2013. Air Emissions Characterization and Management For Natural Gas Hydraulic Fracturing Operations In the United States — A graduate master's project report. Ann Arbor, MI:University of Michigan. Available: http://deepblue.lib.umich.edu/handle/2027.42/97418.

Roy AA, Adams PJ, Robinson AL. 2014. Air pollutant emissions from the development, production, and processing of Marcellus Shale natural gas. J Air Waste Manage Assoc 64:19–37.

Schade GW, Roest G. 2018. Source apportionment of non-methane hydrocarbons, NOx and H2S data from a central monitoring station in the Eagle Ford Shale, Texas. Elem Sci Anth 6.

Schwietzke S, Griffin WM, Matthews HS, Bruhwiler LMP. 2014. Natural gas fugitive emissions rates constrained by global atmospheric methane and ethane. Environ Sci Technol 48:7714–7722.

Stuver SK, Alonzo JR, Burnett DB, Haut RC. 2014. A Better Way to Estimate Emissions from Oil and Gas Sites. J Pet Environ Biotechnol 5:189.

Stuver S, Alonzo J. 2014. White paper — A Comparison of Air Emission Estimation Methods for Drilling Rig Emissions. College Station, TX:Texas A&M Institute of Renewable Natural Resources. Available: http://efdsystems.org/pdf/A_Comparison_of_Estimation_Protocols_for_Drilling_Rig_Emissions.pdf.

Texas Commission on Environmental Quality. 2012. Barnett Shale Special Inventory, Phase Two Workbook. Austin, TX: Texas Commission on Environmental Quality. Available from http://www.tceq.state.tx.us/airquality/point-source-ei/psei.html#barnett2.

U.S. Environmental Protection Agency. 2012. EPA's Air Rules for the Oil & Natural Gas Industry: Summary of Key Changes to the New Source Performance Standards. Available: http://www3.epa.gov/airquality/oilandgas/pdfs/20120417changes.pdf.

U.S. Environmental Protection Agency. 2014. White paper: Oil and Natural Gas Sector Compressors. Washington, DC:U.S. EPA. Available: http://www.epa.gov/airquality/oilandgas/pdfs/20140415compressors.pdf.

U.S. Environmental Protection Agency. 2014. White paper: Oil and Natural Gas Sector Hydraulically Fractured Oil Well Completions and Associated Gas during Ongoing Production. Washington, DC:U.S. EPA. Available: http://www.epa.gov/airquality/oilandgas/pdfs/20140415completions.pdf.

U.S. Environmental Protection Agency. 2014. White paper: Oil and Natural Gas Sector Leaks. Washington, DC:U.S. EPA. Available: http://www.epa.gov/airquality/oilandgas/pdfs/20140415leaks.pdf.

U.S. Environmental Protection Agency. 2014. White paper: Oil and Natural Gas Sector Liquids Unloading Processes. Washington, DC:U.S. EPA. Available: http://www.epa.gov/airquality/oilandgas/pdfs/20140415liquids.pdf.

U.S. Environmental Protection Agency. 2014. White paper: Oil and Natural Gas Sector Pneumatic Devices. Washington, DC:U.S. EPA. Available: http://www.epa.gov/airquality/oilandgas/2014papers/20140415pneumatic.pdf.

Warneke C, Geiger F, Edwards PM, Dube W, Pétron G, Kofler J, et al. 2014. Volatile organic compound emissions from the oil and natural gas industry in the Uintah Basin, Utah: oil and gas well pad emissions compared to ambient air composition. Atmos Chem Phys 14:10977–10988.

Reviews and General Resources

Bolden AL, Schultz K, Pelch KE, Kwiatkowski CF. 2018. Exploring the endocrine activity of air pollutants associated with unconventional oil and gas extraction. Environmental Health 17:26.

Fink J. 2015. Petroleum engineer's guide to oil field chemicals and fluids. Gulf Professional Publishing, Waltham, MA. ISBN-13: 978-0128037348.

STRESSOR FATE AND TRANSPORT

Forensics/Tracers

Hakala JA. 2014. Use of stable isotopes to identify sources of methane in Appalachian Basin shallow groundwaters: a review. Environ Sci Process Impacts 16:2080–2086.

Johnson JD, Graney JR. 2015. Fingerprinting Marcellus Shale waste products from Pb isotope and trace metal perspectives. Appl Geochem 60:104–115.

Kolesar Kohl CA, Capo RC, Stewart BW, Wall AJ, Schroeder KT, Hammack RW, et al. 2014. Strontium isotopes test long-term zonal isolation of injected and Marcellus formation water after hydraulic fracturing. Environ Sci Technol 48:9867–9873.

Kneeland JM, Butler EL. 2013. Hydraulic Fracturing Fluid Forensics: Potential and Pitfalls. Presented at 20th IPEC Conference, 12 November 2013, San Antonio, TX:Gradient.

Lauer NE, Harkness JS, Vengosh A. 2016. Brine spills associated with unconventional oil development in North Dakota. Environ Sci Technol; doi: 101021/acsest5b06349.

Lautz LK, Hoke GD, Lu Z, Siegel DI, Christian K, Kessler JD, et al. 2014. Using discriminant analysis to determine sources of salinity in shallow groundwater prior to hydraulic fracturing. Environ Sci Technol 48:9061–9069.

Loh LJ, Bandara GC, Weber GL, Remcho VT. 2015. Detection of water contamination from hydraulic fracturing wastewater: a μPAD for bromide analysis in natural waters. Analyst 140:5501–5507.

Lu Z, Hummel ST, Lautz LK, Hoke GD, Zhou X, Leone J, et al. 2015. Iodine as a sensitive tracer for detecting influence of organic-rich shale in shallow groundwater. Appl Geochem 60:29–36.

Mayer B, Humez P, Becker V, Nightingale M, Ing J, Kingston A, et al. 2015. Prospects and limitations of chemical and isotopic groundwater monitoring to assess the potential environmental impacts of unconventional oil and gas development. Procedia Earth and Planetary Science 13:320–323.

Sharma S, Baggett JK. 2011. Application of carbon isotopes to detect seepage out of coalbed natural gas produced water impoundments. Appl Geochem 26:1423–1432.

Sharma S, Mulder ML, Sack A, Schroeder K, Hammack R. 2014. Isotope approach to assess hydrologic connections during Marcellus shale drilling. Ground Water 52:424–433.

Vengosh A, Warner NR, Kondash A, Harkness JS, Lauer N, Millot R, et al. 2015. Isotopic Fingerprints for Delineating the Environmental Effects of Hydraulic Fracturing Fluids. Presented at 11th Applied Isotope Geochemistry Conference, AIG-11 BRGM, Orleans, France.

Warner NR, Darrah TH, Jackson RB, Millot R, Kloppmann W, Vengosh A. 2014. New tracers identify hydraulic fracturing fluids and accidental releases from oil and gas operations. Environ Sci Technol 48:12552–12560.

Atmospheric Transport

Mansfield ML, Tran HNQ, Lyman SN, Bowers RL, Smith AP, Keslar C. 2018. Emissions of organic compounds from produced water ponds III: Mass-transfer coefficients, composition-emission correlations, and contributions to regional emissions. Science of The Total Environment 627:860-868.

Walter GR, Benke RR, Pickett DA. 2012. Effect of biogas generation on radon emissions from landfills receiving radium-bearing waste from shale gas development. J Air Waste Manag Assoc 62(9):1040–1049.

Zhang T, Hammack RW, Vidic RD. 2015. Fate of radium in Marcellus shale flowback water impoundments and assessment of associated health risks. Environ Sci Technol 49:9347–9354.

Surface Releases (Liquid and Solid Waste Products)

Clancy SA, Worrall F, Davies RJ, Gluyas JG. 2018. The potential for spills and leaks of contaminated liquids from shale gas developments. Science of The Total Environment 626:1463-1473.

Dresel PE, Rose AW. 2010. Chemistry and origin of oil and gas well brines in western Pennsylvania. Open-File Report OFOG 10:01.00.

Gilmore KR, Hupp RL, Glathar J. 2014. Transport of hydraulic fracturing water and wastes in the Susquehanna River Basin, Pennsylvania. J Environ Eng 140, Special Issue: Environmental Impacts of Shale Gas Development, B4013002.

Harris AE, Hopkinson L, Soeder DJ. 2016. Developing monitoring plans to detect spills related to natural gas production. Environmental Monitoring and Assessment 188:647.

Konkel L. 2016. Salting the Earth: The Environmental Impact of Oil and Gas Wastewater Spills. Environmental health perspectives 124:A230-A235.

McLaughlin MC, Borch T, Blotevogel J. 2016. Spills of hydraulic fracturing chemicals on agricultural topsoil: biodegradation, sorption, and co-contaminant interactions. Environ Sci Technol; doi: 101021/acsest6b00240.

National Academies of Sciences, Engineering, and Medicine. 2016. Flowback and Produced Waters: Opportunities and Challenges for Innovation: Proceedings of a Workshop. Proceeding. The National Academies Press, 101.

Oetjen K, Blotevogel J, Borch T, Ranville JF, Higgins CP. 2018. Simulation of a hydraulic fracturing wastewater surface spill on agricultural soil. Sci Total Environ 645:229-234.

O'Neil P, Harris S, Mettee M, Isaacson H, Evans J. 1992. Biological fate and effect of coalbed methane produced waters discharged into streams of the Warrior Basin, Alabama. In: Produced Water (Ray JP, Engelhardt FR, eds). New York:Springer, 315–327.

Patterson LA, Konschnik KE, Wiseman H, Fargione J, Maloney KO, Kiesecker J, Nicot J-P, Baruch-Mordo S, Entrekin S, Trainor A, Saiers JE. 2017. Unconventional Oil and Gas Spills: Risks, Mitigation Priorities, and State Reporting Requirements. Environmental science & technology.

Pashin JC, McIntyre-Redden MR, Mann SD, Kopaska-Merkel DC, Varonka M, Orem W. 2014. Relationships between water and gas chemistry in mature coalbed methane reservoirs of the Black Warrior Basin. Int J Coal Geol 126:92–105.

Reddy KJ, Helmericks C, Whitman A, Legg D. 2014. Geochemical processes controlling trace elemental mobility in coalbed natural gas (CBNG) disposal ponds in the Powder River Basin, WY. Int J Coal Geol 126:120–127.

Renock D, Landis JD, Sharma M. 2016. Reductive weathering of black shale and release of barium during hydraulic fracturing. Appl Geochem 65:73–86.

Schmidt CW. 2013. Estimating wastewater impacts from fracking. Environ Health Perspect 121:A117.

Stewart BW, Chapman EC, Capo RC, Johnson JD, Graney JR, Kirby CS, et al. 2015. Origin of brines, salts and carbonate from shales of the Marcellus Formation: Evidence from geochemical and Sr isotope study of sequentially extracted fluids. Appl Geochem 60:78–88.

Sun M, Lowry GV, Gregory KB. 2013. Selective oxidation of bromide in wastewater brines from hydraulic fracturing. Water Res 47:3723–3731.

Strong L, Gould T, Kasinkas L, Sadowsky M, Aksan A, Wackett L. 2014. Biodegradation in waters from hydraulic fracturing: chemistry, microbiology, and engineering. J Environ Eng 140, Special Issue: Environmental Impacts of Shale Gas Development, B4013001.

Zhang T, Hammack RW, Vidic RD. 2015. Fate of radium in Marcellus shale flowback water impoundments and

assessment of associated health risks. Environ Sci Technol 49:9347–9354.

Subsurface Migration

Flewelling SA, Sharma M. 2013. Constraints on upward migration of hydraulic fracturing fluid and brine. Ground Water 52:9–19.

Flewelling SA, Sharma M. 2014. Response to Rozell on "Constraints on Upward Migration of Hydraulic Fracturing Fluid and Brine," by S. A. Flewelling and M. Sharma. Groundwater 52:492–494.

Flewelling SA, Sharma M. 2015. Comment on "Hydraulic fracturing in faulted sedimentary basins: numerical simulation of potential contamination of shallow aquifers over long time scales". Water Resour Res; doi: 101002/2014WR015904 [Online 31 March 2015].

Gassiat C, Gleeson T, Lefebvre R, McKenzie J. 2013. Hydraulic fracturing in faulted sedimentary basins: numerical simulation of potential contamination of shallow aquifers over long time scales. Water Resour Res 49:8310–8327.

Geng X, Davatzes N, Soeder D, Torlapati J, Rodriguez R, Boufadel M. 2014. Migration of high-pressure air during gas well drilling in the Appalachian Basin. J Environ Eng (New York) 140:B4014002.

Herckenrath D, Doherty J, Panday S. 2015. Incorporating the effect of gas in modelling the impact of CBM extraction on regional groundwater systems. J Hydrol 523:587–601.

Lefebvre R, Gleeson T, McKenzie JM, Gassiat C. 2015. Reply to comment by Flewelling and Sharma on "Hydraulic fracturing in faulted sedimentary basins: Numerical simulation of potential contamination of shallow aquifers over long time scales". Water Resour Res 51:1877–1882.

Llewellyn G. 2014. Evidence and mechanisms for Appalachian Basin brine migration into shallow aquifers in NE Pennsylvania, USA. Hydrogeol J 22:1055–1066.

Ma L, Hurtado A, Eguilior S, Llamas Borrajo JF. 2018. A model for predicting organic compounds concentration change in water associated with horizontal hydraulic fracturing. Sci Total Environ 625:1164-1174.

McAdams B, Carter K, Blotevogel J, Borch T, Hakala JA. 2018. Fate of organic additives in hydraulic fracturing fluids from injection through production and treatment. Abstr Pap Am Chem Soc 255:1.

Myers T. 2012. Potential contaminant pathways from hydraulically fractured shale to aquifers. Ground Water 50:872–882.

Nowamooz A, Lemieux JM, Molson J, Therrien R. 2015. Numerical investigation of methane and formation fluid leakage along the casing of a decommissioned shale gas well. Water Resour Res 51:4592–4622.

Rozell DJ. 2014. Discussion: Constraints on upward migration of hydraulic fracturing fluid and brine. Ground Water 52:491–492.

Saiers JE, Barth E. 2012. Potential contaminant pathways from hydraulically fractured shale aquifers. Ground Water 50:826–828; discussion 828-830.

Sang W, Stoof CR, Zhang W, Morales VL, Gao B, Kay RW, et al. 2014. Effect of hydrofracking fluid on colloid transport in the unsaturated zone. Environ Sci Technol 48:8266–8274.

Schwartz M. 2015. Modelling the hypothetical methane-leakage in a shale-gas project and the impact on groundwater quality. Environ Earth Sci 73:4619–4632.

Sharma S, Bowman L, Schroeder K, Hammack R. 2014. Assessing changes in gas migration pathways at a hydraulic fracturing site: Example from Greene County, Pennsylvania, USA. Appl Geochem 60:51–58.

Warner NR, Jackson RB, Darrah TH, Osborn SG, Down A, Zhao K, et al. 2012. Geochemical evidence for possible natural migration of Marcellus Formation brine to shallow aquifers in Pennsylvania. Proc Natl Acad Sci U S A

109:11961–11966.

Zhang L, Anderson N, Dilmore R, Soeder DJ, Bromhal G. 2014. Leakage detection of Marcellus shale natural gas at an upper Devonian gas monitoring well: a 3-D numerical modeling approach. Environ Sci Technol 48:10795–10803.

Zhang L, Soeder DJ. 2015. Modeling of methane migration in shallow aquifers from shale gas well drilling. Ground Water; doi: 101111/gwat12361 [Online 17 Aug 2015].

Hydraulic Fracturing Depth and Fracture Propagation (as it relates to Ground Water Quality)

Davies RJ, Mathias SA, Moss J, Hustoft S, Newport L. 2012. Hydraulic fractures: How far can they go? Mar Pet Geol 37:1–6.

Edwards RWJ, Doster F, Celia MA, Bandilla KW. 2017. Numerical modeling of gas and water flow in shale gas formations with a focus on the fate of hydraulic fracturing fluid. Environmental science & technology 51:13779-13787.

Fisher K, Warpinski N. 2011. Hydraulic Fracture-Height Growth: Real Data. Presented at SPE Annual Technical Conference and Exhibition, 30 October–2 November 2011, Denver, CO:Society of Petroleum Engineers.

Fisher K, Warpinski N. 2011. Hydraulic Fracture-Height Growth: Real Data. Presented at SPE Annual Technical Conference and Exhibition, 30 October–2 November 2011, Denver, CO:Society of Petroleum Engineers.

Hammack R, Harbert W, Sharma S, Stewart B, Capo R, Wall AJ, et al. 2014. An Evaluation of Fracture Growth and Gas/Fluid Migration as Horizontal Marcellus Shale Gas Wells are Hydraulically Fractured in Greene County, Pennsylvania. Pittsburgh, PA:US Department of Energy, National Energy Technology Laboratory. Available: http://www.achd.net/shale/pubs/NETL-TRS-3-2014_Greene-County-Site_20140915_1_1.pdf.

Jackson RB, Lowry ER, Pickle A, Kang M, DiGiulio D, Zhao K. 2015. The depths of hydraulic fracturing and accompanying water use across the United States. Environ Sci Technol 49:8969–8976.

Tang Y, Ranjith PG, Perera MSA. 2018. Major factors influencing proppant behaviour and proppant-associated damage mechanisms during hydraulic fracturing. Acta Geotech 13:757-780.

Reviews and General Resources

Glaser D, Dell'Oca A, Tatomir A, Bensabat J, Class H, Guadagnini A, Helmig R, McDermott C, Riva M, Sauter M. 2016. An approach towards a FEP-based model for risk assessment for hydraulic fracturing operations. In: European Geosciences Union General Assembly 2016. (Ask M, Bruckman V, Juhlin C, Kempka T, Kuhn M, eds.), pp. 387-394. Elsevier Science Bv, Amsterdam.

Jabbari N, Aminzadeh F, de Barros FPJ. 2015. Assessing the groundwater contamination potential from a well in a hydraulic fracturing operation. Journal of Sustainable Energy Engineering 3:66–79.

Nicot J-P, Scanlon BR, Reedy RC, Costley RA. 2014. Source and fate of hydraulic fracturing water in the Barnett shale: a historical perspective. Environ Sci Technol 48:2464–2471.

Rozell DJ, Reaven SJ. 2012. Water pollution risk associated with natural gas extraction from the Marcellus shale. Risk Anal 32:1382–1393.

Soeder DJ, Sharma S, Pekney N, Hopkinson L, Dilmore R, Kutchko B, et al. 2014. An approach for assessing engineering risk from shale gas wells in the United States. Int J Coal Geol 126:4–19.

Ziemkiewicz P, Quaranta J, Darnell A, Wise R. 2014. Exposure pathways related to shale gas development and procedures for reducing environmental and public risk. J Nat Gas Sci Eng 16:77–84.

AIR QUALITY

Methane

Advanced Research Projects Agency – Energy. 2014. Methane Observation Networks with Innovative Technology to Obtain Reductions. U.S. Department of Energy. Available: http://arpa-e.energy.gov/?q=arpa-e-programs/monitor.

Albertson JD, Harvey T, Foderaro G, Zhu P, Zhou X, Ferrari S, Amin MS, Modrak M, Brantley H, Thoma ED. 2016. A mobile sensing approach for regional surveillance of fugitive methane emissions in oil and gas production. Environ Sci Technol 50:2487–2497.

Allen DT, Cardoso-Saldaña FJ, Kimura Y. 2017. Variability in Spatially and Temporally Resolved Emissions and Hydrocarbon Source Fingerprints for Oil and Gas Sources in Shale Gas Production Regions. Environmental science & technology 51:12016-12026.

Allen D. 2016. Attributing Atmospheric Methane to Anthropogenic Emission Sources. Acc Chem Res; doi: 101021/acsaccounts6b00081.

Allen DT, Pacsi AP, Sullivan DW, Zavala-Araiza D, Harrison M, Keen K, et al. 2015. Methane emissions from process equipment at natural gas production sites in the United States: pneumatic controllers. Environ Sci Technol 49:633–640.

Allen DT, Sullivan DW, Zavala-Araiza D, Pacsi AP, Harrison M, Keen K, et al. 2015. Methane emissions from process equipment at natural gas production sites in the United States: liquid unloadings. Environ Sci Technol 49:641–648.

Allen DT, Torres VM, Thomas J, Sullivan DW, Harrison M, Hendler A, et al. 2013. Measurements of methane emissions at natural gas production sites in the United States. Proc Natl Acad Sci U S A 110:17768–17773.

Alvarez RA, Zavala-Araiza D, Lyon DR, Allen DT, Barkley ZR, Brandt AR, Davis KJ, Herndon SC, Jacob DJ, Karion A, Kort EA, Lamb BK, Lauvaux T, Maasakkers JD, Marchese AJ, Omara M, Pacala SW, Peischl J, Robinson AL, Shepson PB, Sweeney C, Townsend-Small A, Wofsy SC, Hamburg SP. 2018. Assessment of methane emissions from the U.S. oil and gas supply chain. Science (New York, NY).

Alvarez RA, Pacala SW, Winebrake JJ, Chameides WL, Hamburg SP. 2012. Greater focus needed on methane leakage from natural gas infrastructure. Proc Natl Acad Sci U S A 109:6435–6440.

Assan S, Vogel FR, Gros V, Baudic A, Staufer J, Ciais P. 2018. Can we separate industrial CH4 emission sources from atmospheric observations? - A test case for carbon isotopes, PMF and enhanced APCA. Atmospheric Environment 187:317-327.

Barkley ZR, Lauvaux T, Davis KJ, Deng AJ, Miles NL, Richardson SJ, Cao YN, Sweeney C, Karion A, Smith M, Kort EA, Schwietzke S, Murphy T, Cervone G, Martins D, Maasakkers JD. 2017. Quantifying methane emissions from natural gas production in north-eastern Pennsylvania. Atmospheric Chemistry and Physics 17:13941-13966.

Bell C, Vaughn T, Zimmerle D, Herndon S, Yacovitch T, Heath G, Pétron G, Edie R, Field R, Murphy S. 2017. Comparison of methane emission estimates from multiple measurement techniques at natural gas production pads. Elem Sci Anth 5.

Boothroyd IM, Almond S, Qassim SM, Worrall F, Davies RJ. 2016. Fugitive emissions of methane from abandoned, decommissioned oil and gas wells. Sci Total Environ 547:461–469.

Bouman EA, Ramirez A, Hertwich EG. 2015. Multiregional environmental comparison of fossil fuel power generation—assessment of the contribution of fugitive emissions from conventional and unconventional fossil resources. International Journal of Greenhouse Gas Control 33:1–9.

Brandt AR, Pétron G. 2015. Fugitive Emissions and Air Quality Impacts of US Natural Gas Systems. The Bridge:

Linking Engineering and Science 45:22-31.

Brandt AR. 2015. Embodied energy and GHG emissions from material use in conventional and unconventional oil and gas operations. Environ Sci Technol 49:13059–13066.

Brandt AR, Heath GA, Kort EA, O'Sullivan F, Pétron G, Jordaan SM, et al. 2014. Methane leaks from North American natural gas systems. Science 343:733–735.

Brantley HL, Thoma ED, Squier WC, Guven BB, Lyon D. 2014. Assessment of methane emissions from oil and gas production pads using mobile measurements. Environ Sci Technol 48:14508–14515.

Caulton DR, Shepson PB, Santoro RL, Sparks JP, Howarth RW, Ingraffea AR, et al. 2014. Toward a better understanding and quantification of methane emissions from shale gas development. Proc Natl Acad Sci U S A 111:6237–6242.

Caulton DR, Shepson PB, Santoro RL, Sparks JP, Howarth RW, Ingraffea AR, Cambaliza MO, Sweeney C, Karion A, Davis KJ. 2014. Toward a better understanding and quantification of methane emissions from shale gas development. Proc Natl Acad Sci USA 111:6237–6242.

Chamindu D, Smits KM, Oldenburg CM. 2016. Effect of subsurface soil moisture variability and atmospheric conditions on methane gas migration in shallow subsurface. International Journal of Greenhouse Gas Control 55:105-117.

Dakota Resource Council. 2017. Oil & Gas Pollution's Impacts on North Dakota Families. Dakota Resource Council. Available from http://drcinfo.org/wp-content/uploads/2017/08/ND-Methane-Report-DRC.pdf.

Englander JG, Brandt AR, Conley S, Lyon DR, Jackson RB. 2018. Aerial Interyear Comparison and Quantification of Methane Emissions Persistence in the Bakken Formation of North Dakota, USA. Environmental science & technology 52:8947-8953.

Environmental Defense Fund. 2015. Extensive research effort tackles methane leaks. Available: https://www.edf.org/climate/methane-studies.

Environmental Defense Fund. 2015. Methane Research: The 16 Study Series. Available: https://www.edf.org/sites/default/files/methane_studies_fact_sheet.pdf.

Frankenberg C, Thorpe AK, Thompson DR, Hulley G, Kort EA, Vance N, Borchardt J, Krings T, Gerilowski K, Sweeney C, Conley S, Bue BD, Aubrey AD, Hook S, Green RO. 2016. Airborne methane remote measurements reveal heavy-tail flux distribution in Four Corners region. Proceedings of the National Academy of Sciences.

Gilbert AQ, Sovacool BK. 2017. Benchmarking natural gas and coal-fired electricity generation in the United States. Energy 134:622-628.

Goetz JD, Avery A, Werden B, Floerchinger C, Fortner EC, Wormhoudt J, Massoli P, Herndon SC, Kolb CE, Knighton WB. 2017. Analysis of local-scale background concentrations of methane and other gas-phase species in the Marcellus Shale. Elem Sci Anth 5:1-21.

Gvakharia A, Kort EA, Brandt A, Peischl J, Ryerson TB, Schwarz JP, Smith ML, Sweeney C. 2017. Methane, Black Carbon, and Ethane Emissions from Natural Gas Flares in the Bakken Shale, North Dakota. Environmental science & technology 51:5317-5325.

Harriss R, Alvarez RA, Lyon D, Zavala-Araiza D, Nelson D, Hamburg SP. 2015. Using multi-scale measurements to improve methane emission estimates from oil and gas operations in the Barnett shale region, Texas. Environ Sci Technol 49:7524–7526.

Hendry MJ, Schmeling EE, Barbour SL, Huang M, Mundle SOC. 2017. Fate and Transport of Shale-derived, Biogenic Methane. Scientific reports 7:9.

Johnson DR, Covington AN, Clark NN. 2015. Methane emissions from leak and loss audits of natural gas

compressor stations and storage facilities. Environ Sci Technol 49:8132–8138.

Johnson DR, Heltzel R. 2016. Methane emissions measurements of natural gas components using a utility terrain vehicle and portable methane quantification system. Atmospheric Environment 144:1-7.

Johnson DR, Heltzel R, Nix A. 2014. Trends in unconventional well development—methane emissions associated with the use of dual fuel and dedicated natural gas engines. Energy Technology 2:988–995.

Johnson MR, Tyner DR, Conley S, Schwietzke S, Zavala-Araiza D. 2017. Comparisons of airborne measurements and inventory estimates of methane emissions in the alberta upstream oil and gas sector. Environmental science & technology 51:13008-13017.

Johnson J. 2014. Methane's role in climate change. Chem Eng News 92:10–15.

Kang M, Kanno CM, Reid MC, Zhang X, Mauzerall DL, Celia MA, et al. 2014. Direct measurements of methane emissions from abandoned oil and gas wells in Pennsylvania. Proc Natl Acad Sci U S A 111:18173–18177.

Kang M, Christian S, Celia MA, Mauzerall DL, Bill M, Miller AR, Chen Y, Conrad ME, Darrah TH, Jackson RB. 2016. Identification and characterization of high methane-emitting abandoned oil and gas wells. Proceedings of the National Academy of Sciences 113:13636-13641.

Karion A, Sweeney C, Pétron G, Frost G, Michael Hardesty R, Kofler J, Miller BR, Newberger T, Wolter S, Banta R, Brewer A, Dlugokencky E, Lang P, Montzka SA, Schnell R, Tans P, Trainer M, Zamora R, Conley S. 2013. Methane emissions estimate from airborne measurements over a western United States natural gas field. Geophysical Research Letters 40:4393-4397.

Karion A, Sweeney C, Kort EA, Shepson PB, Brewer A, Cambaliza M, et al. 2015. Aircraft-based estimate of total methane emissions from the Barnett shale region. Environ Sci Technol 49:8124–8131.

Lamb BK, Edburg SL, Ferrara TW, Howard T, Harrison MR, Kolb CE, et al. 2015. Direct measurements show decreasing methane emissions from natural gas local distribution systems in the United States. Environ Sci Technol 49:5161–5169.

Lan X, Talbot R, Laine P, Torres A. 2015. Characterizing fugitive methane emissions in the Barnett shale area using a mobile laboratory. Environ Sci Technol 49:8139–8146.

Lavoie TN, Shepson PB, Cambaliza MOL, Stirm BH, Conley S, Mehrotra S, Faloona IC, Lyon D. 2017. Spatiotemporal Variability of Methane Emissions at Oil and Natural Gas Operations in the Eagle Ford Basin. Environmental science & technology.

Lavoie TN, Shepson PB, Gore CA, Stirm BH, Kaeser R, Wulle B, Lyon D, Rudek J. 2017. Assessing the Methane Emissions from Natural Gas-Fired Power Plants and Oil Refineries. Environmental science & technology 51:3373-3381.

Lavoie TN, Shepson PB, Cambaliza MOL, Stirm BH, Karion A, Sweeney C, et al. 2015. Aircraft-based measurements of point source methane emissions in the Barnett shale basin. Environ Sci Technol 49:7904–7913.

Lyon DR, Zavala-Araiza D, Alvarez RA, Harriss R, Palacios V, Lan X, et al. 2015. Constructing a spatially resolved methane emission inventory for the Barnett shale region. Environ Sci Technol 49:8147–8157.

Maasakkers JD, Jacob DJ, Sulprizio MP, Turner AJ, Weitz M, Wirth T, Hight C, DeFigueiredo M, Desai M, Schmeltz R, Hockstad L, Bloom AA, Bowman KW, Jeong S, Fischer ML. 2016. Gridded National Inventory of US Methane Emissions. Environmental science & technology 50:13123-13133.

McVay R, Hull H, Lyon D. 2017. Oil and gas methane emissions in New Mexico. Environmental Defense Fund.

Mehrotra S, Faloona I, Suard M, Conley S, Fischer ML. 2017. Airborne methane emission measurements for selected oil and gas facilities across california. Environmental science & technology 51:12981-12987.

Miller SM, Wofsy SC, Michalak AM, Kort EA, Andrews AE, Biraud SC, et al. 2013. Anthropogenic emissions of methane in the United States. Proc Natl Acad Sci U S A 110:20018–20022.

Mitchell AL, Tkacik DS, Roscioli JR, Herndon SC, Yacovitch TI, Martinez DM, et al. 2015. Measurements of methane emissions from natural gas gathering facilities and processing plants: measurement results. Environ Sci Technol 49:3219–3227.

Newell RG, Raimi D. 2014. Implications of shale gas development for climate change. Environ Sci Technol 48:8360–8368.

New York State Department of Environmental Conservation, New York State Department of Public Service, New York State Agriculture and Markets, New York State Soil and Water Conservation Committee, NYSERDA. 2017. Methane Reduction Plan. New York. Available from http://www.dec.ny.gov/docs/administration_pdf/mrpfinal.pdf.

Omara M, Sullivan MR, Li X, Subramanian R, Robinson AL, Presto AA. 2016. Methane emissions from conventional and unconventional natural gas production sites in the Marcellus shale basin. Environ Sci Technol 50:2099–2107.

Payne Jr BF, Ackley R, Paige Wicker A, Hildenbrand ZL, Carlton Jr DD, Schug KA. 2017. Characterization of methane plumes downwind of natural gas compressor stations in Pennsylvania and New York. Science of The Total Environment 580:1214-1221.

Peischl J, Ryerson TB, Aikin KC, de Gouw JA, Gilman JB, Holloway JS, et al. 2015. Quantifying atmospheric methane emissions from the Haynesville, Fayetteville, and northeastern Marcellus shale gas production regions. J Geophys Res Atmos 120:2119–2139.

Peischl J, Ryerson TB, Brioude J, Aikin KC, Andrews AE, Atlas E, et al. 2013. Quantifying sources of methane using light alkanes in the Los Angeles basin, California. Journal of Geophysical Research: Atmospheres 118:4974-4990.

Ravikumar AP, Brandt AR. 2017. Designing better methane mitigation policies: the challenge of distributed small sources in the natural gas sector. Environmental Research Letters 12:10.

Ren XR, Hall DL, Vinciguerra T, Benish SE, Stratton PR, Ahn D, Hansford JR, Cohen MD, Sahu S, He H, Grimes C, Salawitch RJ, Ehrman SH, Dickerson RR. 2017. RETRACTED: Methane emissions from the Marcellus Shale in southwestern Pennsylvania and northern West Virginia based on airborne measurements (Retracted article. See vol. 123, pg. 1478, 2018). J Geophys Res-Atmos 122:4639-4653.

Ren X, Hall DL, Vinciguerra T, Benish SE, Stratton PR, Ahn D, Hansford JR, Cohen MD, Sahu S, He H, Grimes C, Salawitch RJ, Ehrman SH, Dickerson RR. 2017. Methane Emissions from the Marcellus Shale in Southwestern Pennsylvania and Northern West Virginia Based on Airborne Measurements. Journal of Geophysical Research: Atmospheres:n/a-n/a.

Robertson AM, Edie R, Snare D, Soltis J, Field RA, Burkhart MD, Bell CS, Zimmerle D, Murphy SM. 2017. Variation in Methane Emission Rates from Well Pads in Four Oil and Gas Basins with Contrasting Production Volumes and Compositions. Environmental science & technology 51:8832-8840.

Roscioli JR, Yacovitch TI, Floerchinger C, Mitchell AL, Tkacik DS, Subramanian R, et al. 2015. Measurements of methane emissions from natural gas gathering facilities and processing plants: measurement methods. Atmos Meas Tech 8:2017–2035.

Schneising O, Burrows JP, Dickerson RR, Buchwitz M, Reuter M, Bovensmann H. 2014. Remote sensing of fugitive methane emissions from oil and gas production in North American tight geologic formations. Earth's Future 2:548–558.

Schwietzke S, Petron G, Conley S, Pickering C, Mielke-Maday I, Dlugokencky EJ, Tans PP, Vaughn T, Bell C, Zimmerle D, Wolter S, King CW, White AB, Coleman T, Bianco L, Schnell RC. 2017. Improved Mechanistic Understanding of Natural Gas Methane Emissions from Spatially Resolved Aircraft Measurements. Environmental

Science & Technology 51:7286-7294.

Sheng JX, Jacob DJ, Turner AJ, Maasakkers JD, Benmergui J, Bloom AA, Arndt C, Gautam R, Zavala-Araiza D, Boesch H, Parker RJ. 2018. 2010-2016 methane trends over Canada, the United States, and Mexico observed by the GOSAT satellite: contributions from different source sectors. Atmospheric Chemistry and Physics 18:12257-12267.

Sheng JX, Jacob DJ, Maasakkers JD, Sulprizio MP, Zavala-Araiza D, Hamburg SP. 2017. A high-resolution (0.1 degrees x 0.1 degrees) inventory of methane emissions from Canadian and Mexican oil and gas systems. Atmospheric Environment 158:211-215.

Shindell DT, Fuglestvedt JS, Collins WJ. 2017. The social cost of methane: theory and applications. Faraday Discuss 200:429-451.

Skone TJ, Littlefield J, Marriott J. 2011. Life Cycle Greenhouse Gas Inventory of Natural Gas Extraction, Delivery and Electricity Production. DOE/NETL-2011/1522. Morgantown, WV:National Energy Technology Laboratory.

Smith ML, Gvakharia A, Kort EA, Sweeney C, Conley SA, Faloona I, Newberger T, Schnell R, Schwietzke S, Wolter S. 2017. Airborne Quantification of Methane Emissions over the Four Corners Region. Environmental science & technology 51:5832-5837.

Smith ML, Kort EA, Karion A, Sweeney C, Herndon SC, Yacovitch TI. 2015. Airborne ethane observations in the Barnett shale: quantification of ethane flux and attribution of methane emissions. Environ Sci Technol 49:8158–8166.

Subramanian R, Williams LL, Vaughn TL, Zimmerle D, Roscioli JR, Herndon SC, et al. 2015. Methane emissions from natural gas compressor stations in the transmission and storage sector: measurements and comparisons with the EPA Greenhouse Gas Reporting Program protocol. Environ Sci Technol 49:3252–3261.

Townsend-Small A, Ferrara TW, Lyon DR, Fries AE, Lamb BK. 2016. Emissions of coalbed and natural gas methane from abandoned oil and gas wells in the United States. Geophys Res Lett 43:2283–2290.

Turner AJ, Jacob DJ, Benmergui J, Brandman J, White L, Randles CA. 2018. Assessing the capability of different satellite observing configurations to resolve the distribution of methane emissions at kilometer scales. Atmospheric Chemistry and Physics 18:8265-8278.

Umeozor EC, Jordaan SM, Gates ID. 2018. On methane emissions from shale gas development. Energy 152:594-600.

Williams PJ, Reeder M, Pekney NJ, Risk D, Osborne J, McCawley M. 2018. Atmospheric impacts of a natural gas development within the urban context of Morgantown, West Virginia. Science of the Total Environment 639:406-416.

Worden JR, Bloom AA, Pandey S, Jiang Z, Worden HM, Walker TW, Houweling S, Röckmann T. 2017. Reduced biomass burning emissions reconcile conflicting estimates of the post-2006 atmospheric methane budget. Nature Communications 8:2227.

Yacovitch TI, Herndon SC, Pétron G, Kofler J, Lyon D, Zahniser MS, Kolb CE. 2015. Mobile Laboratory Observations of Methane Emissions in the Barnett Shale Region. Environmental science & technology 49:7889-7895.

Yacovitch TI, Daube C, Vaughn TL, Bell CS, Roscioli JR, Knighton WB, Nelson DD, Zimmerle D, Pétron G, Herndon SC. 2017. Natural gas facility methane emissions: measurements by tracer flux ratio in two US natural gas producing basins. Elem Sci Anth 5.

Zavala-Araiza D, Lyon DR, Alvarez RA, Davis KJ, Harriss R, Herndon SC, et al. 2015. Reconciling divergent estimates of oil and gas methane emissions. Proc Natl Acad Sci U S A 112:15597–15602.

Zavala-Araiza D, Allen DT, Harrison M, George FC, Jersey GR. 2015. Allocating Methane Emissions to Natural Gas and Oil Production from Shale Formations. ACS Sustain Chem Eng 3:492–498.

Zavala-Araiza D, Lyon D, Alvarez RA, Palacios V, Harriss R, Lan X, et al. 2015. Toward a functional definition of methane super-emitters: application to natural gas production sites. Environ Sci Technol 49:8167–8174.

Zimmerle DJ, Williams LL, Vaughn TL, Quinn C, Subramanian R, Duggan GP, et al. 2015. Methane emissions from the natural gas transmission and storage system in the United States. Environ Sci Technol 49:9374–9383.

Ozone

Ahmadi M, John K. 2015. Statistical evaluation of the impact of shale gas activities on ozone pollution in North Texas. Sci Total Environ 536:457–467.

Ahmadov R, McKeen S, Trainer M, Banta R, Brewer A, Brown S, et al. 2015. Understanding high wintertime ozone pollution events in an oil- and natural gas-producing region of the western US. Atmos Chem Phys 15:411-429.

Bien T, Helmig D. 2018. Changes in summertime ozone in Colorado during 2000-2015. Elementa-Sci Anthrop 6:25.

Chang C-Y, Faust E, Hou X, Lee P, Kim HC, Hedquist BC, Liao K-J. 2016. Investigating ambient ozone formation regimes in neighboring cities of shale plays in the Northeast United States using photochemical modeling and satellite retrievals. Atmospheric Environment 142:152-170.

Cheadle L, Oltmans S, Petron G, Schnell R, Mattson E, Herndon S, Thompson A, Blake D, McClure-Begley A. 2017. Surface ozone in the Colorado northern Front Range and the influence of oil and gas development during FRAPPE/DISCOVER-AQ in summer 2014. Elem Sci Anth 5.

Edwards PM, Brown SS, Roberts JM, Ahmadov R, Banta RM, deGouw JA, et al. 2014. High winter ozone pollution from carbonyl photolysis in an oil and gas basin. Nature 514:351–354.

Evans JM, Helmig D. 2017. Investigation of the influence of transport from oil and natural gas regions on elevated ozone levels in the northern Colorado front range. Journal of the Air & Waste Management Association 67:196-211.

Fann N, Baker KR, Chan EAW, Eyth A, Macpherson A, Miller E, Snyder J. 2018. Assessing Human Health PM2.5 and Ozone Impacts from U.S. Oil and Natural Gas Sector Emissions in 2025. Environmental science & technology.

Field RA, Soltis J, McCarthy MC, Murphy S, Montague DC. 2015. Influence of oil and gas field operations on spatial and temporal distributions of atmospheric non-methane hydrocarbons and their effect on ozone formation in winter. Atmos Chem Phys 15:3527–3542.

Matichuk R, Tonnesen G, Eisele AP, Thoma ED, Kosusko M, Strum M, Beeler C. 2016. Advancing Understanding of Emissions from Oil and Natural Gas Production Operations to Support EPA's Air Quality Modeling of Ozone Non-Attainment Areas. Agency USEP, Washington, DC. Available from https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=531121.

McDuffie EE, Edwards PM, Gilman JB, Lerner BM, Dubé WP, Trainer M, Wolfe DE, Angevine WM, deGouw J, Williams EJ, Tevlin AG, Murphy JG, Fischer EV, McKeen S, Ryerson TB, Peischl J, Holloway JS, Aikin K, Langford AO, Senff CJ, Alvarez RJ, Hall SR, Ullmann K, Lantz KO, Brown SS. 2016. Influence of oil and gas emissions on summertime ozone in the Colorado Northern Front Range. Journal of Geophysical Research: Atmospheres:n/a-n/a.

Olaguer EP. 2012. The potential near-source ozone impacts of upstream oil and gas industry emissions. J Air Waste Manage Assoc 62:966–977.

Oltmans S, Schnell R, Johnson B, Pétron G, Mefford T, Neely R, III. 2014. Anatomy of wintertime ozone associated with oil and natural gas extraction activity in Wyoming and Utah. Elem Sci Anth 2:000024.

Pacsi AP, Kimura Y, McGaughey G, McDonald-Buller EC, Allen DT. 2015. Regional ozone impacts of increased natural gas use in the Texas power sector and development in the Eagle Ford shale. Environ Sci Technol 49:3966–3973.

Roohani YH, Roy AA, Heo J, Robinson AL, Adams PJ. 2017. Impact of natural gas development in the Marcellus

and Utica shales on regional ozone and fine particulate matter levels. Atmospheric Environment 155:11-20.

Radiation

Casey JA, Ogburn EL, Rasmussen SG, Irving JK, Pollak J, Locke PA, et al. 2015. Predictors of indoor radon concentrations in Pennsylvania, 1989–2013. Environ Health Perspect; doi:101289/ehp1409014 [Online 9 April 2015].

Mitchell AL, Griffin WM, Casman EA. 2016. Lung Cancer Risk from Radon in Marcellus Shale Gas in Northeast U.S. Homes. Risk Anal; doi: 101111/risa12570.

Rowan EL, Kraemer TF. 2012. Radon-222 Content of Natural Gas Samples from Upper and Middle Devonian Sandstone and Shale Reservoirs in Pennsylvania: Preliminary Data. Open-File Report Series 2012-1159. Reston, VA: U.S. Geological Survey. Available from http://pubs.usgs.gov/of/2012/1159.

Tian W, Wu X, Shen T, Zhang Z, Kalra S. 2017. Quantitative Prediction of Radon Concentration at Wellhead in Shale Gas Development. Spe Journal 22:235-243.

Walter GR, Benke RR, Pickett DA. 2012. Effect of biogas generation on radon emissions from landfills receiving radium-bearing waste from shale gas development. J Air Waste Manag Assoc 62(9):1040–1049.

Monitoring Methods and Protocols

Albertson JD, Harvey T, Foderaro G, Zhu P, Zhou X, Ferrari S, Amin MS, Modrak M, Brantley H, Thoma ED. 2016. A mobile sensing approach for regional surveillance of fugitive methane emissions in oil and gas production. Environ Sci Technol 50:2487–2497.

Brown D, Weinberger B, Lewis C, Bonaparte H. 2014. Understanding exposure from natural gas drilling puts current air standards to the test. Rev Environ Health 29:277–292.

Carlton AG, Little E, Moeller M, Odoyo S, Shepson PB. 2014. The data gap: can a lack of monitors obscure loss of Clean Air Act benefits in fracking areas? Environ Sci Technol 48:893–894.

Gourdji SM, Yadav V, Karion A, Mueller KL, Conley S, Ryerson T, et al. 2018. Reducing errors in aircraft atmospheric inversion estimates of point-source emissions: The aliso canyon natural gas leak as a natural tracer experiment. Environmental Research Letters 13:045003.

Haynes E. Understanding the Effect of Unconventional Gas Drilling on Air Quality: Environmental Sampling with Passive Samplers Fact Sheet. Cincinnati, OH:University of Cincinnati. Available: http://www.theoec.org/sites/default/files/Fact%20Sheet_env%20sampling_passive%20samplers.pdf.

Houston Advanced Research Center. 2015. Developing Methane Sensors for Leak Detection in Oil and Gas Operations. Available: http://www.harc.edu/work/Developing_Methane_Sensors_for_Leak_Detection_Oil_Gas_Operations.

Knobelspies S, Bierer B, Perez AO, Wollenstein J, Kneer J, Palzer S. 2016. Low-cost gas sensing system for the reliable and precise measurement of methane, carbon dioxide and hydrogen sulfide in natural gas and biomethane. Sensors and Actuators B-Chemical 236:885-892.

Meng Q. 2018. Rethink potential risks of toxic emissions from natural gas and oil mining. Environmental Pollution 240:848-857.

Nielsen CC, Amrhein CG, Osornio-Vargas AR. 2017. Mapping outdoor habitat and abnormally small newborns to develop an ambient health hazard index. International Journal of Health Geographics 16:43.

Olaguer EP, Erickson M, Wijesinghe A, Neish B, Williams J, Colvin J. 2014. New methods for assessing the impacts of nearby gas drilling and production on neighborhood air quality and human health. Environ Health Insights 8:S1.

Olaguer EP, Erickson M, Wijesinghe A, Neish B, Williams J, Colvin J. 2015. Updated methods for assessing the impacts of nearby gas drilling and production on neighborhood air quality and human health. J Air Waste Manag Assoc:N/A.

Rostron B, Arkadakskiy S. 2014. Fingerprinting "Stray" Formation Fluids Associated and Production with Hydrocarbon Exploration and Production. Elements 10:285–290.

Strickland H, Fraser B. 2018. On the Fence about Fenceline Monitoring? Air and Waste Management Association.

Stuver S, Alonzo J. 2014. White paper — A Comparison of Air Emission Estimation Methods for Drilling Rig Emissions. College Station, TX:Texas A&M Institute of Renewable Natural Resources. Available: http://efdsystems.org/pdf/A_Comparison_of_Estimation_Protocols_for_Drilling_Rig_Emissions.pdf.

Stuver SK, Alonzo JR, Burnett DB, Haut RC. 2014. A Better Way to Estimate Emissions from Oil and Gas Sites. J Pet Environ Biotechnol 5:189.

Townsend-Small A, Marrero JE, Lyon DR, Simpson IJ, Meinardi S, Blake DR. 2015. Integrating source apportionment tracers into a bottom-up inventory of methane emissions in the Barnett shale hydraulic fracturing region. Environ Sci Technol 49:8175–8182.

United States Environmental Protection Agency. 2018. Review and analysis of emissions test reports for purposes of reviewing the natural gas production flares volatile organic compounds emissions factor under Clean Air Act Section 130. Research Triangle Park, North Carolina:U.S. Environmental Protection Agency.

Monitoring Data and/or Modeling

Appalachia

Banan Z, Gernard JM. Mapping the pm emissions exposure risk due to hydraulic fracturing in pennsylvania. In: Proceedings of the American Meteorlogical Society, 2018. Austin, TX.

Coughlin JG, Rose LA, Bain DJ, Elliott EM. 2017. The Influence of Marcellus Shale Extraction Emissions on Regionally Monitored Dry Reactive Nitrogen Deposition. Environmental science & technology 51:3542-3549.

Geng X, Davatzes N, Soeder D, Torlapati J, Rodriguez R, Boufadel M. 2014. Migration of high-pressure air during gas well drilling in the Appalachian Basin. J Environ Eng (New York) 140:B4014002.

Goetz JD, Floerchinger C, Fortner EC, Wormhoudt J, Massoli P, Knighton WB, et al. 2015. Atmospheric emission characterization of Marcellus Shale natural gas development sites. Environ Sci Technol 49:7012–7020.

Korfmacher K, Hawker JS, Winebrake J. 2015. Transportation activities associated with high-volume hydraulic fracturing operations in the Marcellus Shale formation. Transportation Research Record: Journal of the Transportation Research Board 2503:70–80.

Kurth LM, McCawley M, Hendryx M, Lusk S. 2014. Atmospheric particulate matter size distribution and concentration in West Virginia coal mining and non-mining areas. J Expo Sci Environ Epidemiol 24:405–411.

Lewis C, Hamel K, Brown D. 2016. Community Assessment of Penn Trafford Outdoor Air Monitoring Results. South West Pennsylvania Environmental Health Project. McMurray, PA. Available from https://www.documentcloud.org/documents/3233438-Community-Assessment-of-Penn-Trafford-Outdoor.html.

Litovitz A, Curtright A, Abramzon S, Burger N, Samaras C. 2013. Estimation of regional air-quality damages from Marcellus Shale natural gas extraction in Pennsylvania. Environ Res Lett 8:1–8.

Marcellus Shale Advisory Commission. 2011. Report of the Governor's Marcellus Shale Advisory Commission. Commonwealth of Pennsylvania: Harrisburg, PA.

Maskrey JR, Insley AL, Hynds ES, Panko JM. 2016. Air monitoring of volatile organic compounds at relevant

receptors during hydraulic fracturing operations in Washington County, Pennsylvania. Environ Monit Assess 188:1-12.

McCawley M. 2013. Air, Noise, and Light Monitoring Results. ETD-10 Project. Morgantown, WV:West Virginia University School of Public Health.

Paulik LB, Donald CE, Smith BW, Tidwell LG, Hobbie KA, Kincl L, Haynes EN, Anderson KA. 2016. Emissions of Polycyclic Aromatic Hydrocarbons from Natural Gas Extraction into Air. Environmental science & technology 50:7921-7929.

Paulik LB, Hobbie KA, Rohlman D, Smith BW, Scott RP, Kincl L, Haynes EN, Anderson KA. 2018. Environmental and individual PAH exposures near rural natural gas extraction. Environmental Pollution 241:397-405.

Pekney N, Reeder M, Mundia-Howe M. 2018. Air Quality Measurements at the Marcellus Shale Energy and Environment Laboratory Site. Air and Waste Management Association.

Pekney NJ, Veloski G, Reeder M, Tamilia J, Rupp E, Wetzel A. 2014. Measurement of atmospheric pollutants associated with oil and natural gas exploration and production activity in Pennsylvania's Allegheny National Forest. J Air Waste Manage Assoc 64:1062–1072.

Pennsylvania Department of Environmental Protection. 2018. Long-Term Ambient Air Monitoring Project: Marcellus Shale Gas Facilities.

Pennsylvania Department of Environmental Protection. 2010. Southwestern Pennsylvania Marcellus Shale Short-Term Ambient Air Sampling Report. Harrisburg, PA:PA DEP Bureau of Air Quality. Available: http://www.dep.state.pa.us/dep/deputate/airwaste/aq/aqm/docs/Marcellus_SW_11-01-10.pdf.

Pennsylvania Department of Environmental Protection. 2010. Southwestern Pennsylvania Marcellus Shale Short-Term Ambient Air Sampling Report. PA DEP Bureau of Air Quality, Harrisburg, PA. Available from http://www.dep.state.pa.us/dep/deputate/airwaste/aq/aqm/docs/Marcellus_SW_11-01-10.pdf.

Pennsylvania Department of Health. 2018. ATSDR Health Consultation: Public Health Evaluation of Long-Term Air Sampling Data Collected in the Vicinity of Natural Gas Operations, Washington County, PA. Available from https://www.atsdr.cdc.gov/HAC/pha/marcellusShale/Air_Marcellus_Shale_HC-508.pdf.

Roohani YH, Roy AA, Heo J, Robinson AL, Adams PJ. 2017. Impact of natural gas development in the Marcellus and Utica shales on regional ozone and fine particulate matter levels. Atmospheric Environment 155:11-20.

Roy AA, Adams PJ, Robinson AL. 2014. Air pollutant emissions from the development, production, and processing of Marcellus Shale natural gas. J Air Waste Manage Assoc 64:19–37.

Russo PN, Carpenter DO. 2017. Health Effects Associated with Stack Chemical Emissions from NYS Natural Gas Compressor Stations: 2008-2014. Institute for Health and the Environment. Project PftSPEH, Rensselaer, New York. Available from https://www.scribd.com/document/361433431/Health-Effects-Associated-With-Stack-Chemical-Emissions-From-NYS-Natural-Gas-Compressor-Stations-2008-2014.

Sharma S, Bowman L, Schroeder K, Hammack R. 2014. Assessing changes in gas migration pathways at a hydraulic fracturing site: Example from Greene County, Pennsylvania, USA. Appl Geochem 60:51–58.

Sibrizzi CMPH, LaPuma PPPECIH. 2016. An Assessment of Life Cycle Greenhouse Gas Emissions Associated With the Use of Water, Sand, and Chemicals in Shale Gas Production of the Pennsylvania Marcellus Shale. Journal of Environmental Health 79:8-15.

Squizzato S, Masiol M, Rich DQ, Hopke PK. 2018. PM2.5 and gaseous pollutants in New York State during 2005–2016: Spatial variability, temporal trends, and economic influences. Atmospheric Environment 183:209-224.

Swarthout RF, Russo RS, Zhou Y, Miller BM, Mitchell B, Horsman E, et al. 2015. Impact of Marcellus Shale natural gas development in Southwest Pennsylvania on volatile organic compound emissions and regional air

quality. Environ Sci Technol 49:3175–3184.

Vinciguerra T, Yao S, Dadzie J, Chittams A, Deskins T, Ehrman S, et al. 2015. Regional air quality impacts of hydraulic fracturing and shale natural gas activity: Evidence from ambient VOC observations. Atmos Environ 110:144–150.

West Virginia Department of Environmental Protection Office of Oil and Gas. 2013. Air Quality Impacts Occuring from Horizontal Well Drilling and Related Activities. Charleston, WV:West Virginia DEP.

West Virginia Department of Environmental Protection Office of Oil and Gas. 2013. Noise, Light, Dust, and Volatile Organic Compounds Generated by the Drilling of Horizontal Wells Related to the Well Location Restriction Regarding Occupied Dwelling Structures. West Virginia Department of Environmental Protection-Office of Oil and Gas. Charleston, WV.

Williams PJ, Reeder M, Pekney NJ, Risk D, Osborne J, McCawley M. 2018. Atmospheric impacts of a natural gas development within the urban context of Morgantown, West Virginia. Science of the Total Environment 639:406-416.

Colorado/Southwest

Agency for Toxic Substances and Disease Registry. 2010. Health Consultation: Public Health Implications of Ambient Air Exposures as Measured in Rural and Urban Oil & Gas Development Areas – an Analysis of 2008 Air Sampling Data. Garfield County, CO.

Allshouse WB, Adgate JL, Blair BD, McKenzie LM. 2017. Spatiotemporal Industrial Activity Model for Estimating the Intensity of Oil and Gas Operations in Colorado. Environmental science & technology 51:10243–10250.

Bahreini R, Ahmadov R, McKeen SA, Vu KT, Dingle JH, Apel EC, Blake DR, Blake N, Campos TL, Cantrell C, Flocke F, Fried A, Gilman JB, Hills AJ, Hornbrook RS, Huey G, Kaser L, Lerner BM, Mauldin RL, Meinardi S, Montzka DD, Richter D, Schroeder JR, Stell M, Tanner D, Walega J, Weibring P, Weinheimer A. 2018. Sources and characteristics of summertime organic aerosol in the Colorado Front Range: perspective from measurements and WRF-Chem modeling. Atmos Chem Phys 18:8293-8312.

ENTRIX C. 2012. Hydraulic Fracturing Study-PXP Inglewood Oil Field. Plains Exploration & Production Company Los Angeles County, Department of Regional Planning. Los Angeles, CA. Available from https://www.eenews.net/assets/2012/10/11/document_ew_01.pdf.

Colborn T, Schultz K, Herrick L, Kwiatkowski C. 2014. An exploratory study of air quality near natural gas operations. Hum Ecol Risk Assess 20:86–105.

Collett JL, Ham J. 2013. North Front Range Oil and Gas Air Pollutant Emission and Dispersion Study: A Proposal. Colorado State University.

Colorado Department of Public Health and Environment. 2017. Investigation of Reported Health Concerns near Waste Connections Oil and Gas Site in Erie. Colorado Department of Public Health and Environment. Available from https://www.erieco.gov/DocumentCenter/View/9708.

Ghosh B. 2018. Impact of changes in oil and gas production activities on air quality in northeastern oklahoma: Ambient air studies in 2015–2017. Environmental Science & Technology 52:3285-3294.

Gilman J, Lerner B, Kuster W, De Gouw J. 2013. Source signature of volatile organic compounds from oil and natural gas operations in northeastern Colorado. Environ Sci Technol 47:1297–1305.

Grant J, Parikh R, Bar-Ilan A. 2018. Future year 2028 emissions from oil and gas activity in the greater San Juan basin and Permian basin-draft report. RAMBOL.

Halliday HS, Thompson AM, Wisthaler A, Blake DR, Hornbrook RS, Mikoviny T, Müller M, Eichler P, Apel EC, Hills AJ. 2016. Atmospheric benzene observations from oil and gas production in the Denver-Julesburg Basin in July and August 2014. Journal of Geophysical Research: Atmospheres 121:11,055-011,074.

Katzenstein AS, Doezema LA, Simpson IJ, Blake DR, Rowland FS. 2003. Extensive regional atmospheric hydrocarbon pollution in the southwestern United States. Proc Natl Acad Sci U S A 100:11975–11979.

LaFranchi BW, Pétron G, Miller JB, Lehman SJ, Andrews AE, Dlugokencky EJ, Hall B, Miller BR, Montzka SA, Neff W, Novelli PC, Sweeney C, Turnbull JC, Wolfe DE, Tans PP, Gurney KR, Guilderson TP. 2013. Constraints on emissions of carbon monoxide, methane, and a suite of hydrocarbons in the Colorado Front Range using observations of 14CO2. Atmos Chem Phys 13:11101-11120.

Li R, Warneke C, Graus M, Field R, Geiger F, Veres PR, Soltis J, Li SM, Murphy SM, Sweeney C, Pétron G, Roberts JM, de Gouw J. 2014. Measurements of hydrogen sulfide (H₂S) using PTR-MS: calibration, humidity dependence, inter-comparison and results from field studies in an oil and gas production region. Atmos Meas Tech 7:3597-3610.

McKenzie LM, Witter RZ, Newman LS, Adgate JL. 2012. Human health risk assessment of air emissions from development of unconventional natural gas resources. Sci Total Environ 424:79–87.

McLeod JD, Brinkman GL, Milford JB. 2014. Emissions implications of future natural gas production and use in the U.S. and in the Rocky Mountain Region. Environ Sci Technol 48:13036–13044.

McMullin TS, Bamber AM, Bon D, Vigil DI, Van Dyke M. 2018. Exposures and Health Risks from Volatile Organic Compounds in Communities Located near Oil and Gas Exploration and Production Activities in Colorado (U.S.A.). International Journal of Environmental Research and Public Health 15.

McMullin T, Flores J, Bamber A, Bon D. 2017. Health Risk Evaluation from Inhalation of VOCs in Ambient Air Near Woolley-Sosa and Erie Champlin Oil and Gas Sites. Colorado Department of Public Health and Environment. Available from https://www.erieco.gov/DocumentCenter/View/9502.

Pétron G, Frost G, Miller BR, Hirsch AI, Montzka SA, Karion A, et al. 2012. Hydrocarbon emissions characterization in the Colorado Front Range: A pilot study. J Geophys Res 117; D04304, doi:101029/2011JD016360.

Pétron G, Karion A, Sweeney C, Miller BR, Montzka SA, Frost GJ, et al. 2014. A new look at methane and nonmethane hydrocarbon emissions from oil and natural gas operations in the Colorado Denver-Julesburg Basin. J Geophys Res Atmos 119:6836–6852.

Pfister G, Flocke F, Hornbrook R, Orlando J, Lee S, Schroeder J. 2017. Process-Based and Regional Source Impact Analysis for FRAPPÉ and DISCOVER-AQ 2014. RFP # FAAA 2016000120. National Center for Atmospheric Research. Boulder, CO. Available from https://www2.acom.ucar.edu/frappe.

Science CSUDoA. 2016. Characterizing Emissions from Natural Gas Drilling and Well Completion Operations in Garfield County, CO. Colorado State University Department of Atmospheric Science. Fort Collins, Co.

Swarthout RF, Russo RS, Zhou Y, Hart AH, Sive BC. 2013. Volatile organic compound distributions during the NACHTT campaign at the Boulder Atmospheric Observatory: Influence of urban and natural gas sources. Journal of Geophysical Research: Atmospheres 118:10,614-610,637.

Thompson CR, Hueber J, Helmig D. 2014. Influence of oil and gas emissions on ambient atmospheric non-methane hydrocarbons in residential areas of Northeastern Colorado. Elem Sci Anth 2:000035.

North Dakota

Brandt AR, Yeskoo T, McNally MS, Vafi K, Yeh S, Cai H, Wang MQ. 2016. Energy Intensity and Greenhouse Gas Emissions from Tight Oil Production in the Bakken Formation. Energy & Fuels 30:9613-9621.

Evanoski-Cole AR, Gebhart KA, Sive BC, Zhou Y, Capps SL, Day DE, Prenni AJ, Schurman MI, Sullivan AP, Li

Y, Hand JL, Schichtel BA, Collett JL. 2017. Composition and sources of winter haze in the Bakken oil and gas extraction region. Atmospheric Environment 156:77-87.

Gebhart KA, Day DE, Prenni AJ, Schichtel BA, Hand JL, Evanoski-Cole AR. 2018. Visibility impacts at Class I areas near the Bakken oil and gas development. Journal of the Air & Waste Management Association 68:477-493.

Gvakharia A, Kort EA, Brandt A, Peischl J, Ryerson TB, Schwarz JP, Smith ML, Sweeney C. 2017. Methane, Black Carbon, and Ethane Emissions from Natural Gas Flares in the Bakken Shale, North Dakota. Environmental science & technology 51:5317-5325.

Kort EA, Smith ML, Murray LT, Gvakharia A, Brandt AR, Peischl J, et al. 2016. Fugitive emissions from the Bakken shale illustrate role of shale production in global ethane shift. Geophys Res Lett 43:4617–4623.

Laurenzi IJ, Bergerson JA, Motazedi K. 2016. Life cycle greenhouse gas emissions and freshwater consumption associated with Bakken tight oil. Proceedings of the National Academy of Sciences 113:E7672-E7680.

Prenni AJ, Day DE, Evanoski-Cole AR, Sive BC, Hecobian A, Zhou Y, Gebhart KA, Hand JL, Sullivan AP, Li Y, Schurman MI, Desyaterik Y, Malm WC, Collett Jr JL, Schichtel BA. 2016. Oil and gas impacts on air quality in federal lands in the Bakken region: an overview of the Bakken Air Quality Study and first results. Atmos Chem Phys 16:1401–1416.

Rossabi S, Helmig D. 2018. Changes in Atmospheric Butanes and Pentanes and Their Isomeric Ratios in the Continental United States. J Geophys Res-Atmos 123:3772-3790.

Schwarz JP, Holloway JS, Katich JM, McKeen S, Kort EA, Smith ML, Ryerson TB, Sweeney C, Peischl J. 2015. Black Carbon Emissions from the Bakken Oil and Gas Development Region. Environmental Science & Technology Letters 2:281-285.

Weyant CL, Shepson PB, Subramanian R, Cambaliza MOL, Heimburger A, McCabe D, Baum E, Stirm BH, Bond TC. 2016. Black carbon emissions from associated natural gas flaring. Environ Sci Technol 50:2075–2081.

Texas

Allen DT, Cardoso-Saldaña FJ, Kimura Y. 2017. Variability in Spatially and Temporally Resolved Emissions and Hydrocarbon Source Fingerprints for Oil and Gas Sources in Shale Gas Production Regions. Environmental science & technology 51:12016-12026.

Bunch AG, Perry CS, Abraham L, Wikoff DS, Tachovsky JA, Hixon JG, et al. 2014. Evaluation of impact of shale gas operations in the Barnett Shale region on volatile organic compounds in air and potential human health risks. Sci Total Environ 468–469:832–842.

City of Fort Worth Texas. 2011. Air Quality Study. Available: http://fortworthtexas.gov/gaswells/default.aspx?id=79548.

Eastern Research Group, Sage Environmental Consulting. 2011. City of Fort Worth Natural Gas Air Quality Study. Fort Worth, TX Available: http://fortworthtexas.gov/gaswells/air-quality-study/final/.

Eapi GR, Sabnis MS, Sattler ML. 2014. Mobile measurement of methane and hydrogen sulfide at natural gas production site fence lines in the Texas Barnett Shale. J Air Waste Manage Assoc 64:927–944.

Ethridge S, Bredfeldt T, Sheedy K, Shirley S, Lopez G, Honeycutt M. 2015. The Barnett Shale: From problem formulation to risk management. Journal of Unconventional Oil and Gas Resources 11:95–110.

Hildenbrand ZL, Mach PM, McBride EM, Dorreyatim MN, Taylor JT, Carlton Jr DD, Meik JM, Fontenot BE, Wright KC, Schug KA, Verbeck GF. 2016. Point source attribution of ambient contamination events near unconventional oil and gas development. Science of The Total Environment 573:382-388.

Koss A, Yuan B, Warneke C, Gilman JB, Lerner BM, Veres PR, Peischl J, Eilerman S, Wild R, Brown SS,

Thompson CR, Ryerson T, Hanisco T, Wolfe GM, Clair JMS, Thayer M, Keutsch FN, Murphy S, de Gouw J. 2017. Observations of VOC emissions and photochemical products over US oil- and gas-producing regions using high-resolution H3O+ CIMS (PTR-ToF-MS). Atmospheric Measurement Techniques 10:2941-2968.

Lan X, Talbot R, Laine P, Torres A, Lefer B, Flynn J. 2015. Atmospheric Mercury in the Barnett Shale Area, Texas: Implications for Emissions from Oil and Gas Processing. Environmental science & technology 49:10692-10700.

Marrero JE, Townsend-Small A, Lyon DR, Tsai TR, Meinardi S, Blake DR. 2016. Estimating Emissions of Toxic Hydrocarbons from Natural Gas Production Sites in the Barnett Shale Region of Northern Texas. Environmental science & technology 50:10756-10764.

Pacsi AP, Alhajeri NS, Zavala-Araiza D, Webster MD, Allen DT. 2013. Regional Air Quality Impacts of Increased Natural Gas Production and Use in Texas. Environmental science & technology 47:3521-3527.

Rich AL, Orimoloye HT. 2016. Elevated atmospheric levels of benzene and benzene-related compounds from unconventional shale extraction and processing: human health concern for residential communities. Environ Health Insights 10:75–82.

Rich A, Grover JP, Sattler ML. 2014. An exploratory study of air emissions associated with shale gas development and production in the Barnett Shale. J Air Waste Manage Assoc 64:61–72.

Rutter AP, Griffin RJ, Cevik BK, Shakya KM, Gong L, Kim S, et al. 2015. Sources of air pollution in a region of oil and gas exploration downwind of a large city. Atmos Environ 120:89–99.

Schade GW, Roest G. 2018. Source apportionment of non-methane hydrocarbons, NO_x and H_2S data from a central monitoring station in the Eagle Ford shale, Texas. Elem Sci Anth 6.

Schade GW, Roest G. 2016. Analysis of non-methane hydrocarbon data from a monitoring station affected by oil and gas development in the Eagle Ford shale, Texas. Elementa (Wash D C) 4:000096.

Yeh S, Ghandi A, Scanlon BR, Brandt AR, Cai H, Wang MQ, Vafi K, Reedy RC. 2017. Energy Intensity and Greenhouse Gas Emissions from Oil Production in the Eagle Ford Shale. Energy & Fuels 31:1440-1449.

Zavala-Araiza D, Sullivan DW, Allen DT. 2014. Atmospheric Hydrocarbon Emissions and Concentrations in the Barnett Shale Natural Gas Production Region. Environmental science & technology 48:5314-5321.

Zielinska B, Fujita E, Campbell D. 2010. Monitoring of Emissions from Barnett Shale Natural Gas Production Facilities for Population Exposure Assessment – Draft. Reno, NV:Desert Research Institute.

Zielinska B, Campbell D, Samburova V. 2014. Impact of emissions from natural gas production facilities on ambient air quality in the Barnett Shale area: a pilot study. Journal of the Air & Waste Management Association (1995) 64:1369-1383.

Utah and Wyoming

Field RA, Soltis J, McCarthy MC, Murphy S, Montague DC. 2015. Influence of oil and gas field operations on spatial and temporal distributions of atmospheric non-methane hydrocarbons and their effect on ozone formation in winter. Atmos Chem Phys 15:3527–3542.

Helmig D, Thompson C, Evans J, Boylan P, Hueber J, Park J-H. 2014. Highly elevated atmospheric levels of volatile organic compounds in the Uintah Basin, Utah. Environ Sci Technol 48:4707–4715.

Mansfield ML, Tran HNQ, Lyman SN, Bowers RL, Smith AP, Keslar C. 2018. Emissions of organic compounds from produced water ponds III: Mass-transfer coefficients, composition-emission correlations, and contributions to regional emissions. Science of The Total Environment 627:860-868.

Meng Q. 2018. Rethink potential risks of toxic emissions from natural gas and oil mining. Environmental Pollution 240:848-857.

Warneke C, Geiger F, Edwards PM, Dube W, Pétron G, Kofler J, et al. 2014. Volatile organic compound emissions from the oil and natural gas industry in the Uintah Basin, Utah: oil and gas well pad emissions compared to ambient air composition. Atmos Chem Phys 14:10977–10988.

U.S. Multi-Regional or National Scale

Brantley HL, Thoma ED, Eisele AP. 2015. Assessment of volatile organic compound and hazardous air pollutant emissions from oil and natural gas well pads using mobile remote and on-site direct measurements. J Air Waste Manag Assoc 65:1072–1082.

Eisele AP, Mukerjee S, Smith LA, Thoma ED, Whitaker DA, Oliver KD, et al. 2016. Volatile organic compounds at two oil and natural gas production well pads in Colorado and Texas using passive samplers. J Air Waste Manag Assoc 66:412–419.

Fann N, Baker KR, Chan EAW, Eyth A, Macpherson A, Miller E, Snyder J. 2018. Assessing Human Health PM2.5 and Ozone Impacts from U.S. Oil and Natural Gas Sector Emissions in 2025. Environmental science & technology.

Franco B, Mahieu E, Emmons L, Tzompa-Sosa Z, Fischer E, Sudo K, et al. 2016. Evaluating ethane and methane emissions associated with the development of oil and natural gas extraction in North America. Environmental Research Letters 11.

Goodman PS, Galatioto F, Thorpe N, Namdeo AK, Davies RJ, Bird RN. 2016. Investigating the traffic-related environmental impacts of hydraulic-fracturing (fracking) operations. Environ Int 89–90:248–260.

Hendler A, Nunn J, Lundeen J, McKaskle R. 2006. VOC Emissions from Oil and Condensate Storage Tanks. Prepared for Houston Advanced Research Center. The Woodlands, TX:HARC.

Islam SMN, Jackson PL, Aherne J. 2016. Ambient nitrogen dioxide and sulfur dioxide concentrations over a region of natural gas production, Northeastern British Columbia, Canada. Atmospheric Environment 143:139-151.

Johnson D, Heltzel R, Nix A, Darzi M, Oliver D. 2018. Estimated Emissions from the Prime-Movers of Unconventional Natural Gas Well Development Using Recently Collected In-Use Data in the United States. Environmental Science & Technology.

Lyon DR, Alvarez RA, Zavala-Araiza D, Brandt AR, Jackson RB, Hamburg SP. 2016. Aerial surveys of elevated hydrocarbon emissions from oil and gas production sites. Environ Sci Technol 50:4877–4886.

Macey GP, Breech R, Chernaik M, Cox C, Larson D, Thomas D, et al. 2014. Air concentrations of volatile compounds near oil and gas production: a community-based exploratory study. Environmental Health 13:82.

Majid A, Martin MV, Lamsal LN, Duncan BN. 2017. A decade of changes in nitrogen oxides over regions of oil and natural gas activity in the United States. Elem Sci Anth 5.

McClellan RO, Snipes MB. 2010. Sublette County Air Toxics Inhalation: Screening Level Health Hazard Assessment –An Overview of Potential Results. Prepared for Shell Exploration and Production.

Peters TM, O'Shaughnessy PT, Grant R, Altmaier R, Swanton E, Falk J, Osterberg D, Parker E, Wyland NG, Sousan S, Stark AL, Thorne PS. 2017. Community airborne particulate matter from mining for sand used as hydraulic fracturing proppant. Sci Total Environ 609:1475-1482.

Shale Oil and Natural Gas Nexus (SONGNEX). 2015. Studying the Atmospheric Effects of Changing Energy Use in the U.S. at the Nexus of Air Quality and Climate Change. Washington, DC:National Oceanic and Atmospheric Administration. Available: http://esrl.noaa.gov/csd/projects/songnex/whitepaper.pdf.

Walter GR, Benke RR, Pickett DA. 2012. Effect of biogas generation on radon emissions from landfills receiving radium-bearing waste from shale gas development. J Air Waste Manag Assoc 62(9):1040–1049.

Yuan B, Kaser L, Karl T, Graus M, Peischl J, Campos TL, et al. 2015. Airborne flux measurements of methane and volatile organic compounds over the Haynesville and Marcellus shale gas production regions. J Geophys Res Atmos

120:6271–6289.

Huang Z, Kong S, Xing X, Mao Y, Hu T, Ding Y, et al. 2018. Monitoring of volatile organic compounds (vocs) from an oil and gas station in northwest china for 1 year. Atmospheric Chemistry and Physics 18:4567.

Canada

Bari MA, Kindzierski WB. 2018. Ambient volatile organic compounds (VOCs) in Calgary, Alberta: Sources and screening health risk assessment. Sci Total Environ 631-632:627-640.

International

Archibald AT, Ordóñez C, Brent E, Williams ML. 2018. Potential impacts of emissions associated with unconventional hydrocarbon extraction on UK air quality and human health. Air Quality, Atmosphere & Health 11:627-637.

Ezani E, Masey N, Gillespie J, Beattie TK, Shipton ZK, Beverland IJ. 2018. Measurement of diesel combustion-related air pollution downwind of an experimental unconventional natural gas operations site. Atmospheric Environment.

Huang K, Fu JS. 2016. A global gas flaring black carbon emission rate dataset from 1994 to 2012. Scientific Data 3:160104.

Reviews and General Resources

Allen DT, Smith D, Torres VM, Saldaña FC. 2016. Carbon dioxide, methane and black carbon emissions from upstream oil and gas flaring in the United States. Current Opinion in Chemical Engineering 13:119-123.

Allen DT. 2016. Emissions from oil and gas operations in the United States and their air quality implications. Journal of the Air & Waste Management Association 66:549-575.

Allen DT. 2014. Atmospheric emissions and air quality impacts from natural gas production and use. Annu Rev Chem Biomol Eng 5:55–75.

Bolden AL, Kwiatkowski CF, Colborn T. 2015. New look at BTEX: are ambient levels a problem? Environ Sci Technol 49:5261–5276.

Centner TJ. 2016. Reducing pollution at five critical points of shale gas production: Strategies and institutional responses. Energy Policy 94:40-46.

Elvidge CD, Bazilian MD, Zhizhin M, Ghosh T, Baugh K, Hsu F-C. 2018. The potential role of natural gas flaring in meeting greenhouse gas mitigation targets. Energy Strateg Rev 20:156-162.

Fawole OG, Cai XM, MacKenzie AR. 2016. Gas flaring and resultant air pollution: A review focusing on black carbon. Environ Pollut 216:182-197.

Field RA, Soltis J, Murphy S. 2014. Air quality concerns of unconventional oil and natural gas production. Environ Sci Process Impacts 16:954–969.

Fleischman L, Banks J, Graham J. 2016. Fossil Fumes: A public health analysis of toxic air pollution from the oil and gas industry. Boston, MA: Clean Air Task Force. Available from http://www.catf.us/resources/publications/files/FossilFumes.pdf.

Haut R, Williams T. 2015. White Paper: Recommendations to Address Flaring Issues, Solutions, and Technologies. Houston Advanced Research Center. Available: http://efdsystems.org/pdf/FIST_Whitepaper_May_2015_Updated_rev.pdf.

Helmig D, Rossabi S, Hueber J, Tans P, Montzka SA, Masarie K, Thoning K, Plass-Duelmer C, Claude A,

Carpenter LJ, Lewis AC, Punjabi S, Reimann S, Vollmer MK, Steinbrecher R, Hannigan JW, Emmons LK, Mahieu E, Franco B, Smale D, Pozzer A. 2016. Reversal of global atmospheric ethane and propane trends largely due to US oil and natural gas production. Nature Geosci 9:490-495.

Hendler A, Nunn J, Lundeen J, McKaskle R. 2006. VOC Emissions from Oil and Condensate Storage Tanks. Prepared for Houston Advanced Research Center. The Woodlands, TX:HARC.

Jackson RB, Vengosh A, Carey JW, Davies RJ, Darrah TH, O'Sullivan F, et al. 2014. The environmental costs and benefits of fracking. Annu Rev Environ Resour 39:327–362.

Lattanzio RK. 2016. An Overview of Air Quality Issues in Natural Gas Systems. Washington, DC: Congressional Research Service. Available from http://nationalaglawcenter.org/wp-content/uploads/assets/crs/R42986.pdf.

Long CM. 2016. Marcellus Shale Development: Analysis of Air Quality Data and Public Health Studies. Gradient. Cambridge, MA.

Macey GP, Breech R, Chernaik M, Cox C, Larson D, Thomas D, et al. 2014. Air concentrations of volatile compounds near oil and gas production: a community-based exploratory study. Environmental Health 13:82.

McCawley, M. A. (2017). "Does increased traffic flow around unconventional resource development activities represent the major respiratory hazard to neighboring communities?: knowns and unknowns." Current Opinion in Pulmonary Medicine 23(2): 161-166.

Moore CW, Zielinska B, Pétron G, Jackson RB. 2014. Air impacts of increased natural gas acquisition, processing, and use: a critical review. Environ Sci Technol 48:8349–8359.

Petron G. 2014. Air Pollution Issues Associated with Shale Gas Production. The Bridge: Linking Engineering and Science 44:19–27.

Pirzadeh P, Lesage KL, Marriott RA. 2014. Hydraulic fracturing additives and the delayed onset of hydrogen sulfide in shale gas. Energy Fuels 28:4993–5001.

Robinson AL. 2013. Air Pollution Emissions from Shale Gas Development and Production. In: Health Impact Assessment of Shale Gas Extraction: Workshop Summary. Washington, DC:The National Academies Press.

Sommariva R, Blake RS, Cuss RJ, Cordell RL, Harrington JF, White IR, et al. 2014. Observations of the release of non-methane hydrocarbons from fractured shale. Environ Sci Technol 48:8891–8896.

Srebotnjak T, Rotkin-Ellman M. 2014. Fracking Fumes: Air Pollution from Hydraulic Fracturing Threatens Public Health and Communities. Washington, DC:Natural Resources Defense Council.

Umukoro GE, Ismail OS. 2017. Modelling emissions from natural gas flaring. Journal of King Saud University - Engineering Sciences 29:178-182.

Zavala-Araiza D, Alvarez RA, Lyon DR, Allen DT, Marchese AJ, Zimmerle DJ, Hamburg SP. 2017. Super-emitters in natural gas infrastructure are caused by abnormal process conditions. Nature Communications 8:10.

WATER QUALITY AND USE

Surface Water Quality Baseline Measurements

Betanzo EA, Hagen ER, Wilson JT, Reckhow KH, Hayes L, Argue DM, et al. 2016. Water data to answer urgent water policy questions: Monitoring design, available data and filling data gaps for determining whether shale gas development activities contaminate surface water or groundwater in the Susquehanna River Basin. Washington, DC:Northeast-Midwest Institute.

Bowen ZH, Oelsner GP, Cade BS, Gallegos TJ, Farag AM, Mott DN, et al. 2015. Assessment of surface water chloride and conductivity trends in areas of unconventional oil and gas development—why existing national data

sets cannot tell us what we would like to know. Water Resour Res 51:704–715.

Chambers DB, Kozar MD, Messinger T, Mulder ML, Pelak AJ, White JS. 2015. Water Quality of Groundwater and Stream Base Flow in the Marcellus Shale Gas Field of the Monongahela River Basin, West Virginia, 2011–12. Scientific Investigations Report 2014-5233. Reston, VA:Survey USG. Available: http://pubs.er.usgs.gov/publication/sir20145233.

Low DJ, Brightbill RA, Eggleston HL, Chaplin JJ. 2016. Physical, chemical, and biological characteristics of selected headwater streams along the Allegheny Front, Blair County, Pennsylvania, July 2011–September 2013. 2015-1173. Reston, VA: Survey USG. Available from http://pubs.er.usgs.gov/publication/ofr20151173.

Surface Water Quality Monitoring and/or Modeling

Akob DM, Mumford AC, Orem WH, Engle MA, Klinges JG, Kent DB, Cozzarelli IM. 2016. Wastewater disposal from unconventional oil and gas development degrades stream quality at a West Virginia injection facility. Environ Sci Technol; doi: 101021/acsest6b00428.

Austin BJ, Scott E, Massey L, Evans-White MA, Entrekin S, Haggard BE. 2017. Unconventional natural gas development did not result in detectable changes in water chemistry (within the South Fork Little Red River). Environmental Monitoring and Assessment 189:14.

Bowen ZH, Oelsner GP, Cade BS, Gallegos TJ, Farag AM, Mott DN, et al. 2015. Assessment of surface water chloride and conductivity trends in areas of unconventional oil and gas development—why existing national data sets cannot tell us what we would like to know. Water Resour Res 51:704–715.

Burton GA, Basu N, Ellis BR, Kapo KE, Entrekin S, Nadelhoffer K. 2014. Hydraulic "fracking": are surface water impacts an ecological concern? Environ Toxicol Chem 33:1679–1689.

Chambers DB, Kozar MD, Messinger T, Mulder ML, Pelak AJ, White JS. 2015. Water Quality of Groundwater and Stream Base Flow in the Marcellus Shale Gas Field of the Monongahela River Basin, West Virginia, 2011–12. Scientific Investigations Report 2014-5233. Reston, VA:Survey USG. Available: http://pubs.er.usgs.gov/publication/sir20145233.

Entrekin SA, Maloney KO, Kapo KE, Walters AW, Evans-White MA, Klemow KM. 2015. Stream vulnerability to widespread and emergent stressors: a focus on unconventional oil and gas. PLoS ONE 10:e0137416.

Entrekin S, Evans-White M, Johnson B, Hagenbuch E. 2011. Rapid expansion of natural gas development poses a threat to surface waters. Front Ecol Environ 9:503–511.

Evans JS, Kiesecker JM. 2014. Shale gas, wind and water: Assessing the potential cumulative impacts of energy development on ecosystem services within the Marcellus play. PLoS One 9:e89210.

Farag AM, Harper DD. 2014. A review of environmental impacts of salts from produced waters on aquatic resources. Int J Coal Geol 126:157–161.

Ferrar KJ, Michanowicz DR, Christen CL, Mulcahy N, Malone SL, Sharma RK. 2013. Assessment of effluent contaminants from three facilities discharging Marcellus shale wastewater to surface waters in Pennsylvania. Environ Sci Technol 47:3472–3481.

Grieve PL, Hynek SA, Heilweil V, Sowers T, Llewellyn G, Yoxtheimer D, Solomon DK, Brantley SL. 2018. Using environmental tracers and modelling to identify natural and gas well-induced emissions of methane into streams. Applied Geochemistry 91:107-121.

Hayes T. 2009. Sampling and Analysis of Water Streams Associated with the Development of Marcellus Shale Gas. Des Plains, IL:Gas Technology Institute. Available: http://energyindepth.org/wp-content/uploads/marcellus/2012/11/MSCommission-Report.pdf.

Heilweil VM, Stolp BJ, Kimball BA, Susong DD, Marston TM, Gardner PM. 2013. A stream-based methane monitoring approach for evaluating groundwater impacts associated with unconventional gas development. Ground

Water 51:511–524.

Heilweil VM, Grieve PL, Hynek SA, Brantley SL, Salomon DK, Risser DW. 2015. Stream measurements locate thermogenic methane fluxes in groundwater discharge in an area of shale-gas development. Environ Sci Technol 49:4057–4065.

Hladik ML, Focazio MJ, Engle M. 2014. Discharges of produced waters from oil and gas extraction via wastewater treatment plants are sources of disinfection by-products to receiving streams. Sci Total Environ 466:1085–1093.

Hopkinson L, Mack B, Streets DA. 2016. Initial study of potential surface water quality impacts of horizontal drilling in the Marcellus shale. Energy Sources Part A - Recovery Utilization and Environmental Effects 38:652-660.

Kassotis CD, Iwanowicz LR, Akob DM, Cozzarelli IM, Mumford AC, Orem WH, Nagel SC. 2016. Endocrine disrupting activities of surface water associated with a West Virginia oil and gas industry wastewater disposal site. Sci Total Environ 557–558:901–910.

Landis MS, Kamal AS, Kovalcik KD, Croghan C, Norris GA, Bergdale A. 2016. The impact of commercially treated oil and gas produced water discharges on bromide concentrations and modeled brominated trihalomethane disinfection byproducts at two downstream municipal drinking water plants in the upper Allegheny River, Pennsylvania, USA. Sci Total Environ 542:505–520.

Low DJ, Brightbill RA, Eggleston HL, Chaplin JJ. 2016. Physical, chemical, and biological characteristics of selected headwater streams along the Allegheny Front, Blair County, Pennsylvania, July 2011–September 2013. 2015-1173. Reston, VA: Survey USG. Available from http://pubs.er.usgs.gov/publication/ofr20151173.

Maloney KO, Young JA, Faulkner SP, Hailegiorgis A, Slonecker ET, Milheim LE. 2017. A detailed risk assessment of shale gas development on headwater streams in the Pennsylvania portion of the Upper Susquehanna River Basin, U.S.A. Sci Total Environ 610-611:154-166.

McBroom M, Thomas T, Zhang Y. 2012. Soil erosion and surface water quality impacts of natural gas development in East Texas, USA. Water 4:944–958.

Medina VF, Suedel B. 2015. Evaluation of Hydraulic Fracturing (Fracking) Plays for Potential Impact on USACE-Managed Waterways. ERDC TN-DOTS-15-1. Vicksburg, MS:U.S. Army Engineer Research and Development Center. Available: http://www.dtic.mil/get-tr-doc/pdf?AD=ADA613061.

Meszaros N, Subedi B, Stamets T, Shifa N. 2017. Assessment of Surface Water Contamination from Coalbed Methane Fracturing-Derived Volatile Contaminants in Sullivan County, Indiana, USA. Bulletin of Environmental Contamination and Toxicology.

Mrdjen I, Lee J. 2015. High volume hydraulic fracturing operations: potential impacts on surface water and human health. Int J Environ Health Res:1–23.

Niu X, Wendt A, Li Z, Agarwal A, Xue L, Gonzales M, et al. 2018. Detecting the effects of coal mining, acid rain, and natural gas extraction in Appalachian basin streams in Pennsylvania (USA) through analysis of barium and sulfate concentrations. Environ Geochem Health 40:865-885.

Olmstead SM, Muehlenbachs LA, Shih J-S, Chu Z, Krupnick AJ. 2013. Shale gas development impacts on surface water quality in Pennsylvania. Proc Natl Acad Sci U S A 110:4962–4967.

Orem W, Varonka M, Crosby L, Haase K, Loftin K, Hladik M, Akob DM, Tatu C, Mumford A, Jaeschke J, Bates A, Schell T, Cozzarelli I. 2017. Organic geochemistry and toxicology of a stream impacted by unconventional oil and gas wastewater disposal operations. Applied Geochemistry 80:155-167.

Parker KM, Zeng T, Harkness J, Vengosh A, Mitch WA. 2014. Enhanced formation of disinfection byproducts in shale gas wastewater-impacted drinking water supplies. Environ Sci Technol 48:11161–11169.

Pelak AJ, Sharma S. 2014. Surface water geochemical and isotopic variations in an area of accelerating Marcellus

Shale gas development. Environ Pollut 195:91–100.

Penningroth SM, Yarrow MM, Figueroa AX, Bowen RJ, Delgado S. 2013. Community-based risk assessment of water contamination from high-volume horizontal hydraulic fracturing. New Solut 23:137–166.

Preston TM, Chesley-Preston TL. 2015. Risk assessment of brine contamination to aquatic resources from energy development in glacial drift deposits: Williston Basin, USA. Sci Total Environ 508:534–545.

Preston TM, Chesley-Preston TL, Thamke JN. 2014. A GIS-based vulnerability assessment of brine contamination to aquatic resources from oil and gas development in eastern Sheridan County, Montana. Sci Total Environ 472:1152–1162.

Shores A, Laituri M, Butters G. 2017. Produced water surface spills and the risk for btex and naphthalene groundwater contamination. Water, Air, & Soil Pollution 228:435.

Tasker TL, Burgos WD, Piotrowski P, Castillo-Meza L, Blewett TA, Ganow KB, Stallworth A, Delompré PLM, Goss GG, Fowler LB, Vanden Heuvel JP, Dorman F, Warner NR. 2018. Environmental and Human Health Impacts of Spreading Oil and Gas Wastewater on Roads. Environmental science & technology.

Torres L, Yadav OP, Khan E. 2017. Holistic risk assessment of surface water contamination due to Pb-210 in oil produced water from the Bakken Shale. Chemosphere 169:627-635.

Truter JC, van Wyk JH, Oberholster PJ, Botha AM, Mokwena LM. 2017. An Evaluation of the Endocrine Disruptive Potential of Cruide Oil Water Accommodated Fractions and Crude Oil Contaminated Surface Water to Freshwater Organisms Using In Vitro and In Vivo Approaches. Environmental Toxicology and Chemistry 36:1330-1342.

U.S. Environmental Protection Agency. 2016. Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States. Office of Research and Development. Washington, DC. Available from https://cfpub.epa.gov/ncea/hfstudy/recordisplay.cfm?deid=332990.

U.S. Environmental Protection Agency. 2015. Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources: External Review Draft. EPA/600/R-15/047a. Washington, DC:U.S. EPA.

Warner NR, Christie CA, Jackson RB, Vengosh A. 2013. Impacts of shale gas wastewater disposal on water quality in western Pennsylvania. Environ Sci Technol 47:11849–11857.

Williams H, Havens D, Banks K, Wachal D. 2008. Field-based monitoring of sediment runoff from natural gas well sites in Denton County, Texas, USA. Environmental Geology 55:1463–1471.

Ziemkiewicz P, Donovan J, Hause J, Gutta B, Fillhart J, Mack B, et al. 2013. Water Quality Literature Review and Field Monitoring of Active Shale Gas Wells, Phase II. Morgantown, WV:West Virginia Water Research Institute, West Virginia University.

Ziemkiewicz P, Hause J, Gutta B, Fillhart J, Mack B, O'Neal M. 2013. Water Quality Literature Review and Field Monitoring of Active Shale Gas Wells, Phase I. Morgantown, WV:West Virginia Water Research Institute, West Virginia University.

Drinking Water Quality (sourced from groundwater or surface water)

Jasechko S, Perrone D. 2017. Hydraulic fracturing near domestic groundwater wells. Proc Natl Acad Sci U S A 114:13138-13143.

U.S. Environmental Protection Agency. 2016. Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States. Office of Research and Development. Washington, DC. Available from https://cfpub.epa.gov/ncea/hfstudy/recordisplay.cfm?deid=332990.

U.S. Environmental Protection Agency. 2015. Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources: External Review Draft. EPA/600/R-15/047a. Washington, DC:U.S. EPA.

Arkansas

McMahon PB, Barlow JRB, Engle MA, Belitz K, Ging PB, Hunt AG, Jurgens BC, Kharaka YK, Tollett RW, Kresse TM. 2017. Methane and Benzene in Drinking-Water Wells Overlying the Eagle Ford, Fayetteville, and Haynesville Shale Hydrocarbon Production Areas. Environmental science & technology 51:6727-6734.

Warner NR, Kresse TM, Hays PD, Down A, Karr JD, Jackson RB, et al. 2013. Geochemical and isotopic variations in shallow groundwater in areas of the Fayetteville Shale development, north-central Arkansas. Appl Geochem 35:207–220.

Appalachia

Alawattegama SK, Kondratyuk T, Krynock R, Bricker M, Rutter JK, Bain DJ, et al. 2015. Well water contamination in a rural community in southwestern Pennsylvania near unconventional shale gas extraction. J Environ Sci Health A Tox Hazard Subst Environ Eng 50:516–528.

Betanzo EA, Hagen ER, Wilson JT, Reckhow KH, Hayes L, Argue DM, et al. 2016. Water data to answer urgent water policy questions: Monitoring design, available data and filling data gaps for determining whether shale gas development activities contaminate surface water or groundwater in the Susquehanna River Basin. Washington, DC:Northeast-Midwest Institute.

Bowman L, Sharma S, Carr T, Sharma M. 2014. Understanding stray gas occurrences in shallow aquifers in Randolph County, West Virginia, USA. Presented at SE Geological Society of America Meeting, April 10–11, Blacksburg, VA:Geological Society of America.

Boyer EW, Swistock BR, Clark J, Madden M, Rizzo DE. 2012. The Impact of Marcellus Gas Drilling on Rural Drinking Water Supplies. Harrisburg, PA:Center for Rural Pennsylvania.

Brantley SL. 2015. Drinking water while fracking: now and in the future. Ground water 53:21-23.

Chambers DB, Kozar MD, Messinger T, Mulder ML, Pelak AJ, White JS. 2015. Water Quality of Groundwater and Stream Base Flow in the Marcellus Shale Gas Field of the Monongahela River Basin, West Virginia, 2011–12. Scientific Investigations Report 2014-5233. Reston, VA:Survey USG. Available: http://pubs.er.usgs.gov/publication/sir20145233.

Darrah TH, Jackson RB, Vengosh A, Warner NR, Whyte CJ, Walsh TB, et al. 2015. The evolution of Devonian hydrocarbon gases in shallow aquifers of the northern Appalachian Basin: insights from integrating noble gas and hydrocarbon geochemistry. Geochim Cosmochim Acta 170:321–355.

Darrah TH, Vengosh A, Jackson RB, Warner NR, Poreda RJ. 2014. Noble gases identify the mechanisms of fugitive gas contamination in drinking-water wells overlying the Marcellus and Barnett Shales. Proc Natl Acad Sci U S A 111:14076–14081.

Davies RJ. 2011. Methane contamination of drinking water caused by hydraulic fracturing remains unproven. Proc Natl Acad Sci U S A 108:E871–E871.

Drollette BD, Hoelzer K, Warner NR, Darrah TH, Karatum O, O'Connor MP, et al. 2015. Elevated levels of diesel range organic compounds in groundwater near Marcellus gas operations are derived from surface activities. Proc Natl Acad Sci U S A; doi: 101073/pnas1511474112 [Online 12 Oct 2015].

Hammond PA. 2015. The relationship between methane migration and shale-gas well operations near Dimock, Pennsylvania, USA. Hydrogeol J:1–17.

Heilweil VM, Risser DW, Conger RW, Grieve PL, Hynek SA. 2014. Estimation of methane concentrations and loads in groundwater discharge to Sugar Run, Lycoming County, Pennsylvania. 2014-1126. Survey USG, Reston, VA. Available from http://pubs.er.usgs.gov/publication/ofr20141126.

Hill E, Ma LL. 2017. Shale Gas Development and Drinking Water Quality. American Economic Review 107:522-525.

Jackson RB, Osborn SG, Vengosh A, Warner NR. 2011. Reply to Davies: Hydraulic fracturing remains a possible mechanism for observed methane contamination of drinking water. Proc Natl Acad Sci U S A 108:E872–E872.

Jackson RB, Vengosh A, Darrah TH, Warner NR, Down A, Poreda RJ, et al. 2013. Increased stray gas abundance in a subset of drinking water wells near Marcellus shale gas extraction. Proc Natl Acad Sci U S A 110:11250–11255.

Kassotis CD, Iwanowicz LR, Akob DM, Cozzarelli IM, Mumford AC, Orem WH, Nagel SC. 2016. Endocrine disrupting activities of surface water associated with a West Virginia oil and gas industry wastewater disposal site. Sci Total Environ 557–558:901–910.

Kreuzer RL, Darrah TH, Grove BS, Moore MT, Warner NR, Eymold WK, et al. 2018. Structural and hydrogeological controls on hydrocarbon and brine migration into drinking water aquifers in southern new york. Groundwater 56:225-244.

Lautz LK, Hoke GD, Lu Z, Siegel DI, Christian K, Kessler JD, et al. 2014. Using discriminant analysis to determine sources of salinity in shallow groundwater prior to hydraulic fracturing. Environ Sci Technol 48:9061–9069.

LeDoux STM, Szynkiewicz A, Faiia AM, Mayes MA, McKinney ML, Dean WG. 2016. Chemical and isotope compositions of shallow groundwater in areas impacted by hydraulic fracturing and surface mining in the Central Appalachian Basin, Eastern United States. Appl Geochem; doi: 101016/japgeochem201605007.

Llewellyn GT, Dorman F, Westland JL, Yoxtheimer D, Grieve P, Sowers T, et al. 2015. Evaluating a groundwater supply contamination incident attributed to Marcellus Shale gas development. Proc Natl Acad Sci U S A 112:6325–6330.

Molofsky LJ, Richardson SD, Gorody AW, Baldassare F, Black JA, McHugh TE, Connor JA. 2016. Effect of different sampling methodologies on measured methane concentrations in groundwater samples. Groundwater; doi: 101111/gwat12415.

Molofsky LJ, Connor JA, McHugh TE, Richardson SD, Woroszlyo C, Alvarez PJ. 2016. Environmental factors associated with natural methane occurrence in the Appalachian Basin. Groundwater; doi: 101111/gwat12401.

Molofsky LJ, Connor JA, Wylie AS, Wagner T, Farhat SK. 2013. Evaluation of methane sources in groundwater in Northeastern Pennsylvania. Ground Water 51:333–349.

Molofsky LJ, Connor JA, Farhat SK, Wylie AS, Jr., Wagner T. 2011. Methane in Pennsylvania water wells unrelated to Marcellus shale fracturing. 109:54-56,58-60,62-67,93.PennWell Corporation, Tulsa.

Osborn SG, Vengosh A, Warner NR, Jackson RB. 2011. Methane contamination of drinking water accompanying gas-well drilling and hydraulic fracturing. Proc Natl Acad Sci U S A 108:8172–8176.

Osborn SG, Vengosh A, Warner NR, Jackson RB. 2011. Reply to Saba and Orzechowski and Schon: Methane contamination of drinking water accompanying gas-well drilling and hydraulic fracturing. Proc Natl Acad Sci U S A 108:E665–E666.

Parker KM, Zeng T, Harkness J, Vengosh A, Mitch WA. 2014. Enhanced formation of disinfection byproducts in shale gas wastewater-impacted drinking water supplies. Environ Sci Technol 48:11161–11169.

Reilly D, Singer D, Jefferson A, Eckstein Y. 2015. Identification of local groundwater pollution in northeastern Pennsylvania: Marcellus flowback or not? Environ Earth Sci 73:8097–8109.

Saba T, Orzechowski M. 2011. Lack of data to support a relationship between methane contamination of drinking water wells and hydraulic fracturing. Proc Natl Acad Sci U S A 108:E663

Siegel DI, Azzolina NA, Smith BJ, Perry AE, Bothun RL. 2015. Methane concentrations in water wells unrelated to proximity to existing oil and gas wells in northeastern Pennsylvania. Environ Sci Technol 49:4106–4112.

States S, Cyprych G, Stoner M, Wydra F, Kuchta J, Monnell J, et al. 2013. Marcellus Shale drilling and brominated THMs in Pittsburgh, Pa., drinking water. J Am Water Works Assoc 105:53–54.

Warner NR, Jackson RB, Darrah TH, Osborn SG, Down A, Zhao K, et al. 2012. Geochemical evidence for possible natural migration of Marcellus Formation brine to shallow aquifers in Pennsylvania. Proc Natl Acad Sci U S A 109:11961–11966.

Weaver J, Xu J, Mravik S. 2015. Scenario analysis of the impact on drinking water intakes from bromide in the discharge of treated oil and gas wastewater. J Environ Eng:04015050.

Wen T, Niu X, Gonzales M, Zheng G, Li Z, Brantley SL. 2018. Big Groundwater Data Sets Reveal Possible Rare Contamination Amid Otherwise Improved Water Quality for Some Analytes in a Region of Marcellus Shale Development. Environmental science & technology 52:7149-7159.

Wilson J, Wang Y, VanBriesen J. 2014. Sources of high total dissolved solids to drinking water supply in Southwestern Pennsylvania. J Environ Eng 140:B4014003.

Wilson JM, VanBriesen JM. 2012. Oil and gas produced water management and surface drinking water sources in Pennsylvania. Environ Pract 14:288–300.

Ziemkiewicz P, Donovan J, Hause J, Gutta B, Fillhart J, Mack B, et al. 2013. Water Quality Literature Review and Field Monitoring of Active Shale Gas Wells, Phase II. Morgantown, WV:West Virginia Water Research Institute, West Virginia University.

Ziemkiewicz P, Hause J, Gutta B, Fillhart J, Mack B, O'Neal M. 2013. Water Quality Literature Review and Field Monitoring of Active Shale Gas Wells, Phase I. Morgantown, WV:West Virginia Water Research Institute, West Virginia University.

Colorado

Li H, Son J-H, Carlson KH. 2016. Concurrence of aqueous and gas phase contamination of groundwater in the Wattenberg oil and gas field of northern Colorado. Water Res 88:458–466.

Li H, Carlson KH. 2014. Distribution and origin of groundwater methane in the Wattenberg oil and gas field of Northern Colorado. Environ Sci Technol 48:1484–1491.

Nelson AW, Knight AW, Eitrheim ES, Schultz MK. 2015. Monitoring radionuclides in subsurface drinking water sources near unconventional drilling operations: a pilot study. J Environ Radioact 142:24–28.

Tasker TL, Burgos WD, Piotrowski P, Castillo-Meza L, Blewett TA, Ganow KB, Stallworth A, Delompré PLM, Goss GG, Fowler LB, Vanden Heuvel JP, Dorman F, Warner NR. 2018. Environmental and Human Health Impacts of Spreading Oil and Gas Wastewater on Roads. Environmental science & technology.

Texas

Burton TG, Rifai HS, Hildenbrand ZL, Carlton Jr DD, Fontenot BE, Schug KA. 2016. Elucidating hydraulic fracturing impacts on groundwater quality using a regional geospatial statistical modeling approach. Sci Total Environ 545–546:114–126.

Committee TGP. 2016. Joint Groundwater Monitoring and Contamination Report - 2015. Quality TCoE. Available from https://www.tceq.texas.gov/assets/public/comm_exec/pubs/sfr/056-15.pdf.

Darrah TH, Vengosh A, Jackson RB, Warner NR, Poreda RJ. 2014. Noble gases identify the mechanisms of fugitive gas contamination in drinking-water wells overlying the Marcellus and Barnett Shales. Proc Natl Acad Sci U S A 111:14076–14081.

Fontenot BE, Hunt LR, Hildenbrand ZL, Carlton Jr DD, Oka H, Walton JL, Hopkins D, Osorio A, Bjorndal B, Hu QH, Schug KA. 2013. An Evaluation of Water Quality in Private Drinking Water Wells Near Natural Gas Extraction Sites in the Barnett Shale Formation. Environmental science & technology 47:10032-10040.

Hildenbrand ZL, Carlton Jr DD, Fontenot BE, Meik JM, Walton JL, Thacker JB, et al. 2016. Temporal variation in groundwater quality in the Permian Basin of Texas, a region of increasing unconventional oil and gas development.

Sci Total Environ 562:906–913.

McMahon PB, Barlow JRB, Engle MA, Belitz K, Ging PB, Hunt AG, Jurgens BC, Kharaka YK, Tollett RW, Kresse TM. 2017. Methane and Benzene in Drinking-Water Wells Overlying the Eagle Ford, Fayetteville, and Haynesville Shale Hydrocarbon Production Areas. Environmental science & technology 51:6727-6734.

Wyoming

DiGiulio DC, Jackson RB. 2016. Impact to underground sources of drinking water and domestic wells from production well stimulation and completion practices in the Pavillion, Wyoming, field. Environ Sci Technol 50:4524–4536.

Ling M, Heglie J. 2016. Pavillion, Wyoming Area Domestic Water Wells Final Report and Palatability Study. Acton Mickelson Environmental Inc. Wyoming Department of Environmental Quality. Quality WDoE. Available from http://deq.wyoming.gov/wqd/pavillion-investigation/resources/investigation-final-report/.

Ground Water Quality Baseline Measurements

Allaire M, Wu H, Upmanu L. 2018. National trends in drinking water quality violations. PNAS 115:2078-2083.

Baldassare FJ, McCaffrey MA, Harper JA. 2014. A geochemical context for stray gas investigations in the northern Appalachian Basin: Implications of analyses of natural gases from Neogene-through Devonian-age strata. AAPG Bulletin 98(2):341–372.

Betanzo EA, Hagen ER, Wilson JT, Reckhow KH, Hayes L, Argue DM, et al. 2016. Water data to answer urgent water policy questions: Monitoring design, available data and filling data gaps for determining whether shale gas development activities contaminate surface water or groundwater in the Susquehanna River Basin. Washington, DC:Northeast-Midwest Institute.

Chapman MJ, Gurley LN, Fitzgerald SA. 2014. Baseline Well Inventory and Groundwater-Quality Data from a Potential Shale Gas Resource Area in Parts of Lee and Chatham Counties, North Carolina, October 2011–August 2012. U.S. Geological Survey. Survey USG, Reston, VA. Available from http://pubs.usgs.gov/ds/0861/.

Christian KM, Lautz LK, Hoke GD, Siegel DI, Lu Z, Kessler J. 2016. Methane occurrence is associated with sodium-rich valley waters in domestic wells overlying the Marcellus shale in New York State. Water Resour Res 52:206–226.

Down A, Schreglmann K, Plata D, Elsner M, Warner N, Vengosh A, et al. 2015. Pre-drilling background groundwater quality in the Deep River Triassic Basin of central North Carolina, USA. Appl Geochem 60:3–13.

Eymold WK, Swana K, Moore MT, Whyte CJ, Harkness JS, Talma S, et al. 2018. Hydrocarbon-rich groundwater above shale-gas formations: A karoo basin case study. Groundwater:n/a-n/a.

Hildenbrand ZL, Carlton DD, Fontenot BE, Meik JM, Walton JL, Taylor JT, et al. 2015. A comprehensive analysis of groundwater quality in the Barnett shale region. Environ Sci Technol 49:8254–8262.

Huang TM, Pang ZH, Tian J, Li YN, Yang S, Luo L. 2017. Methane content and isotopic composition of shallow groundwater: implications for environmental monitoring related to shale gas exploitation. Journal of Radioanalytical and Nuclear Chemistry 312:577-585.

Huang TM, Li YM, Pang ZH, Wang YC, Yang S. 2017. Groundwater baseline water quality in a shale gas exploration site and fracturing fluid - shale rock interaction. In: 15th Water-Rock Interaction International Symposium, Wri-15. (Marques JM, Chambel A, eds.), pp. 638-641. Elsevier Science Bv, Amsterdam.

Kang M, Jackson RB. 2016. Salinity of deep groundwater in California: Water quantity, quality, and protection. Proc Natl Acad Sci U S A; doi: doi: 101073/pnas1600400113.

Lautz LK, Hoke GD, Lu Z, Siegel DI, Christian K, Kessler JD, et al. 2014. Using discriminant analysis to determine sources of salinity in shallow groundwater prior to hydraulic fracturing. Environ Sci Technol 48:9061–9069.

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Law RK, Murphy MW, Choudhary E. 2017. Private well groundwater quality in West Virginia, USA-2010. Science of the Total Environment 586:559-565.

Molofsky LJ, Connor JA, McHugh TE, Richardson SD, Woroszlyo C, Alvarez PJ. 2016. Environmental factors associated with natural methane occurrence in the Appalachian Basin. Groundwater; doi: 101111/gwat12401.

Moortgat J, Schwartz FW, Darrah TH. 2018. Numerical modeling of methane leakage from a faulty natural gas well into fractured tight formations. Groundwater:n/a-n/a.

Moritz A, Helie J-F, Pinti D, Larocque M, Barnatche D, Retailleau S, et al. 2015. Methane baseline concentrations and sources in shallow aquifers from the shale gas-prone region of the St. Lawrence Lowlands (Quebec, Canada). Environ Sci Technol 49:4765–4771.

Reagan MT, Moridis GJ, Keen ND, Johnson JN. 2015. Numerical simulation of the environmental impact of hydraulic fracturing of tight/shale gas reservoirs on near-surface groundwater: Background, base cases, shallow reservoirs, short-term gas, and water transport. Water Resour Res 51:2543–2573.

Rhodes AL, Horton NJ. 2015. Establishing baseline water quality for household wells within the Marcellus Shale gas region, Susquehanna County, Pennsylvania, U.S.A. Appl Geochem 60:14–28.

Senior LA, Cravotta IIICA, Sloto RA. 2016. Baseline assessment of groundwater quality in Wayne County, Pennsylvania, 2014. 2016-5073. Survey USG, Reston, VA. Available from http://pubs.er.usgs.gov/publication/sir20165073.

Siegel DI, Smith B, Perry E, Bothun R, Hollingsworth M. 2015. Pre-drilling water-quality data of groundwater prior to shale gas drilling in the Appalachian Basin: analysis of the Chesapeake Energy Corporation dataset. Appl Geochem 63:37–57.

U.S. Environmental Protection Agency. 2016. Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States. Office of Research and Development. Washington, DC. Available from https://cfpub.epa.gov/ncea/hfstudy/recordisplay.cfm?deid=332990.

U.S. Environmental Protection Agency. 2015. Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources: External Review Draft. EPA/600/R-15/047a. Washington, DC:U.S. EPA.

ED_002185_00000045-00042

Ground Water Quality Modeling and/or Monitoring

Appalachia

Baldassare FJ, McCaffrey MA, Harper JA. 2014. A geochemical context for stray gas investigations in the northern Appalachian Basin: Implications of analyses of natural gases from Neogene-through Devonian-age strata. AAPG Bulletin 98(2):341–372.

Barth-Naftilan E, Sohng J, Saiers JE. 2018. Methane in groundwater before, during, and after hydraulic fracturing of the Marcellus Shale. Proceedings of the National Academy of Sciences.

Betanzo EA, Hagen ER, Wilson JT, Reckhow KH, Hayes L, Argue DM, et al. 2016. Water data to answer urgent water policy questions: Monitoring design, available data and filling data gaps for determining whether shale gas development activities contaminate surface water or groundwater in the Susquehanna River Basin. Washington, DC:Northeast-Midwest Institute.

Birdsell DT, Rajaram H, Dempsey D, Viswanathan H. 2015. Hydraulic fracturing fluid migration in the subsurface: a review and modeling results. Water Resour Res; doi: 101002/2015WR017810 [Online 30 July 2015].

Botner CE, Townsend-Small A, Nash DB, Xu X, Schimmelmann A, Miller JH. 2018. Monitoring concentration and isotopic composition of methane in groundwater in the Utica Shale hydraulic fracturing region of Ohio. Environmental Monitoring and Assessment 190:322.

Bowman L, Sharma S, Shackleton R, Carr T, Sharma M. 2014. Stray gas occurrences unrelated to shale gas development: an example from Randolph County, West Virginia. Presented at Mid-Atlantic Regional Water Conference, 24–25, Shepardstown, WV:The National Institutes for Water Resources.

Bowman L, Sharma S, Carr T, Sharma M. 2014. Understanding stray gas occurrences in shallow aquifers in Randolph County, West Virginia, USA. Presented at SE Geological Society of America Meeting, April 10–11, Blacksburg, VA:Geological Society of America.

Chambers DB, Kozar MD, Messinger T, Mulder ML, Pelak AJ, White JS. 2015. Water Quality of Groundwater and Stream Base Flow in the Marcellus Shale Gas Field of the Monongahela River Basin, West Virginia, 2011–12. Scientific Investigations Report 2014-5233. Reston, VA:Survey USG. Available: http://pubs.er.usgs.gov/publication/sir20145233.

Hammack R, Harbert W, Sharma S, Stewart B, Capo R, Wall AJ, et al. 2014. An Evaluation of Fracture Growth and Gas/Fluid Migration as Horizontal Marcellus Shale Gas Wells are Hydraulically Fractured in Greene County, Pennsylvania. Pittsburgh, PA:US Department of Energy, National Energy Technology Laboratory. Available: http://www.achd.net/shale/pubs/NETL-TRS-3-2014_Greene-County-Site_20140915_1_1.pdf.

Hammond PA. 2015. The relationship between methane migration and shale-gas well operations near Dimock, Pennsylvania, USA. Hydrogeol J:1–17.

Harkness JS, Darrah TH, Warner NR, Whyte CJ, Moore MT, Millot R, Kloppmann W, Jackson RB, Vengosh A. 2017. The geochemistry of naturally occurring methane and saline groundwater in an area of unconventional shale gas development. Geochimica et Cosmochimica Acta 208:302-334.

Heilweil VM, Grieve PL, Hynek SA, Brantley SL, Salomon DK, Risser DW. 2015. Stream measurements locate thermogenic methane fluxes in groundwater discharge in an area of shale-gas development. Environ Sci Technol 49:4057–4065.

Lautz LK, Hoke GD, Lu Z, Siegel DI, Christian K, Kessler JD, et al. 2014. Using discriminant analysis to determine sources of salinity in shallow groundBwater prior to hydraulic fracturing. Environ Sci Technol 48:9061–9069.

Li Z, You C, Gonzales M, Wendt AK, Wu F, Brantley SL. 2016. Searching for anomalous methane in shallow groundwater near shale gas wells. Journal of Contaminant Hydrology.

Llewellyn G. 2014. Evidence and mechanisms for Appalachian Basin brine migration into shallow aquifers in NE

Pennsylvania, USA. Hydrogeol J 22:1055–1066.

Kujawska J, Pawłowska M, Cel W, Pawłowski A. 2016. Potential influence of drill cuttings landfill on groundwater quality—comparison of leaching tests results and groundwater composition. Desalination Water Treat 57:1409–1419.

Wen T, Niu X, Gonzales M, Zheng G, Li Z, Brantley SL. 2018. Big Groundwater Data Sets Reveal Possible Rare Contamination Amid Otherwise Improved Water Quality for Some Analytes in a Region of Marcellus Shale Development. Environmental science & technology 52:7149-7159.

Yan B, Stute M, Panettieri RA, Jr., Ross J, Mailloux B, Neidell MJ, Soares L, Howarth M, Liu X, Saberi P, Chillrud SN. 2017. Association of groundwater constituents with topography and distance to unconventional gas wells in NE Pennsylvania. Sci Total Environ 577:195-201.

Zhang LW, Soeder DJ. 2016. Modeling of Methane Migration in Shallow Aquifers from Shale Gas Well Drilling. Groundwater 54:345–353.

Zhu J, Parris TM, Taylor CJ, Webb SE, Davidson B, Smath R, Richardson SD, Molofsky LJ, Kromann JS, Smith AP. 2017. Assessing Methane in Shallow Groundwater in Unconventional Oil and Gas Play Areas, Eastern Kentucky. Groundwater 56:413-424.

Canada

Cahill AG, Parker BL, Mayer B, Mayer KU, Cherry JA. 2018. High resolution spatial and temporal evolution of dissolved gases in groundwater during a controlled natural gas release experiment. Science of The Total Environment 622-623:1178-1192.

Cahill AG, Steelman CM, Forde O, Kuloyo O, Emil Ruff S, Mayer B, Ulrich Mayer K, Strous M, Cathryn Ryan M, Cherry JA, Parker BL. 2017. Mobility and persistence of methane in groundwater in a controlled-release field experiment. Nature Geosci 10:289-294.

Ferguson G, Grasby SE. 2018. Insights into contaminant transport from unconventional oil and gas developments from analog system analysis of methane-bearing thermal springs in the northern Canadian Rocky Mountains. Hydrogeol J 26:481-493.

Lavoie D, Rivard C, Lefebvre R, Séjourné S, Thériault R, Duchesne MJ, et al. 2014. The Utica Shale and gas play in southern Quebec: Geological and hydrogeological syntheses and methodological approaches to groundwater risk evaluation. Int J Coal Geol 126:77–91.

Moritz A, Helie J-F, Pinti D, Larocque M, Barnatche D, Retailleau S, et al. 2015. Methane baseline concentrations and sources in shallow aquifers from the shale gas-prone region of the St. Lawrence Lowlands (Quebec, Canada). Environ Sci Technol 49:4765–4771.

Nowamooz A, Lemieux JM, Molson J, Therrien R. 2015. Numerical investigation of methane and formation fluid leakage along the casing of a decommissioned shale gas well. Water Resour Res 51:4592–4622.

Colorado and Wyoming

American Petroleum Institute. 2012. API Review: API's Review of Recent USGS Pavillion, Wyoming Reports Show USGS Groundwater Sampling Results Differ From EPA's Results in 2011 Draft Report. Washington, DC:API.

American Petroleum Institute. 2012. API Review: API's Review Shows EPA's Monitoring Wells at Pavillion, Wyoming are Improperly Constructed and Unsuitable for Groundwater Quality Assessment. Washington, DC:API.

American Petroleum Institute. 2013. American Petroleum Institute's Review of EPA's Pavillion December 8, 2011 Draft Report with Focus on Monitoring Well Drilling, Completion, Development, and Sampling Activities Related to Deep Monitoring Wells MW-01 and MW-02. DM 2013-058. Washington, DC:API.

ENTRIX C. 2012. Hydraulic Fracturing Study-PXP Inglewood Oil Field. Plains Exploration & Production Company Los Angeles County, Department of Regional Planning. Los Angeles, CA. Available from https://www.eenews.net/assets/2012/10/11/document_ew_01.pdf.

DiGiulio DC, Jackson RB. 2016. Impact to underground sources of drinking water and domestic wells from production well stimulation and completion practices in the Pavillion, Wyoming, field. Environ Sci Technol 50:4524–4536.

Gross SA, Avens HJ, Banducci AM, Sahmel J, Panko JM, Tvermoes BE. 2013. Analysis of BTEX groundwater concentrations from surface spills associated with hydraulic fracturing operations. J Air Waste Manage Assoc 63:424–432.

Li H, Son J-H, Carlson KH. 2016. Concurrence of aqueous and gas phase contamination of groundwater in the Wattenberg oil and gas field of northern Colorado. Water Res 88:458–466.

Li H, Carlson KH. 2014. Distribution and origin of groundwater methane in the Wattenberg oil and gas field of Northern Colorado. Environ Sci Technol 48:1484–1491.

Sherwood OA, Rogers JD, Lackey G, Burke TL, Osborn SG, Ryan JN. 2016. Groundwater methane in relation to oil and gas development and shallow coal seams in the Denver-Julesburg Basin of Colorado. Proceedings of the National Academy of Sciences.

Stephens DB. 2015. Analysis of the groundwater monitoring controversy at the Pavillion, Wyoming natural gas field. Ground Water 53:29–37.

Son J-H, Hanif A, Dhanasekar A, Carlson KH. 2018. Colorado water watch: Real-time groundwater monitoring for possible contamination from oil and gas activities. Environmental Monitoring and Assessment 190:138.

Montana

Preston TM, Chesley-Preston TL. 2015. Risk assessment of brine contamination to aquatic resources from energy development in glacial drift deposits: Williston Basin, USA. Sci Total Environ 508:534–545.

Preston TM, Chesley-Preston TL, Thamke JN. 2014. A GIS-based vulnerability assessment of brine contamination to aquatic resources from oil and gas development in eastern Sheridan County, Montana. Sci Total Environ 472:1152–1162.

Texas

Burton TG, Rifai HS, Hildenbrand ZL, Carlton Jr DD, Fontenot BE, Schug KA. 2016. Elucidating hydraulic fracturing impacts on groundwater quality using a regional geospatial statistical modeling approach. Sci Total Environ 545–546:114–126.

Hildenbrand ZL, Carlton Jr DD, Meik JM, Taylor JT, Fontenot BE, Walton JL, Henderson D, Thacker JB, Korlie S, Whyte CJ, Hudak PF, Schug KA. 2016. A reconnaissance analysis of groundwater quality in the Eagle Ford shale region reveals two distinct bromide/chloride populations. Science of The Total Environment.

Kell S. 2011. State Oil and Gas Agency Groundwater Investigations, And Their Role in Advancing Regulatory Reforms, A Two-State Review: Ohio and Texas. Oklahoma City, OK:Ground Water Protection Council. Available: https://fracfocus.org/sites/default/files/publications/state_oil__gas_agency_groundwater_investigations_optimized.pdf.

Nicot JP, Mickler P, Larson T, Castro MC, Darvari R, Uhlman K, Costley R. 2017. Methane Occurrences in Aquifers Overlying the Barnett Shale Play with a Focus on Parker County, Texas. Groundwater 55:469-481.

Nicot JP, Larson T, Darvari R, Mickler P, Uhlman K, Costley R. 2017. Controls on Methane Occurrences in Aquifers Overlying the Eagle Ford Shale Play, South Texas. Groundwater 55:455-468.

Nicot JP, Larson T, Darvari R, Mickler P, Slotten M, Aldridge J, Uhlman K, Costley R. 2017. Controls on Methane

Occurrences in Shallow Aquifers Overlying the Haynesville Shale Gas Field, East Texas. Ground water.

Santos IC, Martin MS, Reyes ML, Carlton DD, Stigler-Granados P, Valerio MA, Whitworth KW, Hildenbrand ZL, Schug KA. 2018. Exploring the links between groundwater quality and bacterial communities near oil and gas extraction activities. Science of the Total Environment 618:165-173.

Wen T, Castro MC, Nicot JP, Hall CM, Larson T, Mickler P, Darvari R. 2016. Methane Sources and Migration Mechanisms in Shallow Groundwaters in Parker and Hood Counties, Texas-A Heavy Noble Gas Analysis. Environmental science & technology.

Water Use

Allen WT, Lacewell RD, Zinn M. 2014. Water Value and Environmental Implications of Hydraulic Fracturing: Eagle-Ford Shale. Technical Report TR-466. College Station, TX:Texas Water Research Institute. Available: http://twri.tamu.edu/publications/reports/2014/tr-466/.

Barth-Naftilan E, Aloysius N, Saiers JE. 2015. Spatial and temporal trends in freshwater appropriation for natural gas development in Pennsylvania's Marcellus Shale Play. Geophys Res Lett 42:6348–6356.

Best LC, Lowry CS. 2014. Quantifying the potential effects of high-volume water extractions on water resources during natural gas development: Marcellus Shale, NY. Journal of Hydrology: Regional Studies 1:1–16.

Chen H, Carter KE. 2016. Water usage for natural gas production through hydraulic fracturing in the United States from 2008 to 2014. J Environ Manage 170:152–159.

Cheng X, He L, Lu H, Chen Y, Ren L. 2016. Optimal water resources management and system benefit for the Marcellus shale-gas reservoir in Pennsylvania and West Virginia. Journal of Hydrology 540:412-422.

Clark CE, Horner RM, Harto CB. 2013. Life cycle water consumption for shale gas and conventional natural gas. Environ Earth Sci 47:11829–11836.

Drouven MG, Grossmann IE. 2017. Optimization models for impaired water management in active shale gas development areas. Journal of Petroleum Science and Engineering 156:983-995.

Freyman M. 2014. Hydraulic Fracturing & Water Stress: Water Demand by the Numbers. Boston, MA:Ceres. Available: http://www.ceres.org/resources/reports/hydraulic-fracturing-water-stress-water-demand-by-the-numbers.

Freyman M, Salmon R. 2013. Hydraulic Fracturing & Water Stress: Growing Competitive Pressures for Water. Boston, MA:Ceres. Available: http://www.ceres.org/resources/reports/hydraulic-fracturing-water-stress-growing-competitive-pressures-for-water/view.

Gallegos TJ, Varela BA, Haines SS, Engle MA. 2015. Hydraulic fracturing water use variability in the United States and potential environmental implications. Water Resour Res 51:5839–5845.

Gilmore KR, Hupp RL, Glathar J. 2014. Transport of hydraulic fracturing water and wastes in the Susquehanna River Basin, Pennsylvania. J Environ Eng 140, Special Issue: Environmental Impacts of Shale Gas Development, B4013002.

Goodwin S, Carlson K, Knox K, Douglas C, Rein L. 2014. Water intensity assessment of shale gas resources in the Wattenberg field in northeastern Colorado. Environ Sci Technol 48:5991–5995.

Grubert E, Sanders KT. 2018. Water Use in the United States Energy System: A National Assessment and Unit Process Inventory of Water Consumption and Withdrawals. Environmental science & technology 52:6695-6703.

Hansen E, Mulvaney D, Betcher M. 2013. Water Resource Reporting and Water Footprint from Marcellus Shale Development in West Virginia and Pennsylvania. Morgantown, WV:Downstream Strategies. Available: http://www.downstreamstrategies.com/documents/reports_publication/marcellus_wv_pa.pdf.

Hearne RR, Fernando F. 2016. Strategies for Community and Industry Water Management in the Oil Producing

Region of North Dakota. Water 8:12.

Horner RM, Harto CB, Jackson RB, Lowry ER, Brandt AR, Yeskoo TW, Murphy DJ, Clark CE. 2016. Water use and management in the Bakken shale oil play in North Dakota. Environ Sci Technol 50:3275–3282.

Ikonnikova S, Male F, Scanlon BR, Reedy RC, McDaid G. 2017. Projecting the Water Footprint Associated with Shale Resource Production: Eagle Ford Shale Case Study. Environmental Science & Technology.

Jackson RB, Lowry ER, Pickle A, Kang M, DiGiulio D, Zhao K. 2015. The depths of hydraulic fracturing and accompanying water use across the United States. Environ Sci Technol 49:8969–8976.

Jha MK, Fernandez DG. 2014. Shale gas extraction and water consumption in North Carolina: a primer. American Journal of Engineering and Applied Sciences 7:165–170.

Jiang M, Hendrickson CT, VanBriesen JM. 2014. Life cycle water consumption and wastewater generation impacts of a Marcellus Shale gas well. Environ Sci Technol 48:1911–1920.

Jordaan SM, Diaz Anadon L, Mielke E, Schrag DP. 2013. Regional water implications of reducing oil imports with liquid transportation fuel alternatives in the united states. Environ Sci Technol 47:11976–11984.

Kondash AJ, Lauer NE, Vengosh A. 2018. The intensification of the water footprint of hydraulic fracturing. Science Advances 4.

Kondash A, Vengosh A. 2015. Water footprint of hydraulic fracturing. Environ Sci Technol Lett; doi: 101021/acsestlett5b00211 [Online 15 Sep 2015].

Kuwayama Y, Olmstead S, Krupnick A. 2013. Water Resources and Unconventional Fossil Fuel Development — Linking Physical Impacts to Social Costs. RFF DP 13-34. Washington, DC:Resources for the Future.

Lampert DJ. 2015. Comment on "Comparison of Water Use for Hydraulic Fracturing for Unconventional Oil and Gas versus Conventional Oil". Environ Sci Technol 49:6358–6359.

Laurenzi IJ, Jersey GR. 2013. Life cycle greenhouse gas emissions and freshwater consumption of Marcellus shale gas. Environ Sci Technol 47:4896–4903.

Laurenzi IJ, Bergerson JA, Motazedi K. 2016. Life cycle greenhouse gas emissions and freshwater consumption associated with Bakken tight oil. Proceedings of the National Academy of Sciences 113:E7672-E7680.

Lin WL, Bergquist AM, Mohanty K, Werth CJ. 2018. Environmental Impacts of Replacing Slickwater with Low/No-Water Fracturing Fluids for Shale Gas Recovery. Acs Sustainable Chemistry & Engineering 6:7515-7524.

Lin ZL, Lin T, Lim SH, Hove MH, Schuh WM. 2018. Impacts of bakken shale oil development on regional water uses and supply. J Am Water Resour Assoc 54:225-239.

Mangmeechai A, Jaramillo P, Griffin WM, Matthews HS. 2014. Life cycle consumptive water use for oil shale development and implications for water supply in the Colorado River Basin. Int J Life Cycle Assess 19:677–687.

Mauter MS, Alvarez PJJ, Burton A, Cafaro DC, Chen W, Gregory KB, et al. 2014. Regional variation in water-related impacts of shale gas development and implications for emerging international plays. Environ Sci Technol 48:8298–8306.

Mayor B, Casado RR, Landeta J, López-Gunn E, Villarroya F. 2016. An expert outlook on water security and water for energy trends to 2030–2050. Water Policy 18:1-18.

McAuliff K, Sadiq R, Hewage K. 2017. Water use in unconventional oil and gas development: An assessment on water use metric evaluation and selection. Clean Technol Environ Policy 19:2417-2429.

Meng M, Chen M, Sanders KT. 2016. A Geospatial Feasibility Assessment of Utilizing Produced Water from Oil and Natural Gas Production in California for Beneficial Use. World Environmental and Water Resources Congress

2016: Environmental, Sustainability, Groundwater, Hydraulic Fracturing, and Water Distribution Systems Analysis:207-216.

Mitchell AL, Small M, Casman EA. 2013. Surface water withdrawals for Marcellus shale gas development: performance of alternative regulatory approaches in the upper Ohio River basin. Environ Sci Technol 47:12669–12678.

Murray KE. 2013. State-scale perspective on water use and production associated with oil and gas operations, Oklahoma, U.S. Environ Sci Technol 47:4918–4925.

Nicot J-P, Scanlon BR, Reedy RC, Costley RA. 2014. Source and fate of hydraulic fracturing water in the Barnett shale: a historical perspective. Environ Sci Technol 48:2464–2471.

Oikonomou PD, Kallenberger JA, Waskom RM, Boone KK, Plombon EN, Ryan JN. 2016. Water acquisition and use during unconventional oil and gas development and the existing data challenges: Weld and Garfield counties, CO. J Environ Manage 181:36–47.

Palmer RC, Short D, Auch WET. 2018. The Human Right to Water and Unconventional Energy. Int J Environ Res Public Health 15.

Scanlon BR, Reedy RC, Male F, Hove M. 2016. Managing the Increasing Water Footprint of Hydraulic Fracturing in the Bakken Play, United States. Environmental science & technology 50:10273-10281.

Scanlon BR, Reedy RC, Male F, Walsh M. 2017. Water Issues Related to Transitioning from Conventional to Unconventional Oil Production in the Permian Basin. Environmental Science & Technology.

Scanlon BR, Reedy RC, Nicot JP. 2015. Response to Comment on "Comparison of Water Use for Hydraulic Fracturing for Unconventional Oil and Gas versus Conventional Oil". Environ Sci Technol 49:6360–6361.

Scanlon BR, Reedy RC, Nicot J-P. 2014. Comparison of water use for hydraulic fracturing for unconventional oil and gas versus conventional oil. Environ Sci Technol 48:12386–12393. See Lampert 2015 comment and Scanlon et al. 2015 response to comment.

Tidwell V, Moreland B. 2016. Mapping water consumption for energy production around the Pacific Rim. Environmental Research Letters 11.

Tiedeman K, Yeh S, Scanlon BR, Teter J, Mishra GS. 2016. Recent Trends in Water Use and Production for California Oil Production. Environmental science & technology.

U.S. Environmental Protection Agency. 2015. Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources: External Review Draft. EPA/600/R-15/047a. Washington, DC:U.S. EPA.

Viswanathan HS, Hyman JD, Karra S, Carey JW, Porter ML, Rougier E, et al. 2015. Using Discovery Science To Increase Efficiency of Hydraulic Fracturing While Reducing Water Usage. In: Hydraulic Fracturing: Environmental Issues:American Chemical Society, 71–88. Available: http://dx.doi.org/10.1021/bk-2015-1216.ch003.

Walker EL, Anderson AM, Read LK, Hogue TS. 2017. Water Use for Hydraulic Fracturing of Oil and Gas in the South Platte River Basin, Colorado. J Am Water Resour Assoc 53:839-853.

Wilkins RF, Menefee AH, Clarens AF. 2016. Environmental life cycle analysis of water and CO2-based fracturing fluids used in unconventional gas production. Environmental science & technology.

Wilson JM, VanBriesen JM. 2013. Source water changes and energy extraction activities in the Monongahela River, 2009–2012. Environ Sci Technol 47:12575–12582.

Zou C, Ni Y, Li J, Kondash A, Coyte R, Lauer N, Cui H, Liao F, Vengosh A. 2018. The water footprint of hydraulic fracturing in Sichuan Basin, China. Sci Total Environ 630:349-356.

Reviews and General Resources

Abualfaraj N, Olson MS, Gurian PL, De Roos A, Gross-Davis CA. 2016. Statistical analysis of compliance violations for natural gas wells in Pennsylvania. Energy Policy 97:421-428.

American Petroleum Institute. 2011. Practices for Mitigating Surface Impacts Associated with Hydraulic Fracturing. API Guidance Document HF3 First Edition. Washington, DC:API.

American Petroleum Institute. 2010. Water Management Associated with Hydraulic Fracturing. API Guidance Document HF2 First Edition. Washington, DC:API.

American Petroleum Institute. 2009. Hydraulic Fracturing Operations— Well Construction and Integrity Guidelines. API Guidance Document HF1 First Edition. Washington, DC:API.

American Water Works Association. 2013. Water and Hydraulic Fracturing: A White Paper From the American Water Works Association. Denver, CO:AWWA. Available: www.awwa.org/fracturing.

Austin BJ, Kelso JE, Evans-White MA, Entrekin SA, Haggard BE. Can high volume hydraulic fracturing effects be detected in large watersheds? A case study of the south fork little red river. Current Opinion in Environmental Science & Health.

Bartholomew TV, Mauter MS. 2016. Multiobjective Optimization Model for Minimizing Cost and Environmental Impact in Shale Gas Water and Wastewater Management. ACS Sustain Chem Eng; doi: 101021/acssuschemeng6b00372.

Baur F, Katz B. 2018. Some practical guidance for petroleum migration modeling. Marine and Petroleum Geology 93:409-421.

Brantley SL, Vidic RD, Brasier K, Yoxtheimer D, Pollak J, Wilderman C, Wen T. 2018. Engaging over data on fracking and water quality. Science (New York, NY) 359:395-397.

Brantley SL, Yoxtheimer D, Arjmand S, Grieve P, Vidic R, Pollak J, et al. 2014. Water resource impacts during unconventional shale gas development: the Pennsylvania experience. Int J Coal Geol 126:140–156.

Briskin JS, Yohannes L. 2015. Overview of U.S. EPA's Study of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources. In: Hydraulic Fracturing: Environmental Issues:American Chemical Society, 197–203. Available: http://dx.doi.org/10.1021/bk-2015-1216.ch009.

CH2M Hill Engineers. 2015. U.S. Onshore Unconventional Exploration and Production Water Management Case Studies. Houston, TX:CH2M Hill Engineers.

Cohen HA, Parratt T, Andrews CB. 2013. Potential contaminant pathways from hydraulically fractured shale to aquifers. Ground Water 51:317–319.

Darrah TH. 2018. Time to settle the fracking controversy. Groundwater 56:161-162.

Dilmore RM, Sams JI, Glosser D, Carter KM, Bain DJ. 2015. Spatial and temporal characteristics of historical oil and gas wells in Pennsylvania: implications for new shale gas resources. Environ Sci Technol; doi: 101021/acsest5b00820 [Online 12 Aug 2015].

Edwards RWJ, Celia MA. 2018. Shale Gas Well, Hydraulic Fracturing, and Formation Data to Support Modeling of Gas and Water Flow in Shale Formations. Water Resources Research 54:3196-3206.

Esterhuyse S. 2017. Developing a groundwater vulnerability map for unconventional oil and gas extraction: a case study from South Africa. Environmental Earth Sciences 76:13.

Expert Panel on Harnessing Science and Technology to Understand the Environmental Impacts of Shale Gas Extraction. 2014. Environmental Impacts of Shale Gas Extraction in Canada. Ottawa:Council of Canadian Academies. Available: http://www.scienceadvice.ca/en/assessments/completed/shale-gas.aspx.

Gagnon GA, Krkosek W, Anderson L, McBean E, Mohseni M, Bazri M, et al. 2015. Impacts of hydraulic fracturing

on water quality: a review of literature, regulatory frameworks and an analysis of information gaps. Environmental Reviews 24:122-131.

Graham Sustainability Institute. 2013. Geology/Hydrogeology Technical Report. Volume II, Report 3. Ann Arbor, MI:University of Michigan.

Jackson RE, Gorody AW, Mayer B, Roy JW, Ryan MC, Van Stempvoort DR. 2013. Groundwater protection and unconventional gas extraction: the critical need for field-based hydrogeological research. Ground Water 51:488–510.

Jackson RB, Vengosh A, Carey JW, Davies RJ, Darrah TH, O'Sullivan F, et al. 2014. The environmental costs and benefits of fracking. Annu Rev Environ Resour 39:327–362.

Kappel WM, Williams JH, Szabo Z. 2013. Water Resources and Shale Gas/Oil Production in the Appalachian Basin — Critical Issues and Evolving Developments. Open-File Report 2013–1137. Ithaca, NY:U.S. Geological Survey. Available: http://pubs.usgs.gov/of/2013/1137.

Kharaka YK, Thordsen JJ, Conaway CH, Thomas RB. 2013. The Energy-Water Nexus: Potential Groundwater-Quality Degradation Associated with Production of Shale Gas. Procedia Earth and Planetary Science 7:417-422.

Kinchy A, Parks S, Jalbert K. 2015. Fractured knowledge: mapping the gaps in public and private water monitoring efforts in areas affected by shale gas development. Environ Plann C Gov Policy; doi: 101177/0263774X15614684.

Kretsinger Grabert V, Kaback DS, Briskin J, Brantley SL, Darrah TH, Jackson RB, et al. 2015. Unconventional shale gas development and potential impacts to groundwater. Ground Water 53:19–28.

Kuwayama Y, Olmstead S, Krupnick A. 2015. Water quality and quantity impacts of hydraulic fracturing. Curr Sustainable Renewable Energy Rep 2:17–24.

Kuwayama Y, Olmstead S, Krupnick A. 2013. Water Resources and Unconventional Fossil Fuel Development — Linking Physical Impacts to Social Costs. RFF DP 13-34. Washington, DC:Resources for the Future.

Lange T, Sauter M, Heitfeld M, Schetelig K, Brosig K, Jahnke W, et al. 2013. Hydraulic fracturing in unconventional gas reservoirs: risks in the geological system part 1. Environ Earth Sci 70:3839–3853.

Marcellus Shale Advisory Commission. 2011. Report of the Governor's Marcellus Shale Advisory Commission. Commonwealth of Pennsylvania: Harrisburg, Pennsylvania,

Mauter MS, Alvarez PJJ, Burton A, Cafaro DC, Chen W, Gregory KB, et al. 2014. Regional variation in water-related impacts of shale gas development and implications for emerging international plays. Environ Sci Technol 48:8298–8306.

Meik JM, Lawing AM. 2017. Considerations and Pitfalls in the Spatial Analysis of Water Quality Data and Its Association With Hydraulic Fracturing. In: Advances in Chemical Pollution, Environmental Management and Protection. Elsevier.

Michalski R, Ficek A. 2016. Environmental pollution by chemical substances used in the shale gas extraction—a review. Desalination Water Treat 57:1336–1343.

O'Malley D, Karra S, Currier RP, Makedonska N, Hyman JD, Viswanathan HS. 2016. Where Does Water Go During Hydraulic Fracturing? Groundwater 54:488-497.

Piñero E. 2015. Total Water Cycle Management for Hydraulic Fracturing in Shale Gas Production. In: Hydraulic Fracturing: Environmental Issues:American Chemical Society, 129–133. Available: http://dx.doi.org/10.1021/bk-2015-1216.ch005.

Rahm BG, Riha SJ. 2014. Evolving shale gas management: water resource risks, impacts, and lessons learned. Environ Sci Process Impacts 16:1400–1412.

Rice AK, Lackey G, Proctor J, Singha K. 2018. Groundwater-quality hazards of methane leakage from hydrocarbon wells: A review of observational and numerical studies and four testable hypotheses. Wiley Interdiscip Rev-Water 5:18.

Rivard C, Bordeleau G, Lavoie D, Lefebvre R, Malet X. 2018. Can groundwater sampling techniques used in monitoring wells influence methane concentrations and isotopes? Environmental Monitoring and Assessment 190:191.

Schmidt CW. 2013. Estimating wastewater impacts from fracking. Environ Health Perspect 121:A117.

Schwartz M. 2015. Modelling the hypothetical methane-leakage in a shale-gas project and the impact on groundwater quality. Environ Earth Sci 73:4619–4632.

Shrestha N, Chilkoor G, Wilder J, Gadhamshetty V, Stone JJ. 2017. Potential water resource impacts of hydraulic fracturing from unconventional oil production in the Bakken shale. Water Research 108:1-24.

Soeder DJ. 2018. Groundwater Quality and Hydraulic Fracturing: Current Understanding and Science Needs. Ground water.

Soeder D, Kappel WM. 2009. Water Resources and Natural Gas Production from the Marcellus Shale. 1-6.

Stephens DB. 2015. Analysis of the groundwater monitoring controversy at the Pavillion, Wyoming natural gas field. Ground Water 53:29–37.

U.S. Environmental Protection Agency. 2016. Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States. Office of Research and Development. Washington, DC. Available from https://cfpub.epa.gov/ncea/hfstudy/recordisplay.cfm?deid=332990.

U.S. Environmental Protection Agency. 2015. Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources: External Review Draft. EPA/600/R-15/047a. Washington, DC:U.S. EPA.

U.S. Environmental Protection Agency. 2012. Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources: Progress Report. EPA 601/R-12/011. Washington, DC:U.S. EPA Office of Research and Development.

U.S. Geological Survey. 2012. Summary of Studies Related to Hydraulic Fracturing Conducted by USGS Water Science Centers. Washington, DC:U.S. Geological Survey.

U.S. Geological Survey. 2012. Water Quality Studied in Areas of Unconventional Oil and Gas Development, Including Areas Where Hydraulic Fracturing Techniques are Used, in the United States. FS 2012-3049. Fort Collins, CO:U.S. Geological Survey.

Vengosh A, Jackson RB, Warner N, Darrah TH, Kondash A. 2014. A critical review of the risks to water resources from unconventional shale gas development and hydraulic fracturing in the United States. Environ Sci Technol 48:8334–8348.

Vengosh A, Warner N, Jackson R, Darrah T. 2013. The effects of shale gas exploration and hydraulic fracturing on the quality of water resources in the United States. Procedia Earth and Planetary Science 7:863–866.

Vidic RD, Brantley SL, Vandenbossche JM, Yoxtheimer D, Abad JD. 2013. Impact of shale gas development on regional water quality. Science 340:1235009.

Wright BA, Pyke GW, McEnerney TJ, Getchell FJ. 2011. Hydraulic Fracturing Issues and Research Needs for the Water Community. Denver, CO:Water Research Foundation.

Yang L, Grossmann IE, Mauter MS, Dilmore RM. 2015. Investment optimization model for freshwater acquisition and wastewater handling in shale gas production. AIChE J 61:1770–1782.

Younger PL. 2016. How can we be sure fracking will not pollute aquifers? Lessons from a major longwall coal

mining analogue (Selby, Yorkshire, UK). Earth Environ Sci Trans R Soc Edinb 106:89-113.

Yudhowijoyo A, Rafati R, Sharifi Haddad A, Raja MS, Hamidi H. 2018. Subsurface methane leakage in unconventional shale gas reservoirs: A review of leakage pathways and current sealing techniques. Journal of Natural Gas Science and Engineering 54:309-319.

SOIL QUALITY

Lyman SN, Watkins C, Jones CP, Mansfield ML, McKinley M, Kenney D, Evans J. 2017. Hydrocarbon and Carbon Dioxide Fluxes from Natural Gas Well Pad Soils and Surrounding Soils in Eastern Utah. Environmental Science & Technology.

Oetjen K, Blotevogel J, Borch T, Ranville JF, Higgins CP. 2018. Simulation of a hydraulic fracturing wastewater surface spill on agricultural soil. Sci Total Environ 645:229-234.

SEDIMENT QUALITY

Akob DM, Mumford AC, Orem WH, Engle MA, Klinges JG, Kent DB, et al. 2016. Wastewater disposal from unconventional oil and gas development degrades stream quality at a West Virginia injection facility. Environ Sci Technol; doi: 101021/acsest6b00428.

Laurer NE, Warner NR, Avner V. 2018.Sources of Radium Accumulation in Stream Sediments near Disposal Sites in Pennsylvania: Implications for Disposal of Conventional Oil and Gas Wastewater. Environ Sci Technol. DOI 10.1021/acs.est.7b04952.

FOOD QUALITY

CHEMICAL STRESSOR TOXICITY

Drilling Fluids

Abdullah K, Malloy T, Stenstrom MK, Suffet IHM. 2017. Toxicity of acidization fluids used in California oil exploration. Toxicological and Environmental Chemistry 99:78-94.

McMahon PB, Bohlke JK, Dahm KG, Parkhurst DL, Anning DW, Stanton JS. 2016. Chemical Considerations for an Updated National Assessment of Brackish Groundwater Resources. Groundwater 54:464-475.

Searl A, Galea KS. 2011. Toxicological Review of the Possible Effects Associated with Inhalation and Dermal Exposure to Drilling Fluid Production Streams. Edinburgh:Institute of Occupational Medicine. Available: http://www.iom-world.org/pubs/IOM_TM1104.pdf.

Stringfellow WT, Camarillo MK, Domen JK, Shonkoff SBC. 2017. Comparison of chemical-use between hydraulic fracturing, acidizing, and routine oil and gas development. PLoS One 12:e0175344.

Zoveidavianpoor M, Gharibi A. 2016. Characterization of agro-waste resources for potential use as proppant in hydraulic fracturing. Journal of Natural Gas Science and Engineering 36:679-691.

Hydraulic Fracturing Fluids

Bain PA, Kumar A. 2018. In vitro nuclear receptor inhibition and cytotoxicity of hydraulic fracturing chemicals and their binary mixtures. Chemosphere 198:565-573.

Blewett TA, Delompre PLM, Glover CN, Goss GG. 2018. Physical immobility as a sensitive indicator of hydraulic fracturing fluid toxicity towards Daphnia magna. Sci Total Environ 635:639-643.

Boulé LA, Chapman TJ, Hillman SE, Kassotis CD, O'Dell C, Robert J, Georas SN, Nagel SC, Lawrence BP. 2018. Developmental Exposure to a Mixture of 23 Chemicals Associated with Unconventional Oil and Gas Operations Alters the Immune System of Mice. Toxicological Sciences 163:639-654.

Camarillo MK, Domen JK, Stringfellow WT. 2016. Physical-chemical evaluation of hydraulic fracturing chemicals in the context of produced water treatment. Journal of Environmental Management 183, Part 1:164-174.

Chen H, Carter KE. 2017. Characterization of the chemicals used in hydraulic fracturing fluids for wells located in the Marcellus Shale Play. J Environ Manage 200:312-324.

Elliott EG, Ettinger AS, Leaderer BP, Bracken MB, Deziel NC. 2017. A systematic evaluation of chemicals in hydraulic-fracturing fluids and wastewater for reproductive and developmental toxicity. J Expo Sci Environ Epidemiol 27:90-99.

Elliott EG, Trinh P, Ma X, Leaderer BP, Ward MH, Deziel NC. 2017. Unconventional oil and gas development and risk of childhood leukemia: Assessing the evidence. Science of The Total Environment 576:138-147.

Elsner M, Hoelzer K. 2016. Quantitative survey and structural classification of hydraulic fracturing chemicals reported in unconventional gas production. Environ Sci Technol 50:3290–3314.

Folkerts EJ, Blewett TA, He Y, Goss GG. 2017. Alterations to juvenile zebrafish (danio rerio) swim performance after acute embryonic exposure to sub-lethal exposures of hydraulic fracturing flowback and produced water. Aquatic toxicology (Amsterdam, Netherlands) 193:50-59.

Gordalla BC, Ewers U, Frimmel FH. 2013. Hydraulic fracturing: a toxicological threat for groundwater and drinking-water? Environ Earth Sci 70:3875–3893.

Inayat-Hussain SH, Fukumura M, Aziz AM, Jin CM, Jin LW, Garcia-Milian R, Vasiliou V, Deziel NC. 2018. Prioritization of reproductive toxicants in unconventional oil and gas operations using a multi-country regulatory data-driven hazard assessment. Environment International 117:348-358.

Ishikawa M, Muraguchi R, Azuma A, Nawata S, Miya M, Katsuura T, Naito T, Oyama Y. 2016. Cytotoxic actions of 2, 2-dibromo-3-nitrilopropionamide, a biocide in hydraulic fracturing fluids, on rat thymocytes. Toxicology Research 5:1329-1334.

Kahrilas GA, Blotevogel J, Corrin ER, Borch T. 2016. Downhole Transformation of the Hydraulic Fracturing Fluid Biocide Glutaraldehyde: Implications for Flowback and Produced Water Quality. Environmental science & technology 50:11414-11423.

Kahrilas GA, Blotevogel J, Stewart PS, Borch T. 2015. Biocides in hydraulic fracturing fluids: a critical review of their usage, mobility, degradation, and toxicity. Environ Sci Technol 49:16–32.

Kassotis CD, Klemp KC, Vu DC, Lin C-H, Meng C-X, Besch-Williford CL, et al. 2015. Endocrine-disrupting activity of hydraulic fracturing chemicals and adverse health outcomes after prenatal exposure in male mice. Endocrinology; doi: 101210/en2015-1375 [Online 14 Oct 2015].

Kassotis CD, Tillitt DE, Davis JW, Hormann AM, Nagel SC. 2013. Estrogen and androgen receptor activities of hydraulic fracturing chemicals and surface and ground water in a drilling-dense region. Endocrinology 155:897–907.

Kassotis CD, Bromfield JJ, Klemp KC, Meng CX, Wolfe A, Zoeller RT, Balise VD, Isiguzo CJ, Tillitt DE, Nagel

SC. 2016. Adverse Reproductive and Developmental Health Outcomes Following Prenatal Exposure to a Hydraulic Fracturing Chemical Mixture in Female C57Bl/6 Mice. Endocrinology 157:3469-3481.

Payne ME, Chapman HF, Cumming J, Leusch FD. 2015. In vitro cytotoxicity assessment of a hydraulic fracturing fluid. Environmental Chemistry 12:286-292.

Rogers JD, Burke TL, Osborn SG, Ryan JN. 2015. A framework for identifying organic compounds of concern in hydraulic fracturing fluids based on their mobility and persistence in groundwater. Environ Sci Technol Lett 2:158–164.

Riedl J, Rotter S, Faetsch S, Schmitt-Jansen M, Altenburger R. 2013. Proposal for applying a component-based mixture approach for ecotoxicological assessment of fracturing fluids. Environ Earth Sci 70:3907–3920.

Sapouckey SA, Kassotis CD, Nagel SC, Vandenberg LN. 2018. Prenatal exposure to unconventional oil and gas operation chemical mixtures altered mammary gland development in adult female mice. Endocrinology 159:1277-1289.

Searl A, Galea KS. 2011. Toxicological Review of the Possible Effects Associated with Inhalation and Dermal Exposure to Drilling Fluid Production Streams. Edinburgh:Institute of Occupational Medicine. Available: http://www.iom-world.org/pubs/IOM_TM1104.pdf.

Yost EE, Stanek J, DeWoskin RS, Burgoon LD. 2016. Overview of chronic oral toxicity values for chemicals present in hydraulic fracturing fluids, flowback, and produced waters. Environ Sci Technol 50:4788–4797.

Yost EE, Stanek J, DeWoskin RS, Burgoon LD. 2016. Estimating the Potential Toxicity of Chemicals Associated with Hydraulic Fracturing Operations Using Quantitative Structure–Activity Relationship Modeling. Environmental science & technology 50:7732-7742.

Wastewater

Anderson A, Lebsack M, DeGraeve G, Farrier D, Bergman H. 1980. Toxicity of anin situ oil shale process water to rainbow trout and fathead minnows. Arch Environ Contam Toxicol 9:171–179.

Blewett TA, Delompre PL, He Y, Folkerts EJ, Flynn SL, Alessi DS, Goss GG. 2017. The sub-lethal and reproductive effects of acute and chronic exposure to flowback and produced water from hydraulic fracturing on the water flea Daphnia magna. Environmental science & technology.

Butkovskyi A, Bruning H, Kools SAE, Rijnaarts HHM, Van Wezel AP. 2017. Organic Pollutants in Shale Gas Flowback and Produced Waters: Identification, Potential Ecological Impact, and Implications for Treatment Strategies. Environmental science & technology 51:4740-4754.

Camus L, Brooks S, Geraudie P, Hjorth M, Nahrgang J, Olsen GH, et al. 2015. Comparison of produced water toxicity to Arctic and temperate species. Ecotoxicol Environ Saf 113:248–258.

Cozzarelli I, Kent D, Croteau M, Skalak K, Benthem A, Engle M, Mumford A, Akob D, Farag A, Harper D, Orem W, Haase K. 2016. Unconventional Oil and Gas (UOG) Wastewater Spills: Persistence of Contaminants and Environmental Health Implications. Proceeding from GSA Annual Meeting, Denver, CO.

Dunne E. 2016. Flowback and Produced Waters: Opportunities and Challenges for Innovation-Proceedings of a Workshop. The National Academies Press, Washington, DC.

Elliott EG, Ettinger AS, Leaderer BP, Bracken MB, Deziel NC. 2017. A systematic evaluation of chemicals in hydraulic-fracturing fluids and wastewater for reproductive and developmental toxicity. J Expo Sci Environ Epidemiol 27:90-99.

Elliott EG, Trinh P, Ma X, Leaderer BP, Ward MH, Deziel NC. 2017. Unconventional oil and gas development and risk of childhood leukemia: Assessing the evidence. Science of The Total Environment 576:138-147.

Folkerts EJ, Blewett TA, He Y, Goss GG. 2017. Cardio-respirometry disruption in zebrafish (Danio rerio) embryos

exposed to hydraulic fracturing flowback and produced water. Environ Pollut.

Gandhi H, Sadiq R, Hu GJ, Hewage K. 2018. Ecological risk assessment of accidental release of flowback water: A conceptual framework. Human and Ecological Risk Assessment 24:398-426.

He Y, Flynn SL, Folkerts EJ, Zhang Y, Ruan D, Alessi DS, Martin JW, Goss GG. 2017. Chemical and toxicological characterizations of hydraulic fracturing flowback and produced water. Water Research 114:78-87.

Hull NM, Rosenblum JS, Robertson CE, Harris JK, Linden KG. 2018. Succession of toxicity and microbiota in hydraulic fracturing flowback and produced water in the Denver–Julesburg Basin. Science of The Total Environment 644:183-192.

Kassotis CD, Iwanowicz LR, Akob DM, Cozzarelli IM, Mumford AC, Orem WH, Nagel SC. 2016. Endocrine disrupting activities of surface water associated with a West Virginia oil and gas industry wastewater disposal site. Sci Total Environ 557–558:901–910.

Kassotis CD, Nagel SC, Stapleton HM. Unconventional oil and gas chemicals and wastewater-impacted water samples promote adipogenesis via PPARγ-dependent and independent mechanisms in 3T3-L1 cells. Science of The Total Environment.

Kim SY, Omur-Ozbek P, Dhanasekar A, Prior A, Carlson K. 2016. Temporal analysis of flowback and produced water composition from shale oil and gas operations: Impact of frac fluid characteristics. Journal of Petroleum Science and Engineering 147:202-210.

Kujawska J, Cel W, Wasag H. 2016. Leachability of heavy metals from shale gas drilling waste. Rocznik Ochrona Srodowiska 18:909-919.

Lipus D, Vikram A, Ross D, Bain D, Gulliver D, Hammack R, Bibby K. 2017. Predominance and Metabolic Potential of Halanaerobium in Produced Water from Hydraulically Fractured Marcellus Shale Wells. Applied and Environmental Microbiology.

Stroud Water Research Center. 2013. Ecotoxicity Study for Mayflies Exposed to Ambient Stream Water from the Upper Delaware River Basin, Reference Toxicant, and to Produced-Water from Natural Gas Drilling. SWRC Publication Number 2013003. Avondale, PA:Stroud Water Research Center. Available: http://www.nj.gov/drbc/library/documents/naturalgas/StroudStudyFinal082113.pdf.

Truter JC, van Wyk JH, Oberholster PJ, Botha AM, Mokwena LM. 2017. An Evaluation of the Endocrine Disruptive Potential of Cruide Oil Water Accommodated Fractions and Crude Oil Contaminated Surface Water to Freshwater Organisms Using In Vitro and In Vivo Approaches. Environmental Toxicology and Chemistry 36:1330-1342.

Yao Y, Chen T, Shen SS, Niu Y, DesMarais TL, Linn R, et al. 2015. Malignant human cell transformation of Marcellus Shale gas drilling flow back water. Tox Appl Pharmacol 288:121–130.

Yost EE, Stanek J, DeWoskin RS, Burgoon LD. 2016. Overview of chronic oral toxicity values for chemicals present in hydraulic fracturing fluids, flowback, and produced waters. Environ Sci Technol 50:4788–4797.

HUMAN EXPOSURE[1]

Personal Exposure Monitoring

Allshouse WB, Adgate JL, Blair BD, McKenzie LM. 2017. Spatiotemporal Industrial Activity Model for Estimating

[1] Also see the air quality sections, which include numerous studies that are relevant to human exposure.

the Intensity of Oil and Gas Operations in Colorado. Environmental Science & Technology.

Brown DR, Lewis C, Weinberger BI. 2015. Human exposure to unconventional natural gas development: a public health demonstration of periodic high exposure to chemical mixtures in ambient air. J Environ Sci Health A Tox Hazard Subst Environ Eng 50:460–472.

Bloomdahl R, Abualfaraj N, Olson M, Gurian PL. 2014. Assessing worker exposure to inhaled volatile organic compounds from Marcellus Shale flowback pits. J Nat Gas Sci Eng 21:348–356.

Esswein EJ, Breitenstein M, Snawder J, Kiefer M, Sieber WK. 2013. Occupational exposures to respirable crystalline silica during hydraulic fracturing. J Occup Environ Hyg 10:347–356.

Esswein EJ, Snawder J, King B, Breitenstein M, Alexander-Scott M, Kiefer M. 2014. Evaluation of some potential chemical exposure risks during flowback operations in unconventional oil and gas extraction: preliminary results. J Occup Environ Hyg 11:D174–D184.

Goldstein BD. 2018. The pertinence of Sutton's law to exposure science: Lessons from unconventional shale gas drilling. Journal of Exposure Science & Environmental Epidemiology.

Macey GP, Breech R, Chernaik M, Cox C, Larson D, Thomas D, et al. 2014. Air concentrations of volatile compounds near oil and gas production: a community-based exploratory study. Environmental Health 13:82.

Olawoyin R. 2015. Modelling the health risks of exposure to respirable crystalline silica from hydraulic fracturing operations in the USA shale plays. Journal of Biomedical Engineering and Informatics 1:25–34.

Paulik LB, Hobbie KA, Rohlman D, Smith BW, Scott RP, Kincl L, Haynes EN, Anderson KA. 2018. Environmental and individual PAH exposures near rural natural gas extraction. Environmental Pollution 241:397-405.

On-site and Fenceline Air Quality Monitoring

Allshouse WB, Adgate JL, Blair BD, McKenzie LM. 2017. Spatiotemporal Industrial Activity Model for Estimating the Intensity of Oil and Gas Operations in Colorado. Environmental science & technology 51:10243–10250.

Banan Z, Gernand JM. 2018. Evaluation of gas well setback policy in the Marcellus Shale region of Pennsylvania in relation to emissions of fine particulate matter. Journal of the Air & Waste Management Association 68:988-1000.

Brantley HL, Thoma ED, Eisele AP. 2015. Assessment of volatile organic compound and hazardous air pollutant emissions from oil and natural gas well pads using mobile remote and on-site direct measurements. J Air Waste Manag Assoc 65:1072–1082.

Crowe E, Patton S, Thomas D, Thorpe B. 2016. When the Wind Blows: Tracking Toxic Chemicals in Gas Fields and Impacted Communities. Brattleboro, VT: Coming Clean. Available from http://comingcleaninc.org/assets/media/documents/When%20the%20Wind%20Blows.pdf.

Eapi GR, Sabnis MS, Sattler ML. 2014. Mobile measurement of methane and hydrogen sulfide at natural gas production site fence lines in the Texas Barnett Shale. J Air Waste Manage Assoc 64:927–944.

Eastern Research Group, Sage Environmental Consulting. 2011. City of Fort Worth Natural Gas Air Quality Study. Fort Worth, TX Available: http://fortworthtexas.gov/gaswells/air-quality-study/final/.

Eisele AP, Mukerjee S, Smith LA, Thoma ED, Whitaker DA, Oliver KD, et al. 2016. Volatile organic compounds at two oil and natural gas production well pads in Colorado and Texas using passive samplers. J Air Waste Manag Assoc 66:412–419.

Goetz JD, Floerchinger C, Fortner EC, Wormhoudt J, Massoli P, Knighton WB, et al. 2015. Atmospheric emission characterization of Marcellus Shale natural gas development sites. Environ Sci Technol 49:7012–7020.

Haley M, McCawley M, Epstein AC, Arrington B, Bjerke EF. 2016. Adequacy of Current State Setbacks for

Directional High-Volume Hydraulic Fracturing in the Marcellus, Barnett, and Niobrara Shale Plays. Environ Health Perspect; doi: 101289/ehp1510547.

McCawley M. 2013. Air, Noise, and Light Monitoring Results. ETD-10 Project. Morgantown, WV:West Virginia University School of Public Health.

McKenzie LM, Witter RZ, Newman LS, Adgate JL. 2012. Human health risk assessment of air emissions from development of unconventional natural gas resources. Sci Total Environ 424:79–87.

Pennsylvania Department of Environmental Protection. 2010. Southwestern Pennsylvania Marcellus Shale Short-Term Ambient Air Sampling Report. Harrisburg, PA:PA DEP Bureau of Air Quality. Available: http://www.dep.state.pa.us/dep/deputate/airwaste/aq/aqm/docs/Marcellus_SW_11-01-10.pdf.

Pétron G, Frost G, Miller BR, Hirsch AI, Montzka SA, Karion A, et al. 2012. Hydrocarbon emissions characterization in the Colorado Front Range: A pilot study. J Geophys Res 117; D04304, doi:101029/2011JD016360.

Rich AL, Orimoloye HT. 2016. Elevated atmospheric levels of benzene and benzene-related compounds from unconventional shale extraction and processing: human health concern for residential communities. Environ Health Insights 10:75–82.

Rich A, Grover JP, Sattler ML. 2014. An exploratory study of air emissions associated with shale gas development and production in the Barnett Shale. J Air Waste Manage Assoc 64:61–72.

Walter GR, Benke RR, Pickett DA. 2012. Effect of biogas generation on radon emissions from landfills receiving radium-bearing waste from shale gas development. J Air Waste Manag Assoc 62(9):1040–1049.

Warneke C, Geiger F, Edwards PM, Dube W, Pétron G, Kofler J, et al. 2014. Volatile organic compound emissions from the oil and natural gas industry in the Uintah Basin, Utah: oil and gas well pad emissions compared to ambient air composition. Atmos Chem Phys 14:10977–10988.

West Virginia Department of Environmental Protection Office of Oil and Gas. 2013. Air Quality Impacts Occuring from Horizontal Well Drilling and Related Activities. Charleston, WV:West Virginia DEP.

West Virginia Department of Environmental Protection Office of Oil and Gas. 2013. Noise, Light, Dust, and Volatile Organic Compounds Generated by the Drilling of Horizontal Wells Related to the Well Location Restriction Regarding Occupied Dwelling Structures. West Virginia Department of Environmental Protection-Office of Oil and Gas. Charleston, WV.

Outdoor Air Quality Monitoring (Beyond the Fenceline)

Allshouse WB, Adgate JL, Blair BD, McKenzie LM. 2017. Spatiotemporal Industrial Activity Model for Estimating the Intensity of Oil and Gas Operations in Colorado. Environmental science & technology 51:10243–10250.

Colborn T, Schultz K, Herrick L, Kwiatkowski C. 2014. An exploratory study of air quality near natural gas operations. Hum Ecol Risk Assess 20:86–105.

Colorado Department of Public Health & Environment. 2017. Assessment of Potential Public Health Effects from Oil and Gas Operations in Colorado. Colorado Department of Public Health & Environment. Environment CDoPH. Available from https://www.colorado.gov/pacific/cdphe/oil-and-gas-health-assessment.

Goetz JD, Floerchinger C, Fortner EC, Wormhoudt J, Massoli P, Knighton WB, et al. 2015. Atmospheric emission characterization of Marcellus Shale natural gas development sites. Environ Sci Technol 49:7012–7020.

Hildenbrand ZL, Mach PM, McBride EM, Dorreyatim MN, Taylor JT, Carlton Jr DD, Meik JM, Fontenot BE, Wright KC, Schug KA, Verbeck GF. 2016. Point source attribution of ambient contamination events near unconventional oil and gas development. Science of The Total Environment 573:382-388.

Macey GP, Breech R, Chernaik M, Cox C, Larson D, Thomas D, et al. 2014. Air concentrations of volatile

compounds near oil and gas production: a community-based exploratory study. Environmental Health 13:82.

Maskrey JR, Insley AL, Hynds ES, Panko JM. 2016. Air monitoring of volatile organic compounds at relevant receptors during hydraulic fracturing operations in Washington County, Pennsylvania. Environ Monit Assess 188:1-12.

Paulik LB, Donald CE, Smith BW, Tidwell LG, Hobbie KA, Kincl L, Haynes EN, Anderson KA. 2016. Emissions of Polycyclic Aromatic Hydrocarbons from Natural Gas Extraction into Air. Environmental science & technology 50:7921-7929.

Pekney NJ, Veloski G, Reeder M, Tamilia J, Rupp E, Wetzel A. 2014. Measurement of atmospheric pollutants associated with oil and natural gas exploration and production activity in Pennsylvania's Allegheny National Forest. J Air Waste Manage Assoc 64:1062–1072.

Pétron G, Frost G, Miller BR, Hirsch AI, Montzka SA, Karion A, et al. 2012. Hydrocarbon emissions characterization in the Colorado Front Range: A pilot study. J Geophys Res 117; D04304, doi:101029/2011JD016360.

Prenni AJ, Day DE, Evanoski-Cole AR, Sive BC, Hecobian A, Zhou Y, Gebhart KA, Hand JL, Sullivan AP, Li Y, Schurman MI, Desyaterik Y, Malm WC, Collett Jr JL, Schichtel BA. 2016. Oil and gas impacts on air quality in federal lands in the Bakken region: an overview of the Bakken Air Quality Study and first results. Atmos Chem Phys 16:1401–1416.

Rich A, Grover JP, Sattler ML. 2014. An exploratory study of air emissions associated with shale gas development and production in the Barnett Shale. J Air Waste Manage Assoc 64:61–72.

Schade GW, Roest G. 2016. Analysis of non-methane hydrocarbon data from a monitoring station affected by oil and gas development in the Eagle Ford shale, Texas. Elementa (Wash D C) 4:000096.

Swarthout RF, Russo RS, Zhou Y, Miller BM, Mitchell B, Horsman E, et al. 2015. Impact of Marcellus Shale natural gas development in Southwest Pennsylvania on volatile organic compound emissions and regional air quality. Environ Sci Technol 49:3175–3184.

Thompson CR, Hueber J, Helmig D. 2014. Influence of oil and gas emissions on ambient atmospheric non-methane hydrocarbons in residential areas of Northeastern Colorado. Elem Sci Anth 2:000035.

Warneke C, Geiger F, Edwards PM, Dube W, Pétron G, Kofler J, et al. 2014. Volatile organic compound emissions from the oil and natural gas industry in the Uintah Basin, Utah: oil and gas well pad emissions compared to ambient air composition. Atmos Chem Phys 14:10977–10988.

Zielinska B, Fujita E, Campbell D. 2010. Monitoring of Emissions from Barnett Shale Natural Gas Production Facilities for Population Exposure Assessment – Draft. Reno, NV:Desert Research Institute.

Zielinska B, Campbell D, Samburova V. 2014. Impact of emissions from natural gas production facilities on ambient air quality in the Barnett Shale area: a pilot study. Journal of the Air & Waste Management Association (1995) 64:1369-1383.

Indoor Air Quality Monitoring

Casey JA, Ogburn EL, Rasmussen SG, Irving JK, Pollak J, Locke PA, et al. 2015. Predictors of indoor radon concentrations in Pennsylvania, 1989–2013. Environ Health Perspect; doi:101289/ehp1409014 [Online 9 April 2015].

Surface Water Quality Monitoring

Betanzo EA, Hagen ER, Wilson JT, Reckhow KH, Hayes L, Argue DM, et al. 2016. Water data to answer urgent water policy questions: Monitoring design, available data and filling data gaps for determining whether shale gas development activities contaminate surface water or groundwater in the Susquehanna River Basin. Washington, DC:Northeast-Midwest Institute.

Bowen ZH, Oelsner GP, Cade BS, Gallegos TJ, Farag AM, Mott DN, et al. 2015. Assessment of surface water chloride and conductivity trends in areas of unconventional oil and gas development—why existing national data sets cannot tell us what we would like to know. Water Resour Res 51:704–715.

Chambers DB, Kozar MD, Messinger T, Mulder ML, Pelak AJ, White JS. 2015. Water Quality of Groundwater and Stream Base Flow in the Marcellus Shale Gas Field of the Monongahela River Basin, West Virginia, 2011–12. Scientific Investigations Report 2014-5233. Reston, VA:Survey USG. Available: http://pubs.er.usgs.gov/publication/sir20145233.

Ferrar KJ, Michanowicz DR, Christen CL, Mulcahy N, Malone SL, Sharma RK. 2013. Assessment of effluent contaminants from three facilities discharging Marcellus shale wastewater to surface waters in Pennsylvania. Environ Sci Technol 47:3472–3481.

Heilweil VM, Grieve PL, Hynek SA, Brantley SL, Salomon DK, Risser DW. 2015. Stream measurements locate thermogenic methane fluxes in groundwater discharge in an area of shale-gas development. Environ Sci Technol 49:4057–4065.

Hladik ML, Focazio MJ, Engle M. 2014. Discharges of produced waters from oil and gas extraction via wastewater treatment plants are sources of disinfection by-products to receiving streams. Sci Total Environ 466:1085–1093.

Kassotis CD, Iwanowicz LR, Akob DM, Cozzarelli IM, Mumford AC, Orem WH, Nagel SC. 2016. Endocrine disrupting activities of surface water associated with a West Virginia oil and gas industry wastewater disposal site. Sci Total Environ 557–558:901–910.

Lauer NE, Harkness JS, Vengosh A. 2016. Brine spills associated with unconventional oil development in North Dakota. Environ Sci Technol; doi: 101021/acsest5b06349.

Low DJ, Brightbill RA, Eggleston HL, Chaplin JJ. 2016. Physical, chemical, and biological characteristics of selected headwater streams along the Allegheny Front, Blair County, Pennsylvania, July 2011–September 2013. 2015-1173. Reston, VA: Survey USG. Available from http://pubs.er.usgs.gov/publication/ofr20151173.

McBroom M, Thomas T, Zhang Y. 2012. Soil erosion and surface water quality impacts of natural gas development in East Texas, USA. Water 4:944–958.

Olmstead SM, Muehlenbachs LA, Shih J-S, Chu Z, Krupnick AJ. 2013. Shale gas development impacts on surface water quality in Pennsylvania. Proc Natl Acad Sci U S A 110:4962–4967.

Parker KM, Zeng T, Harkness J, Vengosh A, Mitch WA. 2014. Enhanced formation of disinfection byproducts in shale gas wastewater-impacted drinking water supplies. Environ Sci Technol 48:11161–11169.

Pelak AJ, Sharma S. 2014. Surface water geochemical and isotopic variations in an area of accelerating Marcellus Shale gas development. Environ Pollut 195:91–100.

Penningroth SM, Yarrow MM, Figueroa AX, Bowen RJ, Delgado S. 2013. Community-based risk assessment of water contamination from high-volume horizontal hydraulic fracturing. New Solut 23:137–166.

States S, Cyprych G, Stoner M, Wydra F, Kuchta J, Monnell J, et al. 2013. Marcellus Shale drilling and brominated THMs in Pittsburgh, Pa., drinking water. J Am Water Works Assoc 105:53–54.

Warner NR, Christie CA, Jackson RB, Vengosh A. 2013. Impacts of shale gas wastewater disposal on water quality in western Pennsylvania. Environ Sci Technol 47:11849–11857.

Wilson J, Wang Y, VanBriesen J. 2014. Sources of high total dissolved solids to drinking water supply in Southwestern Pennsylvania. J Environ Eng 140:B4014003.

Wilson JM, VanBriesen JM. 2013. Source water changes and energy extraction activities in the Monongahela River, 2009–2012. Environ Sci Technol 47:12575–12582.

Wilson JM, VanBriesen JM. 2012. Oil and gas produced water management and surface drinking water sources in

Pennsylvania. Environ Pract 14:288–300.

Drinking Water Monitoring

Alawattegama SK, Kondratyuk T, Krynock R, Bricker M, Rutter JK, Bain DJ, et al. 2015. Well water contamination in a rural community in southwestern Pennsylvania near unconventional shale gas extraction. J Environ Sci Health A Tox Hazard Subst Environ Eng 50:516–528.

Betanzo EA, Hagen ER, Wilson JT, Reckhow KH, Hayes L, Argue DM, et al. 2016. Water data to answer urgent water policy questions: Monitoring design, available data and filling data gaps for determining whether shale gas development activities contaminate surface water or groundwater in the Susquehanna River Basin. Washington, DC:Northeast-Midwest Institute.

Burton TG, Rifai HS, Hildenbrand ZL, Carlton Jr DD, Fontenot BE, Schug KA. 2016. Elucidating hydraulic fracturing impacts on groundwater quality using a regional geospatial statistical modeling approach. Sci Total Environ 545–546:114–126.

Bowman L, Sharma S, Shackleton R, Carr T, Sharma M. 2014. Stray gas occurrences unrelated to shale gas development: an example from Randolph County, West Virginia. Presented at Mid-Atlantic Regional Water Conference, 24–25, Shepardstown, WV:The National Institutes for Water Resources.

Boyer EW, Swistock BR, Clark J, Madden M, Rizzo DE. 2012. The Impact of Marcellus Gas Drilling on Rural Drinking Water Supplies. Harrisburg, PA:Center for Rural Pennsylvania.

Chambers DB, Kozar MD, Messinger T, Mulder ML, Pelak AJ, White JS. 2015. Water Quality of Groundwater and Stream Base Flow in the Marcellus Shale Gas Field of the Monongahela River Basin, West Virginia, 2011–12. Scientific Investigations Report 2014-5233. Reston, VA:Survey USG. Available: http://pubs.er.usgs.gov/publication/sir20145233.

Christian KM, Lautz LK, Hoke GD, Siegel DI, Lu Z, Kessler J. 2016. Methane occurrence is associated with sodium-rich valley waters in domestic wells overlying the Marcellus shale in New York State. Water Resour Res 52:206–226.

Committee TGP. 2016. Joint Groundwater Monitoring and Contamination Report - 2015. Quality TCoE. Available from https://www.tceq.texas.gov/assets/public/comm_exec/pubs/sfr/056-15.pdf.

Darrah TH, Jackson RB, Vengosh A, Warner NR, Whyte CJ, Walsh TB, et al. 2015. The evolution of Devonian hydrocarbon gases in shallow aquifers of the northern Appalachian Basin: insights from integrating noble gas and hydrocarbon geochemistry. Geochim Cosmochim Acta 170:321–355.

Darrah TH, Vengosh A, Jackson RB, Warner NR, Poreda RJ. 2014. Noble gases identify the mechanisms of fugitive gas contamination in drinking-water wells overlying the Marcellus and Barnett Shales. Proc Natl Acad Sci U S A 111:14076–14081.

Drollette BD, Hoelzer K, Warner NR, Darrah TH, Karatum O, O'Connor MP, et al. 2015. Elevated levels of diesel range organic compounds in groundwater near Marcellus gas operations are derived from surface activities. Proc Natl Acad Sci U S A; doi: 101073/pnas1511474112 [Online 12 Oct 2015].

Hammond PA. 2015. The relationship between methane migration and shale-gas well operations near Dimock, Pennsylvania, USA. Hydrogeol J:1–17.

Jackson RB, Vengosh A, Darrah TH, Warner NR, Down A, Poreda RJ, et al. 2013. Increased stray gas abundance in a subset of drinking water wells near Marcellus shale gas extraction. Proc Natl Acad Sci U S A 110:11250–11255.

Llewellyn GT, Dorman F, Westland JL, Yoxtheimer D, Grieve P, Sowers T, et al. 2015. Evaluating a groundwater supply contamination incident attributed to Marcellus Shale gas development. Proc Natl Acad Sci U S A 112:6325–6330.

Molofsky LJ, Connor JA, McHugh TE, Richardson SD, Woroszlyo C, Alvarez PJ. 2016. Environmental factors

associated with natural methane occurrence in the Appalachian Basin. Groundwater; doi: 101111/gwat12401.

Molofsky LJ, Connor JA, Wylie AS, Wagner T, Farhat SK. 2013. Evaluation of methane sources in groundwater in Northeastern Pennsylvania. Ground Water 51:333–349.

Nelson AW, Knight AW, Eitrheim ES, Schultz MK. 2015. Monitoring radionuclides in subsurface drinking water sources near unconventional drilling operations: a pilot study. J Environ Radioact 142:24–28.

Osborn SG, Vengosh A, Warner NR, Jackson RB. 2011. Methane contamination of drinking water accompanying gas-well drilling and hydraulic fracturing. Proc Natl Acad Sci U S A 108:8172–8176.

Osborn SG, Vengosh A, Warner NR, Jackson RB. 2011. Reply to Saba and Orzechowski and Schon: Methane contamination of drinking water accompanying gas-well drilling and hydraulic fracturing. Proc Natl Acad Sci U S A 108:E665–E666.

Parker KM, Zeng T, Harkness J, Vengosh A, Mitch WA. 2014. Enhanced formation of disinfection byproducts in shale gas wastewater-impacted drinking water supplies. Environ Sci Technol 48:11161–11169.

Reilly D, Singer D, Jefferson A, Eckstein Y. 2015. Identification of local groundwater pollution in northeastern Pennsylvania: Marcellus flowback or not? Environ Earth Sci 73:8097–8109.

Siegel DI, Azzolina NA, Smith BJ, Perry AE, Bothun RL. 2015. Methane concentrations in water wells unrelated to proximity to existing oil and gas wells in northeastern Pennsylvania. Environ Sci Technol 49:4106–4112.

States S, Cyprych G, Stoner M, Wydra F, Kuchta J, Monnell J, et al. 2013. Marcellus Shale drilling and brominated THMs in Pittsburgh, Pa., drinking water. J Am Water Works Assoc 105:53–54.

Warner NR, Jackson RB, Darrah TH, Osborn SG, Down A, Zhao K, et al. 2012. Geochemical evidence for possible natural migration of Marcellus Formation brine to shallow aquifers in Pennsylvania. Proc Natl Acad Sci U S A 109:11961–11966.

Wilson J, Wang Y, VanBriesen J. 2014. Sources of high total dissolved solids to drinking water supply in Southwestern Pennsylvania. J Environ Eng 140:B4014003.

Ziemkiewicz P, Donovan J, Hause J, Gutta B, Fillhart J, Mack B, et al. 2013. Water Quality Literature Review and Field Monitoring of Active Shale Gas Wells, Phase II. Morgantown, WV:West Virginia Water Research Institute, West Virginia University.

Ziemkiewicz P, Hause J, Gutta B, Fillhart J, Mack B, O'Neal M. 2013. Water Quality Literature Review and Field Monitoring of Active Shale Gas Wells, Phase I. Morgantown, WV:West Virginia Water Research Institute, West Virginia University.

Groundwater Monitoring

Baldassare FJ, McCaffrey MA, Harper JA. 2014. A geochemical context for stray gas investigations in the northern Appalachian Basin: Implications of analyses of natural gases from Neogene-through Devonian-age strata. AAPG Bulletin 98(2):341–372.

Betanzo EA, Hagen ER, Wilson JT, Reckhow KH, Hayes L, Argue DM, et al. 2016. Water data to answer urgent water policy questions: Monitoring design, available data and filling data gaps for determining whether shale gas development activities contaminate surface water or groundwater in the Susquehanna River Basin. Washington, DC:Northeast-Midwest Institute.

Bowman L, Sharma S, Carr T, Sharma M. 2014. Understanding stray gas occurrences in shallow aquifers in Randolph County, West Virginia, USA. Presented at SE Geological Society of America Meeting, April 10–11, Blacksburg, VA:Geological Society of America.

Chambers DB, Kozar MD, Messinger T, Mulder ML, Pelak AJ, White JS. 2015. Water Quality of Groundwater and Stream Base Flow in the Marcellus Shale Gas Field of the Monongahela River Basin, West Virginia, 2011–12. Scientific Investigations Report 2014-5233. Reston, VA:Survey USG. Available: http://pubs.er.usgs.gov/publication/sir20145233.

Committee TGP. 2016. Joint Groundwater Monitoring and Contamination Report - 2015. Quality TCoE. Available from https://www.tceq.texas.gov/assets/public/comm_exec/pubs/sfr/056-15.pdf.

Gross SA, Avens HJ, Banducci AM, Sahmel J, Panko JM, Tvermoes BE. 2013. Analysis of BTEX groundwater concentrations from surface spills associated with hydraulic fracturing operations. J Air Waste Manage Assoc 63:424–432.

Hammond PA. 2015. The relationship between methane migration and shale-gas well operations near Dimock, Pennsylvania, USA. Hydrogeol J:1–17.

Heilweil VM, Grieve PL, Hynek SA, Brantley SL, Salomon DK, Risser DW. 2015. Stream measurements locate thermogenic methane fluxes in groundwater discharge in an area of shale-gas development. Environ Sci Technol 49:4057–4065.

Kujawska J, Pawłowska M, Cel W, Pawłowski A. 2016. Potential influence of drill cuttings landfill on groundwater quality—comparison of leaching tests results and groundwater composition. Desalination Water Treat 57:1409–1419.

Llewellyn G. 2014. Evidence and mechanisms for Appalachian Basin brine migration into shallow aquifers in NE Pennsylvania, USA. Hydrogeol J 22:1055–1066.

Su XB, Zhou FD, Tyson S. 2018. Numerical investigation of the potential contamination of a shallow aquifer in producing coalbed methane. Energy Explor Exploit 36:282-296.

Soil and Sediment Monitoring

Bern CR, Clark ML, Schmidt TS, Holloway JM, McDougal RR. 2015. Soil disturbance as a driver of increased stream salinity in a semiarid watershed undergoing energy development. J Hydrol 524:123–136.

Brantley SL, Yoxtheimer D, Arjmand S, Grieve P, Vidic R, Pollak J, et al. 2014. Water resource impacts during unconventional shale gas development: the Pennsylvania experience. Int J Coal Geol 126:140–156.

Chen SS, Sun Y, Tsang DCW, Graham NJD, Ok YS, Feng Y, Li X-D. 2016. Potential impact of flowback water from hydraulic fracturing on agricultural soil quality: Metal/metalloid bioaccessibility, Microtox bioassay, and enzyme activities. Science of The Total Environment.

Kassotis CD, Tillitt DE, Davis JW, Hormann AM, Nagel SC. 2013. Estrogen and androgen receptor activities of hydraulic fracturing chemicals and surface and ground water in a drilling-dense region. Endocrinology 155:897–907.

Konkel L. 2016. Salting the Earth: The Environmental Impact of Oil and Gas Wastewater Spills. Environmental health perspectives 124:A230-A235.

Olmstead SM, Muehlenbachs LA, Shih J-S, Chu Z, Krupnick AJ. 2013. Shale gas development impacts on surface water quality in Pennsylvania. Proc Natl Acad Sci U S A 110:4962–4967.

Pichtel J. 2016. Oil and Gas Production Wastewater: Soil Contamination and Pollution Prevention. Applied and Environmental Soil Science 2016:24.

Rich AL, Crosby EC. 2013. Analysis of reserve pit sludge from unconventional natural gas hydraulic fracturing and drilling operations for the presence of technologically enhanced naturally occurring radioactive material (TENORM). New Solut 23:117–135.

Skalak KJ, Engle MA, Rowan EL, Jolly GD, Conko KM, Benthem AJ, et al. 2013. Surface disposal of produced

waters in western and southwestern Pennsylvania: potential for accumulation of alkali-earth elements in sediments. Int J Coal Geol 126:162–170.

Varona-Torres E, Carlton DD, Hildenbrand ZL, Schug KA. 2018. Matrix-effect-free determination of BTEX in variable soil compositions using room temperature ionic liquid co-solvents in static headspace gas chromatography mass spectrometry. Analytica Chimica Acta 1021:41-50.

Warner NR, Christie CA, Jackson RB, Vengosh A. 2013. Impacts of shale gas wastewater disposal on water quality in western Pennsylvania. Environ Sci Technol 47:11849–11857.

Ying L, O'Connor F, Stolz JF. 2015. Scintillation gamma spectrometer for analysis of hydraulic fracturing waste products. J Environ Sci Health A Tox Hazard Subst Environ Eng 50:511–515.

Zhang T, Hammack RW, Vidic RD. 2015. Fate of radium in Marcellus shale flowback water impoundments and assessment of associated health risks. Environ Sci Technol 49:9347–9354.

Biomonitoring

Chambers DM, Reese CM, Thornburg LG, Sanchez E, Rafson JP, Blount BC, Ruhl JRE, De Jesús VR. 2018. Distinguishing Petroleum (Crude Oil and Fuel) From Smoke Exposure within Populations Based on the Relative Blood Levels of Benzene, Toluene, Ethylbenzene, and Xylenes (BTEX), Styrene and 2,5-Dimethylfuran by Pattern Recognition Using Artificial Neural Networks. Environmental Science & Technology 52:308-316.

Crowe E, Patton S, Thomas D, Thorpe B. 2016. When the Wind Blows: Tracking Toxic Chemicals in Gas Fields and Impacted Communities. Brattleboro, VT: Coming Clean. Available from http://comingcleaninc.org/assets/media/documents/When%20the%20Wind%20Blows.pdf.

Esswein EJ, Snawder J, King B, Breitenstein M, Alexander-Scott M, Kiefer M. 2014. Evaluation of some potential chemical exposure risks during flowback operations in unconventional oil and gas extraction: preliminary results. J Occup Environ Hyg 11:D174–D184.

Exposure Pathway Reviews

Adgate JL, Goldstein BD, McKenzie LM. 2014. Potential public health hazards, exposures and health effects from unconventional natural gas development. Environ Sci Technol 48:8307–8320.

Brown D, Weinberger B, Lewis C, Bonaparte H. 2014. Understanding exposure from natural gas drilling puts current air standards to the test. Rev Environ Health 29:277–292.

Brownlow JW, James SC, Yelderman JC. 2018. Uncertainty analysis: influence of hydraulic fracturing on overlying aquifers in the presence of leaky abandoned wells. Environmental Earth Sciences 77:16.

Brownlow JW, James SC, Yelderman JC. 2016. Influence of Hydraulic Fracturing on Overlying Aquifers in the Presence of Leaky Abandoned Wells. Groundwater 54:781-792.

Brownlow JW, Yelderman JC, Jr., James SC. 2016. Spatial Risk Analysis of Hydraulic Fracturing near Abandoned and Converted Oil and Gas Wells. Ground water.

Czolowski ED, Santoro RL, Srebotnjak T, Shonkoff SBC. 2017. Toward Consistent Methodology to Quantify Populations in Proximity to Oil and Gas Development: A National Spatial Analysis and Review. Environmental health perspectives 125:086004.

International Associatio of Oil and Gas Producers, CEFIC, EOSCA. 2016. Generic exposure scenario for the use of chemicals in the exploration and production of hydrocarbons using high-volume hydraulic fracturing. Available from http://www.eosca.eu/wp-content/uploads/553-Hydraulic_Fracturing_Final_Report.pdf.

Kassotis CD, Tillitt DE, Lin CH, McElroy JA, Nagel SC. 2016. Endocrine-disrupting chemicals and oil and natural gas operations: potential environmental contamination and recommendations to assess complex environmental mixtures. Environ Health Perspect 124:256–264.

EPA-HQ-2019-460

Konkel L. 2016. Salting the Earth: The Environmental Impact of Oil and Gas Wastewater Spills. Environmental health perspectives 124:A230-A235.

Ma L, Hurtado A, Eguilior S, Llamas Borrajo JF. 2018. A model for predicting organic compounds concentration change in water associated with horizontal hydraulic fracturing. Sci Total Environ 625:1164-1174.

Mouser P, Heyob K, Blotevogel J, Lenhart J, Borch T. 2018. Pathways and mechanisms for natural attenuation of nonionic surfactants in hydraulic fracturing fluids if released to agricultural soil and groundwater. Abstr Pap Am Chem Soc 255:1.

Witter RZ, Tenney L, Clark S, Newman LS. 2014. Occupational exposures in the oil and gas extraction industry: state of the science and research recommendations. Am J Ind Med 57:847–856.

Yost EE, Stanek J, Burgoon LD. 2016. A decision analysis framework for estimating the potential hazards for drinking water resources of chemicals used in hydraulic fracturing fluids. Sci Total Environ 574:1544–1558.

Ziemkiewicz P, Quaranta J, Darnell A, Wise R. 2014. Exposure pathways related to shale gas development and procedures for reducing environmental and public risk. J Nat Gas Sci Eng 16:77–84.

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HEALTH

PUBLIC HEALTH

Human Health Risk Assessment and Human Health Impact Assessments

Abualfaraj N, Gurian P, Olson M. 2018. Assessing residential exposure risk from spills of flowback water from Marcellus shale hydraulic fracturing activity. International Journal of Environmental Research and Public Health 15:727.

ATSDR Division of Community Health Investigations. 2010. Health consultation: Public Health Implications of Ambient Air Exposures as Measured in Rural and Urban Oil & Gas Development Areas – an Analysis of 2008 Air Sampling Data. Garfield County, Colorado. (Natural Gas Ambient Air Quality Monitoring Initiative). Atlanta, Georgia: US Department of Health and Human Services

ATSDR Division of Community Health Investigations. 2016. Health consultation: Dimock Groundwater Site, Carter Road and State Route 3023, Dimock, Susquehanna County, Pennsylvania. (Natural Gas Ambient Air Quality Monitoring Initiative). Atlanta, Georgia: US Department of Health and Human Services.

ATSDR. 2016. Health consultation: Brigich compressor station chartiers township, washington county, pennsylvania. (Natural Gas Ambient Air Quality Monitoring Initiative). Atlanta, Georgia:US Department of Health and Human Services.

Bari MA, Kindzierski WB. 2018. Ambient volatile organic compounds (VOCs) in Calgary, Alberta: Sources and screening health risk assessment. Sci Total Environ 631-632:627-640.

Bunch AG, Perry CS, Abraham L, Wikoff DS, Tachovsky JA, Hixon JG, et al. 2014. Evaluation of impact of shale gas operations in the Barnett Shale region on volatile organic compounds in air and potential human health risks. Sci Total Environ 468–469:832–842.

Chen L, Miller SA, Ellis BR. 2017. Comparative human toxicity impact of electricity produced from shale gas and coal. Environmental science & technology 51:13018-13027.

Claudio F, de Rijke K, Page A. 2018. The csg arena: A critical review of unconventional gas developments and best-practice health impact assessment in queensland, australia. Impact Assessment and Project Appraisal 36:105-114.

Coons T, Walker R. 2008. Community Health Risk Analysis of Oil and Gas Impacts in Garfield County. Saccomanno Research Institute. Environment CDoPHa. Available from https://www.garfield-county.com/public-health/documents/1._COMMUNITY_HEALTH_RISK_ANALYSIS-(Complete_Report_16MB).pdf.

Gradient. 2013. National Human Health Risk Evaluation for Hydraulic Fracturing Fluid Additives. Cambridge, MA:Gradient.

Greiner L, Brown D. 2016. Health of Older Adults Living in Communities with Intense Unconventional Natural Gas Development. Gerontologist 56:1.

Faber AH, Annevelink M, Gilissen HK, Schot P, van Rijswick M, de Voogt P, et al. 2017. How to adapt chemical risk assessment for unconventional hydrocarbon extraction related to the water system. Reviews of environmental contamination and toxicology.

Intrinsik Environmental Services Inc. 2014. Detailed Human Health Risk Assessment of Oil and Gas Activities in Northeastern British Columbia Calgary, Alberta:British Columbia Ministry of Health. Available: http://www.health.gov.bc.ca/library/publications/year/2014/detailed-health-risk-assessment.pdf.

McClellan RO, Snipes MB. 2010. Sublette County Air Toxics Inhalation: Screening Level Health Hazard Assessment –An Overview of Potential Results. Prepared for Shell Exploration and Production.

McKenzie LM, Blair BD, Hughes J, Allshouse WB, Blake N, Helmig D, et al. 2018. Ambient non-methane hydrocarbon levels along colorado's northern front range: Acute and chronic health risks. Environmental science & technology.

McMullin TS, Bamber AM, Bon D, Vigil DI, Van Dyke M. 2018. Exposures and Health Risks from Volatile Organic Compounds in Communities Located near Oil and Gas Exploration and Production Activities in Colorado (U.S.A.). International Journal of Environmental Research and Public Health 15.

McMullin T, Flores J, Bamber A, Bon D. 2017. Health Risk Evaluation from Inhalation of VOCs in Ambient Air Near Woolley-Sosa and Erie Champlin Oil and Gas Sites. Colorado Department of Public Health and Environment. Available from https://www.erieco.gov/DocumentCenter/View/9502.

McMullin T, Bamber A, Flores J, Vigil D, Van Dyke M. 2017. Assessment of potential public health effects from oil and gas operations in colorado. Colorado Department of Public Health & Environment.

Meng Q. 2018. Rethink potential risks of toxic emissions from natural gas and oil mining. Environmental Pollution 240:848-857.

Mitchell AL, Griffin WM, Casman EA. 2016. Lung Cancer Risk from Radon in Marcellus Shale Gas in Northeast U.S. Homes. Risk Anal; doi: 101111/risa12570.

McKenzie LM, Witter RZ, Newman LS, Adgate JL. 2012. Human health risk assessment of air emissions from development of unconventional natural gas resources. Sci Total Environ 424:79–87.

McMullin T, Flores J, Bamber A, Bon D. 2017. Health Risk Evaluation from Inhalation of VOCs in Ambient Air Near Woolley-Sosa and Erie Champlin Oil and Gas Sites. Colorado Department of Public Health and Environment. Available from https://www.erieco.gov/DocumentCenter/View/9502.

McMullin T, Bamber A, Flores J, Vigil D, Van Dyke M. 2017. Assessment of potential public health effects from oil and gas operations in colorado. Colorado Department of Public Health & Environment. Available from https://www.colorado.gov/pacific/cdphe/oil-and-gas-health-assessment.

Mrdjen I, Lee J. 2015. High volume hydraulic fracturing operations: Potential impacts on surface water and human health. Int J Environ Health Res:1–23.

National Research Council. 2014. Health Impact Assessment of Shale Gas Extraction: Workshop Summary. Washington, DC:The National Academies Press.

Paulik LB, Donald CE, Smith BW, Tidwell LG, Hobbie KA, Kincl L, Haynes EN, Anderson KA. 2016. Emissions of Polycyclic Aromatic Hydrocarbons from Natural Gas Extraction into Air. Environmental science & technology 50:7921-7929.

Penningroth SM, Yarrow MM, Figueroa AX, Bowen RJ, Delgado S. 2013. Community-based risk assessment of water contamination from high-volume horizontal hydraulic fracturing. New Solut 23:137–166.

Pennsylvania Department of Environmental Protection. 2018. Long-Term Ambient Air Monitoring Project: Marcellus Shale Gas Facilities.

Reap E. 2015. The risk of hydraulic fracturing on public health in the UK and the UK's fracking legislation. Environmental Sciences Europe 27:1–7.

Regli S, Chen J, Messner M, Elovitz MS, Letkiewicz FJ, Pegram RA, et al. 2015. Estimating potential increased bladder cancer risk due to increased bromide concentrations in sources of disinfected drinking waters. Environ Sci Technol 49:13094–13102.

Riedl J, Rotter S, Faetsch S, Schmitt-Jansen M, Altenburger R. 2013. Proposal for applying a component-based mixture approach for ecotoxicological assessment of fracturing fluids. Environ Earth Sci 70:3907–3920.

Rish WR, Pfau EJ. 2017. Bounding analysis of drinking water health risks from a spill of hydraulic fracturing

flowback water. Risk Anal, doi: 10.1111/risa.12884.

Scientific Consulting Group Inc. 2011. Integrating Chemical and Non-Chemical Stressors in Cumulative Risk Assessment. Washington, DC:U.S. EPA.

Sexton K. 2012. Cumulative risk assessment: an overview of methodological approaches for evaluating combined health effects from exposure to multiple environmental stressors. Int J Environ Res Public Health 9:370–390.

Sexton K, Linder SH. 2011. Cumulative risk assessment for combined health effects from chemical and nonchemical stressors. Am J Public Health 101(Suppl 1):S81–S88.

Torres L, Yadav OP, Khan E. 2018. Risk assessment of human exposure to Ra-226 in oil produced water from the Bakken Shale. The Science of the Total Environment 626:867-874.

Torres L, Yadav OP, Khan E. 2016. A review on risk assessment techniques for hydraulic fracturing water and produced water management implemented in onshore unconventional oil and gas production. Sci Total Environ 539:478–493.

Witter RZ, McKenzie L, Stinson KE, Scott K, Newman LS, Adgate J. 2013. The use of health impact assessment for a community undergoing natural gas development. Am J Public Health 103:1002–1010.

Veiguela M, Hurtado A, Eguilior S, Recreo F, Roqueñi N, Loredo J. 2016. A risk assessment tool applied to the study of shale gas resources. Science of The Total Environment 571:551-560.

Ziemkiewicz P, Quaranta J, Darnell A, Wise R. 2014. Exposure pathways related to shale gas development and procedures for reducing environmental and public risk. J Nat Gas Sci Eng 16:77–84.

Zhang T, Hammack RW, Vidic RD. 2015. Fate of radium in Marcellus shale flowback water impoundments and assessment of associated health risks. Environ Sci Technol 49:9347–9354.

Public Safety

Abualfaraj N, Gurian P, Olson M. 2018. Frequency Analysis of Failure Scenarios from Shale Gas Development. International Journal of Environmental Research and Public Health 15:885.

Blair BD, McKenzie LM, Allshouse WB, Adgate JL. 2017. Is reporting "significant damage" transparent? Assessing fire and explosion risk at oil and gas operations in the united states. Energy Research & Social Science 29:36-43.

Graham J, Irving J, Tang X, Sellers S, Crisp J, Horwitz D, et al. 2015. Increased traffic accident rates associated with shale gas drilling in Pennsylvania. Accid Anal Prev 74:203–209.

Muehlenbachs L, Krupnick A. 2013. Shale Gas Development Linked to Traffic Accidents in Pennsylvania. Washington, DC:Resources for the Future. Available: http://common-resources.org/2013/shale-gas-development-linked-to-traffic-accidents-in-pennsylvania/.

Epidemiology

Busby C, Mangano J. 2017. There's a World Going on Underground—Infant Mortality and Fracking in Pennsylvania. Journal of Environmental Protection:381-393.

Casey JA, Wilcox HC, Hirsch AG, Pollak J, Schwartz BS. 2018. Associations of unconventional natural gas development with depression symptoms and disordered sleep in Pennsylvania. Scientific reports 8:11375.

Casey JA, Goldman-Mellor S, Catalano R. 2018. Association between Oklahoma earthquakes and anxiety-related Google search episodes. Environmental Epidemiology 2:e016.

Casey JA, Schwartz BS, Stewart WF, Adler NE. 2016. Using Electronic Health Records for Population Health Research: A Review of Methods and Applications. Annual Review of Public Health 37:61-81.

Casey JA, Schwartz BS. 2016. The Authors Respond. Epidemiology Publish Ahead of Print.

Casey JA, Savitz DA, Rasmussen SG, Ogburn EL, Pollak J, Mercer DG, et al. 2015. Unconventional natural gas development and birth outcomes in Pennsylvania, USA. Epidemiology; doi: 101097/EDE0000000000000387 [Online 30 Sep 2015].

Cox LAJ. 2016. Re: Unconventional Natural Gas Development and Birth Outcomes in Pennsylvania, USA. Epidemiology 27:e37.

Currie J, Greenstone M, Meckel K. 2017. Hydraulic fracturing and infant health: New evidence from pennsylvania. Science Advances 3.

Desrosiers TA, Herring AH, Shapira SK, Hooiveld M, Luben TJ, Herdt-Losavio ML, Lin S, Olshan AF, Study tNBDP. 2012. Paternal occupation and birth defects: findings from the National Birth Defects Prevention Study. Occupational and Environmental Medicine 69:534-542.

Deziel NC, Humeau Z, Elliott EG, Warren JL, Niccolai LM. 2018. Shale gas activity and increased rates of sexually transmitted infections in ohio, 2000–2016. PLOS ONE 13:e0194203.

Finkel ML. 2016. Shale gas development and cancer incidence in southwest Pennsylvania. Public health 141:198-206.

Fryzek J, Pastula S, Jiang X, Garabrant DH. 2013. Childhood cancer incidence in Pennsylvania counties in relation to living in counties with hydraulic fracturing sites. J Occup Environ Med 55:796–801.

Goldstein BD, Malone S. 2013. Obfuscation does not provide comfort: response to the article by Fryzek et al on hydraulic fracturing and childhood cancer. J Occup Environ Med 55:1376–1378.

Gulland A. 2016. Fracking is linked to asthma increase, study finds. Bmj-British Medical Journal 354.

Hill EL. 2014. Shale Gas Development and Infant Health: Evidence from Pennsylvania. Working Paper. Cornell University, Ithaca, NY.

Jemielita T, Gerton GL, Neidell M, Chillrud S, Yan B, Stute M, et al. 2015. Unconventional Gas and Oil Drilling Is Associated with Increased Hospital Utilization Rates. PLoS One 10:e0131093.

Koehler K, Ellis JH, Casey JA, Manthos D, Bandeen-Roche K, Platt R, Schwartz BS. 2018. Exposure Assessment Using Secondary Data Sources in Unconventional Natural Gas Development and Health Studies. Environmental science & technology 52:6061–6069.

Komarek T, Cseh A. 2017. Fracking and public health: Evidence from gonorrhea incidence in the Marcellus Shale region. Journal of Public Health Policy. J Public Health Policy 38(4):464-481.

Lin C-K, Hung H-Y, Christiani DC, Forastiere F, Lin R-T. 2017. Lung cancer mortality of residents living near petrochemical industrial complexes: A meta-analysis. Environmental Health 16:101.

Ma Z, Sneeringer K, Liu L, Kuller L. 2016. Time Series Evaluation of Birth Defects in Areas with and without Unconventional Natural Gas Development. J Epidemiol Public Health Rev 1.

McKenzie LM, Allshouse WB, Byers TE, Bedrick EJ, Serdar B, Adgate JL. 2017. Childhood hematologic cancer and residential proximity to oil and gas development. PLOS ONE 12:e0170423.

McKenzie LM, Guo R, Witter RZ, Savitz DA, Newman LS, Adgate JL. 2014. Birth outcomes and maternal residential proximity to natural gas development in rural Colorado. Environ Health Perspect 122:412–417.

Mokry BJ. 2010. Summary of investigation into the occurrence of cancer: Zip codes 75022 and 75028, Flower Mound Denton County, Texas 1998–2007, 2007–2009.Texas Cancer Registry Branch, Department of State Health Services.

Peng L, Meyerhoefer C, Chou SY. 2018. The health implications of unconventional natural gas development in Pennsylvania. Health economics.

Rasmussen SG, Ogburn EL, McCormack M, et al. 2016. Association between unconventional natural gas development in the Marcellus shale and asthma exacerbations. JAMA Internal Medicine. 176(9):1334-1343.

Stacy SL, Brink LL, Larkin JC, Sadovsky Y, Goldstein BD, Pitt BR, et al. 2015. Perinatal Outcomes and Unconventional Natural Gas Operations in Southwest Pennsylvania. PLoS One 10:e0126425.

Tustin A, Hirsch A, Rasmussen S, Casey J, Bandeen-Roche K, Schwartz B. 2016. Associations between Unconventional Natural Gas Development and Nasal and Sinus, Migraine Headache, and Fatigue Symptoms in Pennsylvania. Environmental health perspectives, DOI: 10.1289/EHP281.

Weinberger B, Greiner LH, Walleigh L, Brown D. 2017. Health symptoms in residents living near shale gas activity: A retrospective record review from the Environmental Health Project. Preventive medicine reports 8:112-115.

Werner AK, Watt K, Cameron C, Vink S, Page A, Jagals P. 2018. Examination of child and adolescent hospital admission rates in Queensland, Australia, 1995–2011: A comparison of coal seam gas, coal mining, and rural areas. Maternal and Child Health Journal.

Whitworth KW, Marshall AK, Symanski E. 2018. Drilling and production activity related to unconventional gas development and severity of preterm birth. Environmental health perspectives.

Whitworth KW, Marshall AK, Symanski E. 2017. Maternal residential proximity to unconventional gas development and perinatal outcomes among a diverse urban population in Texas. PLOS ONE 12:e0180966.

Willis MD, Jusko TA, Halterman JS, Hill EL. 2018. Unconventional natural gas development and pediatric asthma hospitalizations in Pennsylvania. Environ Res 166:402-408.

Reviews of Potential Public Health Impacts and Recommendations for Future Research

Adgate JL, Goldstein BD, McKenzie LM. 2014. Potential public health hazards, exposures and health effects from unconventional natural gas development. Environ Sci Technol 48:8307–8320.

Arbelaez J, Baizel B. 2015. Californians at Risk: An Analysis of Health Threats from Oil and Gas Pollution in Two Communities. Washington, DC:Clean Water Fund and Earthworks. Available: https://www.earthworksaction.org/files/publications/CaliforniansAtRiskFINAL.pdf.

Balise VD, Meng C-X, Cornelius-Green JN, Kassotis CD, Kennedy R, Nagel SC. 2016. Systematic review of the association between oil and natural gas extraction processes and human reproduction. Fertility and Sterility 106:795-819.

Bamberger M, Oswald RE. 2012. Impacts of gas drilling on human and animal health. New Solut 22:51–77.

Bamberger M, Oswald RE. 2014. Unconventional oil and gas extraction and animal health. Environ Sci Process Impacts 16:1860–1865.

Bamberger M, Oswald RE. 2015. Long-term impacts of unconventional drilling operations on human and animal health. J Environ Sci Health A Tox Hazard Subst Environ Eng 50:447–459.

Bechtel DG, Waldner CL, Wickstrom M. 2009. Associations Between In Utero Exposure to Airborne Emissions From Oil and Gas Production and Processing Facilities and Immune System Outcomes in Neonatal Beef Calves. Archives of Environmental & Occupational Health 64:59-71.

Bharadwaj L, Goldstein BD. 2015. Shale gas development in Canada: What are the potential health effects? Canadian Medical Association Journal 187:E99–E100.

Boyle MD, Payne-Sturges DC, Sangaramoorthy T, Wilson S, Nachman KE, Babik K, et al. 2016. Hazard Ranking

Methodology for Assessing Health Impacts of Unconventional Natural Gas Development and Production: The Maryland Case Study. PLoS ONE 11:e0145368.

Brown DR, Lewis C, Weinberger BI. 2015. Human exposure to unconventional natural gas development: a public health demonstration of periodic high exposure to chemical mixtures in ambient air. J Environ Sci Health A Tox Hazard Subst Environ Eng 50:460–472.

Bunch AG, Perry CS, Abraham L, Wikoff DS, Tachovsky JA, Hixon JG, et al. 2014. Evaluation of impact of shale gas operations in the Barnett Shale region on volatile organic compounds in air and potential human health risks. Sci Total Environ 468–469:832–842.

Chiang C, Mahalingam S, Flaws JA. 2017. Environmental Contaminants Affecting Fertility and Somatic Health. Semin Reprod Med 35:241-249.

Colorado Department of Health & Environment. 2017. Assessment of Potential Public Health Effects from Oil and Gas Operations in Colorado. Colorado Department of Public Health & Environment. Environment CDoPH. Available from https://www.colorado.gov/pacific/cdphe/oil-and-gas-health-assessment.

Cox RS, Irwin P, Scannell L, Ungar M, Bennett TD. 2017. Children and youth's biopsychosocial wellbeing in the context of energy resource activities. Environ Res 158:499-507.

Devlin DJ, Beatty P, White RD, Naufal Z, Sarang SS. 2014. Collaborative Industry Initiative to Assess Potential Health Effects Related to the Production of Unconventional Resources. Presented at SPE International Conference on Health, Safety, and Environment, 17–19 March 2014, Long Beach, CA:Society of Petroleum Engineers.

Fleischman L, McCabe D, Graham J. 2016. Gasping for Breath: An analysis of the health effects from ozone pollution from the oil and gas industry. Clean Air Task Force. Force CAT.

Furlow B. 2016. Unconventional natural gas development and respiratory health. The Lancet Respiratory Medicine 4.

Graham Sustainability Institute. 2013. Public Health Technical Report. Volume II, Report 5. Ann Arbor, MI:University of Michigan.

Granados PS. 2017. Public Health Concerns and Unconventional Oil and Gas Development. In: Advances in Chemical Pollution, Environmental Management and Protection. Elsevier.

Hays J SS. 2016. Toward an Understanding of the Environmental and Public Health Impacts of Unconventional Natural Gas Development: A Categorical Assessment of the Peer-Reviewed Scientific Literature, 2009-2015. PloS ONE 11:e0154164.

Hays J, Shonkoff SB. 2015. Working Paper: Toward an Understanding of the Environmental and Public Health Impacts of Shale Gas Development: An Analysis of the Peer-Reviewed Scientific Literature, 2009–2015. Physicians, Scientists, and Engineers for Healthy Energy. Available: http://www.psehealthyenergy.org/data/Database_Analysis_2015.6_.16_.pdf.

Hirsch JK, Bryant Smalley K, Selby-Nelson EM, Hamel-Lambert JM, Rosmann MR, Barnes TA, et al. 2017. Psychosocial impact of fracking: A review of the literature on the mental health consequences of hydraulic fracturing. International Journal of Mental Health and Addiction.

Krupnick AJ, Echarte I, Zachary L, Raimi D. 2017. WHIMBY (What's Happening in My Backyard?): A Community Risk-Benefit Matrix of Unconventional Oil and Gas Development. Available from http://www.rff.org/research/publications/whimby-what-s-happening-my-backyard-community-risk-benefit-matrix.

Maryland Institute for Applied Environmental Health. 2014. Potential Public Health Impacts of Natural Gas Development and Production in the Marcellus Shale in Western Maryland. College Park, MD:School of Public Health, University of Maryland.

McCawley, M. A. (2017). "Does increased traffic flow around unconventional resource development activities

represent the major respiratory hazard to neighboring communities?: knowns and unknowns." Current Opinion in Pulmonary Medicine 23(2): 161-166.

McCawley M. 2015. Air contaminants associated with potential respiratory effects from unconventional resource development activities. Semin Respir Crit Care Med 36:379–387.

Mickley SE. 2017. Health and well-ness: Analysis of key public health indicators in six of the most heavily drilled marcellus shale counties in pennsylvania. Lehigh Valley, PA.

New York State Department of Health. 2014. A Public Health Review of High Volume Hydraulic Fracturing for Shale Gas Development. Albany, NY:NYS DOH.

Penning TM, Breysse PN, Gray K, Howarth M, Yan B. 2014. Environmental health research recommendations from the Inter-Environmental Health Sciences Core Center Working Group on unconventional natural gas drilling operations. Environ Health Perspect 122:1155–1159.

PSE Healthy Energy. 2014. Toward an Understanding of the Environmental and Public Health Impacts of Shale Gas Development: An Analysis of the Peer Reviewed Scientific Literature, 2009–2014. Physicians, Scientists, and Engineers for Healthy Energy. Available: http://www.psehealthyenergy.org/site/view/1233#sthash.ZzT37SzX.dpuf.

Public Health England, Kibble A, Cabianca T, Daraktchieva, Gooding T, Smithard J, et al. 2013. Review of the Potential Public Health Impacts of Exposures to Chemical and Radioactive Pollutants as a Result of Shale Gas Extraction: Draft for Comment. PHE-CRCE-002. London:PHE. Available: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/329744/PHE-CRCE-002_for_website_protected.pdf.

Research Triangle Environmental Health Collaborative. 2012. Shale Gas Extraction in North Carolina: Public Health Implications — Recommendations from the Research Triangle Environmental Health Collaborative. Research Triangle Park, NC:EHC. Available: http://environmentalhealthcollaborative.org/images/2012SummitWorkProduct.pdf.

Russo PN, Carpenter DO. 2017. Health Effects Associated with Stack Chemical Emissions from NYS Natural Gas Compressor Stations: 2008-2014. Institute for Health and the Environment. Project PftSPEH, Rensselaer, New York. Available from https://www.scribd.com/document/361433431/Health-Effects-Associated-With-Stack-Chemical-Emissions-From-NYS-Natural-Gas-Compressor-Stations-2008-2014.

Saunders PJ, McCoy D, Goldstein R, Saunders AT, Munroe A. 2016. A review of the public health impacts of unconventional natural gas development. Environ Geochem Health:1-57.

Shonkoff SB, Hays J, Finkel ML. 2014. Environmental public health dimensions of shale and tight gas development. Environ Health Perspect 122:787–795.

Stacy SL. 2017. A Review of the Human Health Impacts of Unconventional Natural Gas Development. Current Epidemiology Reports 4:38-45.

Watterson A, Dinan W. 2018. Public health and unconventional oil and gas extraction including fracking: Global lessons from a scottish government review. International Journal of Environmental Research and Public Health 15:675.

Webb E, Bushkin-Bedient S, Cheng A, Kassotis CD, Balise V, Nagel SC. 2014. Developmental and reproductive effects of chemicals associated with unconventional oil and natural gas operations. Rev Environ Health 29:307–318.

Webb E, Moon J, Dyrszka L, Rodriguez B, Cox C, Patisaul H, Bushkin S, London E. 2017. Neurodevelopmental and neurological effects of chemicals associated with unconventional oil and natural gas operations and their potential effects on infants and children.

Webb E, Hays J, Dyrszka L, Rodriguez B, Cox C, Huffling K, et al. 2016. Potential hazards of air pollutant emissions from unconventional oil and natural gas operations on the respiratory health of children and infants. Rev Environ Health; 101515/reveh-2014-0070.

Werner AK, Vink S, Watt K, Jagals P. 2015. Environmental health impacts of unconventional natural gas development: A review of the current strength of evidence. Sci Total Environ 505:1127–1141.

Wilke RA, Freeman JW. 2017. Potential health implications related to fracking. JAMA.

Witter RZ, Tenney L, Clark S, Newman LS. 2014. Occupational exposures in the oil and gas extraction industry: state of the science and research recommendations. Am J Ind Med 57:847–856.

Wright R, Muma RD. 2018. High-volume Hydraulic Fracturing and Human Health Outcomes: A Scoping Review. Journal of occupational and environmental medicine.

Community-Engaged Research (Perception, Symptoms, and Other Anecdotal Information)

Andrade A, Carrera T, Martinez F, Pantoja L, Rubens M, Zerecero E. Urban oil drilling and community health: Results from a UCLA health survey UCLA Institute of Environment and Sustainability.

Colorado Department of Public Health and Environment. 2017. Investigation of Reported Health Concerns near Waste Connections Oil and Gas Site in Erie. Colorado Department of Public Health and Environment. Available from https://www.erieco.gov/DocumentCenter/View/9708.

Ferrar KJ, Kriesky J, Christen CL, Marshall LP, Malone SL, Sharma RK, et al. 2013. Assessment and longitudinal analysis of health impacts and stressors perceived to result from unconventional shale gas development in the Marcellus Shale region. Int J Occup Environ Health 19:104–112.

McDermott-Levy R, Garcia V. 2016. Health concerns of Northeastern Pennsylvania residents living in an unconventional oil and gas development county. Public Health Nurs; doi: 101111/phn12265.

Korfmacher K, Gray K, Haynes E. 2014. Health Impacts of Unconventional Oil and Gas Development: A Comparative Assessment of Community Information Needs in New York, North Carolina, and Ohio. University of Rochester, University of North Carolina, University of Cincinatti. Available: https://www.urmc.rochester.edu/MediaLibraries/URMCMedia/environmental-health-sciences-center/COEC/documents/UNGD-information-needs-asssessment-Final-project-report-091514.pdf.

Malin SA, Mayer A, Shreeve K, Olson-Hazboun SK, Adgate J. 2017. Free market ideology and deregulation in colorado's oilfields: Evidence for triple movement activism? Env Polit 26:521-545.

Malomo M. 2015. Pennsylvania Asthma Focus Report 2015: Inpatient Hospitalizations with a Primary Diagnosis of Asthma. Pennsylvania Department of Health. Pennsylvania.

Perry SL. 2013. Using ethnography to monitor the community health implications of onshore unconventional oil and gas developments: examples from Pennsylvania's Marcellus Shale. New Solut 23:33–53.

Rabinowitz P, Slizovskiy I. 2014. Proximity to natural gas wells and reported health status: results of a household survey in Washington County, Pennsylvania. Environ Health Perspect 123:21–26.

Saberi P, Propert KJ, Powers M, Emmett E, Green-McKenzie J. 2014. Field survey of health perception and complaints of Pennsylvania residents in the Marcellus shale region. Int J Environ Res Public Health 11:6517–6527.

Shamasunder B, Collier-Oxandale A, Blickley J, Sadd J, Chan M, Navarro S, et al. 2018. Community-based health and exposure study around urban oil developments in south los angeles. International Journal of Environmental Research and Public Health 15:138.

Slizovskiy IB, Conti LA, Trufan SJ, Reif JS, Lamers VT, Stowe MH, et al. 2015. Reported health conditions in animals residing near natural gas wells in southwestern Pennsylvania. J Environ Sci Health A Tox Hazard Subst Environ Eng 50:473–481.

Steinzor N, Subra W, Sumi L. 2013. Investigating links between shale gas development and health impacts through a community survey project in Pennsylvania. New Solut 23:55–83.

Weinberger B, Greiner LH, Walleigh L, Brown D. 2017. Health symptoms in residents living near shale gas activity: A retrospective record review from the Environmental Health Project. Preventive medicine reports 8:112-115.

Whitworth KW, De LaRosa E, Mackay T, Hernandez A, Martin MK, Lopez J, et al. 2017. Exploring perceptions of fracking and environmental health in a 3-county population in south texas. Journal of Epidemiological Research 3:8.

General Resources and Guidance

Butler K, Tayour C, Batikian C, Contreras C, Bane M, Rhoades E, et al. 2018. Public health and safety risks of oil and gas facilities in los angeles county. Los Angeles:Los Angeles County Department of Health.moni

Carpenter DO. 2016. Hydraulic fracturing for natural gas: impact on health and environment. Rev Environ Health 31:47–51.

Colborn T, Kwiatkowski C, Schultz K, Bachran M. 2011. Natural gas operations from a public health perspective. Hum Ecol Risk Assess 17:1039–1056.

Colorado Oil and Gas Association. 2016. Oil and Gas Development and Public Health Whitepaper. Denver, CO: COGA. Available from http://www.coga.org/wp-content/uploads/2016/02/Public-Health-Whitepaper.pdf.

Center for Biological Diversity. 2018. Fracking and dangerous drilling in california: Briefing book.

Centers for Disease Control and Prevention. 2013. Health-Related Quality of Life (HRQOL): Well-being Concepts. Available: http://www.cdc.gov/hrqol/wellbeing.htm.

Centner TJ, Petetin L. 2015. Permitting program with best management practices for shale gas wells to safeguard public health. J Environ Manage 163:174–183.

Concerned Health Professionals of New York, Physicians for Social Responsibility. 2018. Compendium of scientific, medical, and media findings demonstrating risks and harms of fracking (unconventional gas and oil extraction).Concerned Health Professionals of New York Physicians for Social Responsibility.

Concerned Health Professionals of New York, Physicians for Social Responsibility. 2016. Compendium of Scientific, Medical, and Media Findings Demonstrating Risks and Harms of Fracking (Unconventional Gas and Oil Extraction). Available from http://concernedhealthny.org/wp-content/uploads/2016/12/COMPENDIUM-4.0_FINAL_11_16_16Corrected.pdf.

Concerned Health Professionals of New York, Physicians for Social Responsibility. 2015. Compendium of Scientific, Medical, And Media Findings Demonstrating Risks and Harms of Fracking (Unconventional Gas and Oil Extraction). Available: http://www.psr.org/assets/pdfs/fracking-compendium.pdf.

Cropper M, Gamkhar S, Malik K, Limonov A, Partridge I. 2012. The Health Effects of Coal Electricity Generation in India. RFF DP 12-25. Washington, DC:Resources for the Future.

Dixon DW. 2001. Radon exposures from the use of natural gas in buildings. Radiat Prot Dosimetry 97:259–264.

Duarte-Davidson R, Courage C, Rushton L, Levy L. 2001. Benzene in the environment: an assessment of the potential risks to the health of the population. Occup Environ Med 58:2–13.

Energy in Depth. 2017. Compendium of Studies Demonstrating the Safety and Health Benefits of Fracking.

Finkel ML, Hays J. 2013. The implications of unconventional drilling for natural gas: a global public health concern. Public Health 127:889–893.

Finkel ML, Hays J. 2015. Environmental and health impacts of 'fracking': why epidemiological studies are necessary. J Epidemiol Community Health

Fleischman L, Banks J, Graham J. 2016. Fossil Fumes: A public health analysis of toxic air pollution from the oil

and gas industry. Boston, MA: Clean Air Task Force. Available from http://www.catf.us/resources/publications/files/FossilFumes.pdf.

Goldenberg S, Shoveller J, Koehoorn M, Ostry A. 2008. Barriers to STI testing among youth in a Canadian oil and gas community. Health Place 14:718–729.

Goldenberg SMBAM, Shoveller JAP, Ostry ACP, Koehoorn MP. 2008. Sexually transmitted infection (STI) testing among young oil and gas workers: the need for innovative, place-based approaches to STI control. Can J Public Health 99:350–354.

Goldstein B. 2012. The Public Health Implications of Unconventional Gas Drilling: For presentation to the Energy and Environment Subcommittee, Committee on Science, Space, and Technology. Presented, 1 February 2012, Washington, DC:U.S. House of Representatives, Committee on Science, Space, and Technology.

Goldstein BD, Kriesky J, Pavliakova B. 2012. Missing from the table: role of the environmental public health community in governmental advisory commissions related to Marcellus shale drilling. Environ Health Perspect 120:483–486.

Haswell M, Bethmont A, Bethmont MHA. 2016. Health concerns associated with unconventional gas mining in rural Australia. Rural and Remote Health 16.

Hendrickson RG, Chang A, Hamilton RJ. 2004. Co-worker fatalities from hydrogen sulfide. Am J Ind Med 45:346–350.

Hill M. 2014. Shale gas regulation in the UK and health implications of fracking. Lancet 383:2211–2212.

Hricak H, Brenner D, Dauer L, Ding G, Dominici F, Grogan H, et al. 2014. Research on Health Effects of Low-Level Ionizing Radiation Exposure: Opportunities for the Armed Forces Radiobiology Research Institute. Washington, DC:National Academy of Sciences.

Independent Petroleum Assocation of America. 2018. Review and analysis of key public health indicators in Colorado's largest oil and gas producing county.

International Agency for Research on Cancer. 2010. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals: Volume 100F. Lyon, France:IARC.

International Agency for Research on Cancer. 2012. IARC: Diesel Engine Exhaust Carcinogenic. Press Release N° 213. Lyon, France:IARC.

Kaden D, Rose T. 2015. Environmental and Health Issues in Unconventional Oil and Gas Development. Elsevier, Inc.

Kirkeleit J, Riise T, Bråtveit M, Moen BE. 2008. Increased risk of acute myelogenous leukemia and multiple myeloma in a historical cohort of upstream petroleum workers exposed to crude oil. Cancer Causes Control 19:13-23.

Koehler K, Ellis JH, Casey JA, Manthos D, Bandeen-Roche K, Platt R, Schwartz BS. 2018. Exposure Assessment Using Secondary Data Sources in Unconventional Natural Gas Development and Health Studies. Environmental science & technology 52:6061–6069.

League of Women Voters of Pennsylvania. 2015. Shale Gas Extraction and Public Health: A Resource Guide-- 2015 Update to Addendum. Harrisburg, PA: League of Women Voters of Pennsylvania.

Lewis AS, Sax SN, Wason SC, Campleman SL. 2011. Non-chemical stressors and cumulative risk assessment: an overview of current initiatives and potential air pollutant interactions. Int J Environ Res Public Health 8:2020–2073.

Long CM. 2016. Marcellus Shale Development: Analysis of Air Quality Data and Public Health Studies. Gradient. Cambridge, MA.

McCoy D, Saunders P. 2015. Health and Fracking: The Impacts and Opportunity Costs. London:Medact. Available: http://www.medact.org/resources/health-fracking-report/.

McCoy D, Saunders P. 2018. Fracking and health. BMJ 361.

McDermott-Levy R, Kaktins N, Sattler B. 2013. Fracking, the environment, and health. American Journal of Nursing 113:45–51.

Meng Q. 2015. Spatial analysis of environment and population at risk of natural gas fracking in the state of Pennsylvania, USA. Sci Total Environ 515–516:198–206.

Mitchell AL. 2013. Analysis of health and environmental risks associated with Marcellus Shale development. Paper 267. Pittsburgh, PA:Carnegie Mellon University.

Mitka M. 2012. Rigorous evidence slim for determining health risks from natural gas fracking. JAMA 307:2135–2136.

Korfmacher KS, Jones WA, Malone SL, Vinci LF. 2013. Public health and high volume hydraulic fracturing. New Solut 23:13–31.

Kovats S, Depledge M, Haines A, Fleming LE, Wilkinson P, Shonkoff SB, et al. 2014. The health implications of fracking. Lancet 383:757–758.

Kravchenko J, Darrah T, Miller R, Lyerly HK, Vengosh A. 2014. A review of the health impacts of barium from natural and anthropogenic exposure. Environ Geochem Health 36:797–814.

Nielsen NR, Kristensen TS, Schnohr P, Gronbaek M. 2008. Perceived stress and cause-specific mortality among men and women: results from a prospective cohort study. Am J Epidemiol 168:481–491.

Nuckols JR, Ward MH, Jarup L. 2004. Using geographic information systems for exposure assessment in environmental epidemiology studies. Environ Health Perspect 112:1007–1015.

Pride KR, Peel JL, Robinson BF, Busacker A, Grandpre J, Bisgard KM, Yip FY, Murphy TD. 2015. Association of short-term exposure to ground-level ozone and respiratory outpatient clinic visits in a rural location – Sublette County, Wyoming, 2008–2011. Environ Res 137:1-7, doi: 10.1016/j.envres.2014.10.033.

Saberi P. 2013. Navigating medical issues in shale territory. New Solut 23:209–221.

Seguljic TS, Martin JP. 2016. Air Regulation Requirements in the Marcellus and Utica Shale Region: Management Approaches and Case Study. Environmental Quality Management 26:73-87.

Sipes NS, Padilla S, Knudsen TB. 2011. Zebrafish: as an integrative model for twenty-first century toxicity testing. Birth Defects Res C Embryo Today 93:256–267.

Southwest Pennsylvania Environmental Health Project (SWPA EHP). 2013. Health Issues and Concerns Related to Unconventional Gas Development. McMurray, PA:SWPA-EHP. Available: http://www.environmentalhealthproject.org/wp-content/uploads/2013/09/6.13.13-general.pdf.

Srebotnjak T, Rotkin-Ellman M. 2014. Fracking Fumes: Air Pollution from Hydraulic Fracturing Threatens Public Health and Communities. Washington, DC:Natural Resources Defense Council.

Steinzor N, Subra W, Sumi L. 2012. Gas Patch Roulette: How Shale Gas Development Risks Public Health in Pennsylvania. Washington, DC:Earthworks. Available: https://www.earthworksaction.org/files/publications/Health-Report-Full-FINAL-sm.pdf.

Tuller D. 2015. As fracking booms, dearth of health risk data remains. Health Aff (Millwood) 34:903–906.

Veiguela M, Hurtado A, Eguilior S, Recreo F, Roqueñi N, Loredo J. 2016. A risk assessment tool applied to the study of shale gas resources. Science of The Total Environment 571:551-560.

Ward H, Eykelbosh A, Nicol A-M. 2016. Addressing uncertainty in public health risks due to hydraulic fracturing. Environmental Health Review 59:57-61.

Wright RJ. 2011. Epidemiology of stress and asthma: from constricting communities and fragile families to epigenetics. Immunol Allergy Clin North Am 31:19–39.

OIL AND GAS WORKER HEALTH

Alexander BM, Esswein EJ, Gressel MG, Kratzer JL, Amy Feng H, King B, Miller AL, Cauda E. 2016. The development and testing of a prototype mini-baghouse to control the release of respirable crystalline silica from sand movers. J Occup Environ Hyg; doi: 101080/1545962420161168239.

Allard DJ. 2015. Pennsylvania's technologically enhanced, naturally occurring radioactive material experiences and studies of the oil and gas industry. Health Phys 108:178.

Argonne National Laboratory, Veil JA, Puder MG, Elcock D, Robert J. Redweik J. 2004. A White Paper Describing Produced Water from Production of Crude Oil, Natural Gas, and Coal Bed Methane. U.S. Department of Energy, National Energy Technology Laboratory. Available: http://www.netl.doe.gov/KMD/cds/disk23/D-Water%20Management%20Projects/Produced%20Water/W-31-109-ENG-38/pw%20white%20paper.pdf.

Bamberger M, Oswald R. 2014. The Shale Gas Revolution from the Viewpoint of a Former Industry Insider. New Solut 1:1–16.

Blackley DJ, Retzer KD, Hubler WG, Hill RD, Laney AS. 2014. Injury rates on new and old technology oil and gas rigs operated by the largest United States onshore drilling contractor. Am J Ind Med 57:1188–1192.

Blair BD, Brindley S, Dinkeloo E, McKenzie LM, Adgate JL. 2018. Residential noise from nearby oil and gas well construction and drilling. Journal of Exposure Science & Environmental Epidemiology.

Blair BD, McKenzie LM, Allshouse WB, Adgate JL. 2017. Is reporting "significant damage" transparent? Assessing fire and explosion risk at oil and gas operations in the United States. Energy Research & Social Science 29:36-43.

Bloomdahl R, Abualfaraj N, Olson M, Gurian PL. 2014. Assessing worker exposure to inhaled volatile organic compounds from Marcellus Shale flowback pits. J Nat Gas Sci Eng 21:348–356.

Broni-Bediako E, Amorin R. 2010. Effects of drilling fluid exposure to oil and gas workers presented with major areas of exposure and exposure indicators. Research Journal of Applied Sciences, Engineering and Technology 2:710–719.

Chen H, Carter KE. 2017. Modeling potential occupational inhalation exposures and associated risks of toxic organics from chemical storage tanks used in hydraulic fracturing using AERMOD. Environ Pollut 224:300-309.

Desrosiers TA, Herring AH, Shapira SK, Hooiveld M, Luben TJ, Herdt-Losavio ML, Lin S, Olshan AF, Study tNBDP. 2012. Paternal occupation and birth defects: findings from the National Birth Defects Prevention Study. Occupational and Environmental Medicine 69:534-542.

Durant B, Abualfaraj N, Olson MS, Gurian PL. 2016. Assessing dermal exposure risk to workers from flowback water during shale gas hydraulic fracturing activity. Journal of Natural Gas Science and Engineering 34:969-978.

Esswein EJ, Alexander-Scott M, Snawder J, Breitenstein M. 2018. Measurement of area and personal breathing zone concentrations of diesel particulate matter (dpm) during oil and gas extraction operations, including hydraulic fracturing. Journal of Occupational and Environmental Hygiene 15:63-70.

Esswein EJ, Breitenstein M, Snawder J, Kiefer M, Sieber WK. 2013. Occupational exposures to respirable crystalline silica during hydraulic fracturing. J Occup Environ Hyg 10:347–356.

Esswein EJ, Snawder J, King B, Breitenstein M, Alexander-Scott M, Kiefer M. 2014. Evaluation of some potential chemical exposure risks during flowback operations in unconventional oil and gas extraction: preliminary results. J Occup Environ Hyg 11:D174–D184.

Esswein EJ, Hill R. 2013. Keeping up with the oil and gas rush: NIOSH seeks to improve worker safety and health in the U.S. upstream oil and gas industry. The Synergist June/July 2013:24–27.

Fan ZJ, Bonauto DK, Foley MP, Silverstein BA. 2006. Underreporting of work-related injury or illness to workers' compensation: individual and industry factors. J Occup Environ Med 48:914–922.

Fedan JS, Thompson JA, Russ KA, Roberts JR, Schwegler-Berry D, Mercer RR. 2018. Interaction of Respirable Fracking Sand Dust (FSD) with Pulmonary Tissues In vivo and In vitro. FASEB J 32:2.

Fedan JS, Thompson JA, Russ KA, Newcomer D, McKinney W, Cumpston AM, Jackson MC, Reynolds JS. 2017. In vivo and In Vitro Effects of Work Site Fracking Sand Dust (FSD) Inhalation on Rat Lung: Dose- and Time-Response Evaluation. FASEB J 31:1.

Franks CM. Too Little Too Late: The Infeasibility of OSHA's Silica Standards in the Oil Industry. St Mary's Law Journal 49:17.

Gabbay DS, De Roos F, Perrone J. 2001. Twenty-foot fall averts fatality from massive hydrogen sulfide exposure. J Emerg Med 20:141–144.

Gilman J, Lerner B, Kuster W, De Gouw J. 2013. Source signature of volatile organic compounds from oil and natural gas operations in northeastern Colorado. Environ Sci Technol 47:1297–1305.

Givehchi S, Zohdirad H, Ebadi T. 2016. Utilization of regression technique to develop a predictive model for hazard radius from release of typical methane-rich natural gas. J Loss Prev Process Ind 44:24-30.

Gligor A, Petrescu V, Deac C, Bibu M. 2016. Determining the explosion risk level and the explosion hazard area for a group of natural gas wells. In: 20th Innovative Manufacturing Engineering and Energy Conference. (Maropoulos S, Kyratsis P, Kakoulis K, Taousanidis N, Oancea G, Dodun O, eds.).

Goldenberg S, Shoveller J, Koehoorn M, Ostry A. 2008. Barriers to STI testing among youth in a Canadian oil and gas community. Health Place 14:718–729.

Goldenberg SMBAM, Shoveller JAP, Ostry ACP, Koehoorn MP. 2008. Sexually transmitted infection (STI) testing among young oil and gas workers: the need for innovative, place-based approaches to STI control. Can J Public Health 99:350–354.

Guidotti TL. 1994. Occupational exposure to hydrogen-sulfide in the sour gas-industry - some unresolved issues. Int Arch Occup Environ Health 66:153–160.

Guidotti TL. 2010. Hydrogen sulfide: advances in understanding human toxicity. Int J Toxicol 29:569–581.

Harrison R, Retzer K, Kosnett MJ, Hodgson M, Jordan T, Ridl S, et al. 2016. Sudden Deaths Among Oil and Gas Extraction Workers Resulting from Oxygen Deficiency and Inhalation of Hydrocarbon Gases and Vapors — United States, January 2010–March 2015. MMWR Morb Mortal Wkly Rep 65:6–9.

Heinecke J, Jabbari N, Meshkati N. 2014. The role of human factors considerations and safety culture in the safety of hydraulic fracturing (fracking). Journal of Sustainable Energy Engineering 2:130–151.

Hendler A, Nunn J, Lundeen J, McKaskle R. 2006. VOC Emissions from Oil and Condensate Storage Tanks. Prepared for Houston Advanced Research Center. The Woodlands, TX:HARC.

Hendrickson RG, Chang A, Hamilton RJ. 2004. Co-worker fatalities from hydrogen sulfide. Am J Ind Med 45:346–350.

Khan F. 2011. Take home lead exposure in children of oil field workers. J Okla State Med Assoc 104:252–253.

King B, Esswein E, Retzer K, Snawder J, Ridl S, Breitenstein M, et al. 2015. UPDATE: Reports of Worker Fatalities during Manual Tank Gauging and Sampling in the Oil and Gas Extraction Industry. National Institute of Occupation Safety and Health. Available: http://blogs.cdc.gov/niosh-science-blog/2015/04/10/flowback-3/.

Kirkeleit J, Riise T, Bråtveit M, Moen BE. 2008. Increased risk of acute myelogenous leukemia and multiple myeloma in a historical cohort of upstream petroleum workers exposed to crude oil. Cancer Causes Control 19:13–23.

Liu JC, Jiang JL, Mei L, Liu JM, Wang Y. 2016. Study on Prediction for Fracturing Operation noise and Impact Assessment.

Marquié J-C, Tucker P, Folkard S, Gentil C, Ansiau D. 2014. Chronic effects of shift work on cognition: findings from the VISAT longitudinal study. Occup Environ Med 72:258–264.

Mason KL, Retzer KD, Hill R, Lincoln JM. 2015. Occupational fatalities during the oil and gas boom - United States, 2003-2013. MMWR Morb Mortal Wkly Rep 64:551–554.

McKenzie LM, Guo R, Witter RZ, Savitz DA, Newman LS, Adgate JL. 2014. Birth outcomes and maternal residential proximity to natural gas development in rural Colorado. Environ Health Perspect 122:412–417.

McKenzie LM, Witter RZ, Newman LS, Adgate JL. 2012. Human health risk assessment of air emissions from development of unconventional natural gas resources. Sci Total Environ 424:79–87.

Mulloy KB. 2014. Occupational Health and Safety Considerations in Oil and Gas Extraction Operations. The Bridge: Linking Engineering and Science 44:41–46.

National Institute for Occupational Safety and Health. 2010. NIOSH Field Effort to Assess Chemical Exposure Risks to Gas and Oil Workers. Cincinnati, OH:NIOSH. Available: http://www.cdc.gov/niosh/docs/2010-130/pdfs/2010-130.pdf.

Occupational Safety and Health Administration. 2018. Preventing hearing loss caused by chemical (ototoxicity) and noise exposure. 2018-124.Occupational Safety and Health Administration Centers for Disease Control and Prevention.

Occupational Safety and Health Administration. 2005. Hydrogen Sulfide (H2S). Washington, DC:OSHA. Available: https://www.osha.gov/OshDoc/data_Hurricane_Facts/hydrogen_sulfide_fact.pdf.

Occupational Safety and Health Administration. 2014. Hydraulic Fracturing and Flowback Hazards Other than Respirable Silica. OSHA 3763-12 2014. Washington, DC:OSHA. Available: https://www.osha.gov/Publications/OSHA3763.pdf.

Olawoyin R. 2015. Modelling the health risks of exposure to respirable crystalline silica from hydraulic fracturing operations in the USA shale plays. Journal of Biomedical Engineering and Informatics 1:25–34.

Pétron G, Frost G, Miller BR, Hirsch AI, Montzka SA, Karion A, et al. 2012. Hydrocarbon emissions characterization in the Colorado Front Range: A pilot study. J Geophys Res 117; D04304, doi:101029/2011JD016360.

Poinen-Rughooputh S, Rughooputh MS, Guo Y, Rong Y, Chen W. 2016. Occupational exposure to silica dust and risk of lung cancer: an updated meta-analysis of epidemiological studies. BMC public health 16:1137.

Pride KR, Peel JL, Robinson BF, Busacker A, Grandpre J, Bisgard KM, Yip FY, Murphy TD. 2015. Association of short-term exposure to ground-level ozone and respiratory outpatient clinic visits in a rural location – Sublette County, Wyoming, 2008–2011. Environ Res 137:1-7, doi: 10.1016/j.envres.2014.10.033.

Quail MT. 2017. Overview of silica-related clusters in the united states: Will fracking operations become the next cluster? J Environ Health 79:20-27.

Radtke C, Autenrieth DA, Lipsey T, Brazile WJ. 2017. Noise Characterization of Oil and Gas Operations. J Occup Environ Hyg:0.

Rahman HH, Johnson GT, Harbison RD. 2016. Occupational Health Surveillance: Pulmonary Function Test in Proppant Exposures. Occupational Diseases and Environmental Medicine 4:37.

Retzer K, Ridl S, Hill R. 2014. Oil and gas extraction worker fatalities, 2014 mid-year report. DHHS (NIOSH) Publication No. 2015-239. Denver, CO:U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

Retzer KD, Hill RD, Pratt SG. 2013. Motor vehicle fatalities among oil and gas extraction workers. Accid Anal Prev 51:168–174.

Rich AL, Patel JT, Al-Angari SS. 2016. Carbon Disulfide (CS_2) Interference in Glucose Metabolism from Unconventional Oil and Gas Extraction and Processing Emissions. Environmental Health Insights 10:51–57.

Rosenman KD. 2014. Hydraulic fracturing and the risk of silicosis. Clin Pulm Med 21:167–172.

Searl A, Galea KS. 2011. Toxicological Review of the Possible Effects Associated with Inhalation and Dermal Exposure to Drilling Fluid Production Streams. Edinburgh:Institute of Occupational Medicine. Available: http://www.iom-world.org/pubs/IOM_TM1104.pdf.

Skalny AV, Kaminskaya GA, Krekesheva TI, Abikenova SK, Skalnaya MG, Berezkina ES, Grabeklis AR, Tinkov AA. 2017. The level of toxic and essential trace elements in hair of petrochemical workers involved in different technological processes. Environ Sci Pollut Res 24:5576-5584.

Snawder J, Esswein EJ, King B, Breitenstein M, Alexander-Scott M, Retzer KD, et al. 2014. Reports of Worker Fatalities during Flowback Operations. NIOSH Science Blog,

Turcot A, Girard SA, Courteau M, Baril J, Larocque R. 2015. Noise-induced hearing loss and combined noise and vibration exposure. Occup Med (Lond) 65:238–244.

U.S. Bureau of Labor Statistics. 2014. Fatal and Nonfatal Occupational Injuries and Illnesses in the Oil and Gas Industry. Washington, DC:U.S. Department of Labor. Available: http://www.bls.gov/iif/oshwc/cfoi/osar0018.htm.

Wattenberg EV, Bielicki JM, Suchomel AE, Sweet JT, Vold EM, Ramachandran G. 2015. Assessment of the acute and chronic health hazards of hydraulic fracturing fluids. J Occup Environ Hyg 12:611–624.

Williams JF, Lundy JB, Chung KK, Chan RK, King BT, Renz EM, et al. 2014. Traumatic injuries incidental to hydraulic well fracturing: a case series. J Burn Care Res; doi:101097/BCR0000000000000219.

Witter RZ, Tenney L, Clark S, Newman LS. 2014. Occupational exposures in the oil and gas extraction industry: state of the science and research recommendations. Am J Ind Med 57:847–856.

INDIVIDUAL AND COMMUNITY WELL-BEING[2]

Alcorn J, Rupp J, Graham JD. 2017. Attitudes Toward "Fracking": Perceived and Actual Geographic Proximity. Review of Policy Research:n/a-n/a.

[2]This category excludes articles that are explicitly health related (e.g., community perceptions of health impacts), which can be found in the "General Health" Section.

Alter TR, Ooms T, Brasier K, McLaughlin D, Willits F, Tracewski S. 2010. Baseline Socioeconomic Analysis for the Marcellus Shale Development in Pennsylvania. Scranton/Wilkes-Barre:Institute for Public Policy & Economic Development.

Arnold G, Farrer B, Holahan R. 2018. How do landowners learn about high-volume hydraulic fracturing? A survey of eastern ohio landowners in active or proposed drilling units. Energy Policy 114:455-464.

Bacigalupi LM, Freudenberg WR. 1983. Increased mental health caseloads in an energy boomtown. Adm Ment Health 10(4):306–322.

Bamberger M, Oswald RE. 2012. Impacts of gas drilling on human and animal health. New Solut 22:51–77.

Bartik AW, Currie J, Greenstone M, Knittel CR. 2016. The Local Economic and Welfare Consequences of Hydraulic Fracturing.119.

Bastian E. 2017. Drilling and community consent: How oil and gas boards can address the public health threats posed by fracking. Minn L Rev 102:343.

BBC Research and Consulting, for Montana Board of Crime Control. 2013. Social Impacts of Oil and Gas Development on Eastern Montana Communities. Denver, CO:BBC Research and Consulting. Available: http://www.bbcresearch.com/images/Final_Report_07262013_R.pdf.

Berry EH, Krannich RS, Greider T. 1990. A longitudinal analysis of neighboring in rapidly changing rural places. J Rural Stud 6:175–186.

Boudet HS, Zanocco CM, Howe PD, Clarke CE. 2018. The Effect of Geographic Proximity to Unconventional Oil and Gas Development on Public Support for Hydraulic Fracturing. Risk Anal.

Boudet H, Bugden D, Zanocco C, Maibach E. 2016. The effect of industry activities on public support for 'fracking'. Environmental Politics 25:593-612.

Boudet H, Clarke C, Bugden D, Maibach E, Roser-Renouf C, Leiserowitz A. 2014. "Fracking" controversy and communication: using national survey data to understand public perceptions of hydraulic fracturing. Energy Policy 65:57–67.

Boyle MD, Soneja S, Quirós-Alcalá L, Dalemarre L, Sapkota AR, Sangaramoorthy T, Wilson S, Milton D, Sapkota A. 2017. A pilot study to assess residential noise exposure near natural gas compressor stations. PLOS ONE 12:e0174310.

Branch K, Hooper D, Thompson J. 1984. Guide to Social Assessment: A Framework for Assessing Social Change. Boulder, CO:Westview Press.

Brasier KJ, Filteau MR, McLaughlin DK, Jacquet J, Stedman RC, Kelsey TW, et al. 2011. Residents' perceptions of community and environmental impacts from development of natural gas in the Marcellus shale: a comparison of Pennsylvania and New York cases. J Rural Soc Sci 26:32–61.

Brown RB, Dorins SF, Krannich RS. 2005. The boom-bust-recovery cycle: dynamics of change in community satisfaction and social integration in Delta, Utah. Rural Sociol 70:28–49.

Brown RB, Geertsen HR, Krannich RS. 1989. Community satisfaction and social integration in a boom town: a longitudinal analysis. Rural Sociol 54:568–586.

Burri P. 2016. Unconventionals in Europe: Best Practice vs. Worst Case - The Conflict Between Facts and Public Perception. 23:377.

Cary Institute of Ecosystem Studies. 2012. Hydrofracking in Focus: What Every Citizen Needs to Know. Cary Institute, Millbrook, NY.

Casey JA, Goldman-Mellor S, Catalano R. 2018. Association between Oklahoma earthquakes and anxiety-related Google search episodes. Environmental Epidemiology 2:e016.

Choma BL, Hanoch Y, Currie S. 2016. Attitudes toward hydraulic fracturing: The opposing forces of political conservatism and basic knowledge about fracking. Glob Environ Change 38:108–117.

Christenson DP, Goldfarb JL, Kriner DL. 2017. Costs, benefits, and the malleability of public support for "Fracking". Energy Policy 105:407-417.

Christopherson S, Rightor N. 2015. Confronting An Uncertain Future: How US Communities are Responding to Shale Gas and Oil Development. In: Our Energy Future: Socioeconomic Implications and Policy Options for Rural America (Albrecht DE, ed). Oxford, UK and New York:Routledge, 40–60.

Christopherson S, Rightor N. 2011. A Comprehensive Economic Impact Analysis of Natural Gas Extraction in the Marcellus Shale. Working Paper (May, 2011) http://www. greenchoices.cornell.edu/downloads/development/marcellus/Marcellus_SC_NR. pdf. Available: http://greenchoices.cornell.edu/downloads/development/shale/Thinking_about_Economic_Consequences.pdf.

Clancy SA, Worrall F, Davies RJ, Gluyas JG. 2018. An assessment of the footprint and carrying capacity of oil and gas well sites: The implications for limiting hydrocarbon reserves. Science of the Total Environment 618:586-594.

Clarke CE, Bugden D, Hart PS, Stedman RC, Jacquet JB, Evensen DTN, Boudet HS. 2016. How geographic distance and political ideology interact to influence public perception of unconventional oil/natural gas development. Energy Policy 97:301-309.

Considine TJ. 2010. The Economic Impacts of the Marcellus Shale: Implications for New York, Pennsylvania, and West Virginia — A Report to the American Petroleum Institute. Laramie, WY:API. Available: http://www.api.org/~/media/files/policy/exploration/api-economic-impacts-marcellus-shale.pdf.

Cooley R, Casagrande D. 2017. MARCELLUS SHALE AS GOLDEN GOOSE The Discourse of Development and the Marginalization of Resistance in Northcentral Pennsylvania. Routledge, Abingdon.

Coons T, Walker R. 2008. Community Health Risk Analysis of Oil and Gas Impacts in Garfield County. Saccomanno Research Institute. Environment CDoPHa. Available from https://www.garfield-county.com/public-health/documents/1._COMMUNITY_HEALTH_RISK_ANALYSIS-(Complete_Report_16MB).pdf.

Cooper J, Stamford L, Azapagic A. 2016. Shale Gas: A Review of the Economic, Environmental, and Social Sustainability. Energy Technology 4:772-792.

Cortese CF. 1982. The impacts of rapid growth on local organizations and community services. In: Coping with Rapid Growth in Rural Communities (Weber B, Howell R, eds). Boulder, CO:Westview Press, 115–135.

Cortese CF, Jones B. 1977. The sociological analysis of boom towns. Western Sociological Review 8:76–90.

Crowe J, Ceresola R, Silva T. 2015. The influence of value orientations, personal beliefs, and knowledge about resource extraction on local leaders' positions on shale development. Rural Sociol 80:397–430.

Davidson DJ. 2018. Evaluating the effects of living with contamination from the lens of trauma: a case study of fracking development in Alberta, Canada. Envir Sociol 4:196-209.

Davidson DJ. 2018. Emotion, reflexivity and social change in the era of extreme fossil fuels. The British Journal of Sociology 0.

Davis LA, McLaughlin DK, Uberoi N. 2015. The Impact of Marcellus Shale Development on Health and Health Care: The Marcellus Impacts Project Report #2. Harrisburg, PA:The Center for Rural Pennsylvania. Available: http://www.rural.palegislature.us/documents/reports/Marcellus-Report-2-Health.pdf.

de Rijke K. 2018. Produced water, money water, living water: Anthropological perspectives on water and fracking. Wiley Interdiscip Rev-Water 5:8.

Dixon M. 1978. What Happened to Fairbanks? Effects of the Trans-Alaska Oil Pipeline on the Community of Fairbanks, Alaska. Boulder, CO:Westview Press.

Dodge J. 2016. Crowded Advocacy: Framing Dynamic in the Fracking Controversy in New York. VOLUNTAS: International Journal of Voluntary and Nonprofit Organizations:1-28.

Eaton E, Kinchy A. 2016. Quiet voices in the fracking debate: Ambivalence, nonmobilization, and individual action in two extractive communities (Saskatchewan and Pennsylvania). Energy Res Soc Sci; doi: 101016/jerss201605005.

Ecosystem Research Group. 2008. Sublette County Socioeconomic Impact Study: Phase I Final Report. Missoula, MT:Ecosystem Research Group. Available: http://www.sublettewyo.com/DocumentCenter/Home/View/392.

Edelstein MR. 1988. Contaminated Communities: The Social and Psychological Impacts of Residential Toxic Exposure. Boulder, CO:Westview Press.

Ellis C, Theodori GL, Petrzelka P, Jackson-Smith D, Luloff AE. 2016. Unconventional risks: The experience of acute energy development in the Eagle Ford Shale. Energy Res Soc Sci; doi: 101016/jerss201605006.

England JL, Albrecht SL. 1984. Boomtowns and social disruption. Rural Sociol 49:230–246.

Environmental Law Institute, Washington and Jefferson College Center for Energy Policy and Management. 2014. Getting the Boom Without the Bust: Guiding Southwest Pennsylvania Through Shale Gas Development. Washington, DC:Environmental Law Institute. Available: http://www.eli.org/research-report/getting-boom-without-bust-guiding-southwestern-pennsylvania-through-shale-gas-development.

Equitable Origin. 2015. Equitable Origin Standard for Shale Oil and Gas Operations Available: http://www.equitableorigin.org//eo100-standard/shale/.

Evensen D, Stedman R. 2016. Scale matters: variation in perceptions of shale gas development across national, state, and local levels. Energy Res Soc Sci; doi: 101016/jerss201606010.

Evensen D, Clarke C, Stedman R. 2014. A New York or Pennsylvania state of mind: social representations in newspaper coverage of gas development in the Marcellus Shale. J Environ Stud Sci 4:65–77.

Evensen D, Jacquet JB, Clarke CE, Stedman RC. 2014. What's the 'fracking' problem? One word can't say it all. The Extractive Industries and Society 1:130–136.

Fernando FN, Cooley DR. 2016. Socioeconomic system of the oil boom and rural community development in Western North Dakota. Rural Sociol; doi: 101111/ruso12100.

Fernando FN, Cooley DR. 2016. An Oil Boom's Effect on Quality of Life (QoL): Lessons from Western North Dakota. Applied Research in Quality of Life 11:1083-1115.

Fernando FN, Cooley DR. 2016. Attitudes toward shale oil development in western North Dakota: The role of place based community values in attitude formation. Journal of Rural Studies 46:132-146.

Ferrar KJ, Kriesky J, Christen CL, Marshall LP, Malone SL, Sharma RK, et al. 2013. Assessment and longitudinal analysis of health impacts and stressors perceived to result from unconventional shale gas development in the Marcellus Shale region. Int J Occup Environ Health 19:104–112.

Filteau MR. 2015. A localized masculine crisis: local men's subordination within the Marcellus shale region's masculine structure. Rural Sociol 80:431–455.

Finkel ML. 2015. The Human and Environmental Impact of Fracking: How Fracturing Shale for Gas Affects Us and Our World. ABC-CLIO.

Finkel ML, Selegean J, Hays J, Kondamudi N. 2013. Marcellus shale drilling's impact on the dairy industry in Pennsylvania: a descriptive report. New Solut 23:189–201.

Finley-Brook M, Williams TL, Caron-Sheppard JA, Jaromin MK. 2018. Critical energy justice in US natural gas infrastructuring. Energy Research & Social Science 41:176-190.

Fisher MP, Mayer A, Vollet K, Hill EL, Haynes EN. 2017. Psychosocial implications of unconventional natural gas development: Quality of life in Ohio's Guernsey and Noble counties. Journal of Environmental Psychology 55:90-98.

Flanagan K, Heitkamp T, Nedegaard RC, Jayasundara DS. 2014. Black gold and the dark underside of its development on human service delivery. Contemporary Rural Social Work 6:86–106.

Fleischman L, Kingland D, Maxwell C, Rios E. 2016. Latino Communities at Risk: The Impact of Air Pollution from the Oil and Gas Industry. Clean Air Task Force, League of United Latin American Citizens, National Hispanic Medical Association.

Forsyth CJ, Luthra AD, Bankston WB. 2007. Framing perceptions of oil development and social disruption. Soc Sci J 44:287–299.

Freudenburg WR. 1982. The impacts of rapid growth on the social and personal well-being of local community residents. In: Coping with rapid growth in rural communities (Weber B, Howell R, eds):Westview Press, 70.

Freudenburg WR. 1984. Boomtown's youth: the differential impacts of rapid community growth on adolescents and adults. Am Sociol Rev 49:697–705.

Freudenburg WR. 1986. The density of acquaintanceship: an overlooked variable in community research? Am J Sociol 92:27–63.

Freudenburg WR. 1997. Contamination, corrosion and the social order: an overview. Curr Sociol 45:19–39.

Freudenburg WR, Bacigalupi LM, Landoll-Young C. 1982. Mental health consequences of rapid community growth: a report from the longitudinal study of boomtown mental health impacts. Journal of Health and Human Services Administration 4:334–352.

Freudenburg WR, Jones RE. 1991. Criminal behavior and rapid community growth: examining the evidence. Rural Sociol 56:619–645.

Fry M, Brannstrom C, Sakinejad M. 2017. Suburbanization and shale gas wells: Patterns, planning perspectives, and reverse setback policies. Landscape and Urban Planning 168:9-21.

Gehman J, Thompson DY, Alessi DS, Allen DM, Goss GG. 2016. Comparative Analysis of Hydraulic Fracturing Wastewater Practices in Unconventional Shale Development: Newspaper Coverage of Stakeholder Concerns and Social License to Operate. Sustainability 8.

Gilmore JS, Duff MK. 1975. Boom Town Growth Management: A Case Study of Rock Springs-Green River, Wyoming. Boulder, CO:Westview Press.

Gold RL. 1985. Ranching, Mining, and the Human Impact of Natural Resources Development. Brunswick, NJ:Transaction Publishers.

Goldenberg S, Shoveller J, Ostry A, Koehoorn M. 2008. Youth sexual behaviour in a boomtown: implications for the control of sexually transmitted infections. Sex Transm Infect 84:220–223.

Gopalakrishnan S, Klaiber HA. 2014. Is the shale energy boom a bust for nearby residents? Evidence from housing values in Pennsylvania. Am J Agric Econ 96:43–66.

Gosnell H, Abrams J. 2011. Amenity migration: diverse conceptualizations of drivers, socioeconomic dimensions, and emerging challenges. GeoJournal 76:303–322.

Graham JD, Rupp JA, Schenk O. 2015. Unconventional gas development in the USA: exploring the risk perception issues. Risk Analysis 35:1770–1788.

Graham J, Irving J, Tang X, Sellers S, Crisp J, Horwitz D, et al. 2015. Increased traffic accident rates associated with shale gas drilling in Pennsylvania. Accid Anal Prev 74:203–209.

Graham Sustainability Institute. 2013. Economics Technical Report. Volume II, Report 7. Ann Arbor, MI:University of Michigan.

Graham Sustainability Institute. 2013. Public Perceptions Technical Report. Volume II, Report 8. Ann Arbor, MI:University of Michigan.

Gramling R, Freudenburg WR. 1992. Opportunity-threat, development, and adaptation: toward a comprehensive framework for social impact assessment. Rural Sociol 57:216–234.

Greider T, Krannich RS. 1985. Neighboring patterns, social support, and rapid growth a comparison analysis from three western communities. Sociol Perspect 28:51–70.

Greider T, Krannich RS, Berry EH. 1991. Local identity, solidarity, and trust in changing rural communities. Sociol Focus 24:263–282.

Greider T, Little RL. 1988. Social action and social impacts: subjective interpretation of environmental change. Soc Nat Resour 1:45–55.

Greider TR, Krannich RS. 1985. Perceptions of problems in rapid growth and stable communities: a comparative analysis. J Community Dev Soc 16:80–96.

Greiner L. 2017. To frack or not to frack: Understanding community concerns about health and hydraulic fracturing. Boston, MA:Boston University.

Guillaume CL, Wenson SR. 1980. Child abuse in impact communities. In: The Boom Town: Problems and Promises of the Energy Vortex (Davenport III J, Davenport J, eds). Laramie, WY:Department of Social Work, University of Wyoming, 85–98.

Habib S, Hinojosa MS, Hinojosa R. 2017. Societal Implications of Unconventional Oil and Gas Development. In: Advances in Chemical Pollution, Environmental Management and Protection. Elsevier.

Hagström EL, Berkman MP. 2015. The Legal and Economic Implications of Hydraulic Fracturing Bans. In: Hydraulic Fracturing: Environmental Issues:American Chemical Society, 181–196. Available: http://dx.doi.org/10.1021/bk-2015-1216.ch008.

Hammer RB, Winkler RL. 2006. Housing affordability and population change in the upper midwestern North Woods. In: Population Change and Rural Society (Kandel WA, Brown DL, eds). Dordrecht:Springer, 293-309.

Hansen E, Cushing L, Betcher M, Thomas C. 2017. In Everyone's Backyard: Assessing Proximity of Fracking to Communities At-Risk in West Virginia's Marcellus Shale Morgantown, WV. Available from https://www.switzernetwork.org/sites/default/files/file-attachments/frackfinder_8-14-17_final_0.pdf.

Hastings K, Heller LR, Stephenson EF. 2015. Fracking and labor market conditions: a comparison of Pennsylvania and New York border counties. Eastern Econ J; doi:101057/eej201547.

Headwaters Economics. 2014. How Is Fracking Shaping Your Community and Economy? Recommendations for Monitoring and Measuring Socioeconomic Impacts. Bozeman, MT:Headwaters Economics. Available: http://headwaterseconomics.org/energy/western/energy-monitoring-practices#summary.

Hearne RR, Fernando F. 2016. Strategies for Community and Industry Water Management in the Oil Producing Region of North Dakota. Water 8:12.

Hedding KJ. 2017. Sources and Framing of Fracking: A Content Analysis of Newspaper Coverage in North Carolina, New York, and Pennsylvania. Environmental Communication-a Journal of Nature and Culture 11:370-385.

Heuer MA, Lee ZC. 2014. Marcellus shale development and the Susquehanna River: an exploratory analysis of cross-sector attitudes on natural gas hydraulic fracturing. Organ Environ 27:25–42.

Ho JS, Shih J-S, Muehlenbachs LA, Munnings C, Krupnick AJ. 2018. Managing environmental liability: An evaluation of bonding requirements for oil and gas wells in the united states. Environmental Science & Technology.

Hoffmann HM. 2017. Fracking the sacred: Resolving the tension between unconventional oil and gas development and tribal cultural resources. Denver Law Rev 94:319-362.

Hopke JE. 2016. Translocal anti-fracking activism: an exploration of network structure and tie content. Environmental Communication-a Journal of Nature and Culture 10:380-394.

Howell EL, Li N, Akin H, Scheufele DA, Xenos MA, Brossard D. 2017. How do US state residents form opinions about 'fracking' in social contexts? A multilevel analysis. Energy Policy 106:345-355.

Hübner A, Horsfield B, Kapp I. 2013. Fact-based communication: the Shale Gas Information Platform SHIP. Environ Earth Sci 70:3921–3925.

Hunter LM, Boardman JD, Onge JMS. 2005. The association between natural amenities, rural population growth, and long-term residents' economic well-being. Rural Sociol 70:452–469.

Hunter LM, Krannich RS, Smith MD. 2002. Rural migration, rapid growth, and fear of crime. Rural Sociol 67:71–89.

IPIECA. 2015. Community grievance mechanisms in the oil and gas industry: a manual for implementing operational-level grievance mechanisms and designing corporate frameworks. London:IPIECA.

Irwin MD, Pischke EC. 2016. Socio-spatial Holes in the Advocacy Umbrella: The Spatial Diffusion of Risk and Network Response Among Environmental Organizations in the Marcellus Hydro-fracturing Region. In: Recapturing Space: New Middle-Range Theory in Spatial Demography. (Howell FM, Porter JR, Matthews SA, eds.), pp. 199-233. Springer International Publishing, Cham.

Jacquet JB, Junod AN, Bugden D, Wildermuth G, Fergen JT, Jalbert K, Rahm B, Hagley P, Brasier KJ, Schafft K, Glenna L, Kelsey T, Fershee J, Kay DL, Stedman RC, Ladlee J. 2018. A decade of Marcellus Shale: Impacts to people, policy, and culture from 2008 to 2018 in the Greater Mid-Atlantic region of the United States. The Extractive Industries and Society.

Jacquet J, Kay DL. 2014. The unconventional boomtown: updating the impact model to fit new spatial and temporal scales. J Rural Community Dev 9:1–23.

Jacquet JB. 2014. Review of risks to communities from shale energy development. Environ Sci Technol 48:8321–8333.

Jacquet JB, Stedman RC. 2013. The risk of social-psychological disruption as an impact of energy development and environmental change. J Environ Plan Manage 57(9):1285–1304.

Jacquet JB. 2013. Risks to Communities from Shale Gas Development. Presented at Workshop on Risks of Unconventional Shale Gas Development, 30–31 May 2013, Washington, DC:National Research Council.

Jacquet J. 2009. Energy Boomtowns & Natural Gas: Implications for Marcellus Shale Local Governments & Rural Communities. Paper No. 43. Northeast Regional Center for Rural Development. University Park, PA:Pennsylvania State University.

Jalbert K, Rubright SM, Edelstein K. 2017. The civic informatics of fractracker alliance: Working with communities to understand the unconventional oil and gas industry. Engaging Science, Technology, and Society 3:528-559.

James A, Smith B. 2017. There will be blood: Crime rates in shale-rich US counties. JEnvironEconManage 84:125-152.

Jerolmack C BN. 2016. Fracking Communities. Public Culture 28:193-214.

Jenkins J, Boone K, Bosworth K, Lehman J, Loder T. 2015. Boom and bust methodology: opportunities and challenges with conducting research at sites of resource extraction. The Extractive Industries and Society; doi:101016/jexis201507001 [Online 17 July 2015].

Johnston JE, Werder E, Sebastian D. 2016. Wastewater Disposal Wells, Fracking, and Environmental Injustice in Southern Texas. Am J Public Health 106:550-556.

Junod AN, Jacquet JB, Fernando F, Flage L. 2018. Life in the goldilocks zone: Perceptions of place disruption on the periphery of the bakken shale. Society & Natural Resources 31:200-217.

Kellison TB, Bunds KS, Casper JM, Newman JI. 2017. Public parks usage near hydraulic fracturing operations. Journal of Outdoor Recreation and Tourism 18:75-80.

Kinchy A. 2016. Citizen Science and Democracy: Participatory Water Monitoring in the Marcellus Shale Fracking Boom. Science as Culture:1-23.

Kinchy A, Perry S, Rhubart D, Brasier K, Jacquet J. 2014. New natural gas development and rural communities: Key issues and research priorities. In: Rural America in a Globalizing World: Problems and Prospects for the 2010s (Bailey C, Jensen L, Ransom E, eds). Morgantown, WV:West Virginia University Press.

Kolb B, Williamson J. 2012. Environmental reviews and case studies: water and sewer infrastructure challenges as a barrier to housing development in the Marcellus shale region. Environ Pract 14:332–341.

Komarek TM. 2018. Crime and natural resource booms: evidence from unconventional natural gas production. Ann Reg Sci 61:113-137.

Konkel L. 2017. In the neighborhood of 18 million: Estimating how many people live near oil and gas wells. Environmental health perspectives 125:124003.

Korfmacher K, Hawker JS, Winebrake J. 2015. Analysis of Environmental and Infrastructure Impacts of Transportation Activities Associated with High Volume Hydraulic Fracturing Operations in the Marcellus Shale Formation. Presented at Transportation Research Board 94th Annual Meeting, 10–14 January 2015, Washington, DC:Transportation Research Board.

Krannich RS. 2012. Social change in natural resource-based rural communities: the evolution of sociological research and knowledge as influenced by William R. Freudenburg. J Environ Stud Sci 2:18–27.

Krannich RS, Greider T. 1984. Personal well-being in rapid growth and stable communities: multiple indicators and contrasting results. Rural Sociol 49:541–552.

Krannich RS, Greider T, Little RL. 1985. Rapid growth and fear of crime: a four-community comparison. Rural Sociol 50(2):193–209.

Krannich RS, Luloff AE, Field DR. 2011. People, Places and Landscapes: Social Change in High Amenity Rural Areas. New York:Springer.

Krannich RS, Robertson PG, Olson SK. 2015. Renewable energy in the United States. In: Our Energy Future: Socioeconomic Implications and Policy Options for Rural America (Albrecht DE, ed). London:Routledge, 125.

Krause A, Bucy EP. 2018. Interpreting images of fracking: How visual frames and standing attitudes shape perceptions of environmental risk and economic benefit. Environmental Communication-a Journal of Nature and Culture 12:322-343.

Kriesky J. 2014. Socioeconomic Change and Human Stress Associated with Shale Gas Extraction.

Kroll-Smith JS, Couch SR. 1990. The Real Disaster is Above Ground: A Mine Fire and Social Conflict. Lexington, KY:University Press of Kentucky.

Kroll-Smith JS, Couch SR, Levine AG. 2002. Technological hazards and disasters. In: Handbook of Environmental Sociology (Dunlap RE, Michelson W, eds). Westport, CT:Greenwood Press, 295–328.

Krupnick AJ, Siikamäki J. 2014. Would You Pay to Reduce Risks from Shale Gas Development? Public Attitudes in Pennsylvania and Texas. 185:38-43.Resources for the Future, Washington, DC.

Kuwayama Y, Olmstead S, Krupnick A. 2013. Water Resources and Unconventional Fossil Fuel Development — Linking Physical Impacts to Social Costs. RFF DP 13-34. Washington, DC:Resources for the Future.

Ladd AE. 2013. Stakeholder Perceptions of Socioenvironmental Impacts from Unconventional Natural Gas Development and Hydraulic Fracturing in the Haynesville Shale. J Rural Soc Sci 28:56–89.

Ladd AE. 2014. Environmental disputes and opportunity-threat impacts surrounding natural gas fracking in Louisiana. Soc Curr 1:293–311.

Lai PH, Lyons KD, Gudergan SP, Grimstad S. 2017. Understanding the psychological impact of unconventional gas developments in affected communities. Energy Policy 101:492-501.

Lantz A, Sackett K, Halpern J. 1980. Alcohol-related problems in rapidly growing communities. In: Boom Towns: Problems and Promises in the Energy Vortex (Davenport III J, Davenport J, eds). Laramie, WY:University of Wyoming Department of Social Work, 71–83.

Leistritz FL, Murdock SH, Leholm AG. 1982. Local economic changes associated with rapid growth. In: Coping with Rapid Growth in Rural Communities (Weber BA, Howell RE, eds). Boulder, CO:Westview Press, 25–62.

Lendel I. 2014. Social Impacts of Shale Development on Municipalities. The Bridge: Linking Engineering and Science 44:47–51.

Leonard R, McCrea R, Walton A. 2016. Perceptions of community responses to the unconventional gas industry: The importance of community agency. Journal of Rural Studies 48:11-21.

Livy MR, Gopalakrishnan S, Klaiber HA, Roe BE. 2018. The impact of intensity on perceived risk from unconventional shale gas development. J Environ Manage 218:630-638.

Loh CG, Osland AC. 2016. Local land use planning responses to hydraulic fracturing. J Am Plann Assoc; doi: 101080/0194436320161176535.

Lorig R. 2016. Noise Mapping: Modeling Chronic Natural Gas Compressor Noise across Pennsylvania State Forests in the Marcellus Shale Formation. Pennsylvania State University. University Park, PA. Available from https://gis.e-education.psu.edu/sites/default/files/capstone/Lorig_596B_20160601.pdf.

Macnaghten P. 2017. Distrust for fracking. Nat Energy 2:2.

Maguire K, Winters JV. 2017. Energy boom and gloom? Local effects of oil and natural gas drilling on subjective well-being. Growth Change 48:590-610.

Malin SA, DeMaster KT. 2016. A devil's bargain: Rural environmental injustices and hydraulic fracturing on Pennsylvania's farms. Journal of Rural Studies; doi: 101016/jjrurstud201512015.

Mando J. 2016. Constructing the vicarious experience of proximity in a Marcellus Shale public hearing. Environmental Communication 10:352-364.

Maniloff P, Mastromonaco R. 2017. The local employment impacts of fracking: A national study. Resource and Energy Economics 49:62-85.

Marré A, Pender J. 2013. The distribution of household net worth within and across rural areas: are there links to the natural resource base? Am J Agric Econ 95:457–462.

Maryland Institute for Applied Environmental Health. 2014. Potential Public Health Impacts of Natural Gas Development and Production in the Marcellus Shale in Western Maryland. College Park, MD:School of Public Health, University of Maryland.

Mayer A, Malin SA, Olson-Hazboun SK. 2018. Unhollowing rural America? Rural human capital flight and the demographic consequences of the oil and gas boom. Popul Env 39:219-238.

Mayer A. 2017. Quality of life and unconventional oil and gas development: Towards a comprehensive impact model for host communities. The Extractive Industries and Society.

Mayer A. 2016. Risk and benefits in a fracking boom: Evidence from Colorado. Extr Ind Soc 3:744-753.

McGranahan DA, Fernando FN, Kirkwood MLE. 2017. Reflections on a boom: Perceptions of energy development impacts in the Bakken oil patch inform environmental science & policy priorities. Sci Total Environ 599-600:1993-2018.

McHenry KA. 2017. Fracking Women: A Feminist Critical Analysis of Hydraulic Fracturing in Pennsylvania. IJFAB: International Journal of Feminist Approaches to Bioethics 10:79-104.

McKenzie LM, Allshouse WB, Burke T, Blair BD, Adgate JL. 2016. Population Size, Growth, and Environmental Justice Near Oil and Gas Wells in Colorado. Environmental science & technology 50:11471-11480.

McKeown RL, Lantz A. 1977. Rapid Growth and the Impact on Quality of Life in Rural Communities: A Case Study. Denver, CO:Denver Research Institute.

McLaughlin DM, Cutts BB. 2018. Neither Knowledge Deficit nor NIMBY: Understanding Opposition to Hydraulic Fracturing as a Nuanced Coalition in Westmoreland County, Pennsylvania (USA). Environmental Management.

Meng QM. 2018. Fracking equity: A spatial justice analysis prototype. Land Use Pol 70:10-15.

Molinatti G, Simonneau L. 2015. A socioenvironmental shale gas controversy: scientists' public communications, social responsibility and collective versus individual positions. Sci Commun 37:190–216.

Mount DJ, Kelsey TW, Brasier KJ. 2014. The Impact of Marcellus Shale Development on Hotel Revenues in Pennsylvania. Penn State School of Hospitality Management. University Park, PA Available: http://extension.psu.edu/natural-resources/natural-gas/news/2014/10/the-impact-of-marcellus-shale-development-on-hotel-revenues-in-pennsylvania.

Muehlenbachs L, Spiller E, Timmins C. 2015. The Housing Market Impacts of Shale Gas Development. Am Econ Rev 105:3633–3659.

Muehlenbachs L, Krupnick A. 2013. Shale Gas Development Linked to Traffic Accidents in Pennsylvania. Washington, DC:Resources for the Future. Available: http://common-resources.org/2013/shale-gas-development-linked-to-traffic-accidents-in-pennsylvania/.

Muehlenbachs L, Spiller E, Timmins C. 2013. The Housing Market Impacts of Shale Gas Development. RFF DP 13-39. Washington, DC:Resources for the Future.

Murdock SH. 1999. Hazardous Wastes in Rural America: Impacts, Implications, and Options for Rural Communities. Lanham, MD:Rowman & Littlefield.

Murdock SH, Leistritz FL. 1979. Energy Development in the Western United States: Impact on Rural Areas. New York:Praeger.

Murphy T, Brannstrom C, Fry M. 2017. Ownership and Spatial Distribution of Eagle Ford Mineral Wealth in Live Oak County, Texas. Prof Geogr 69:616-628.

Murray JA, Weber BA. 1982. The impacts of rapid growth on the provision and financing of local public services. In: Coping with Rapid Growth in Rural Communities (Weber B, Howell R, eds). Boulder, CO:Westview Press, 97–114.

Neville KJ, Weinthal E. 2016. Mitigating Mistrust? Participation and Expertise in Hydraulic Fracturing Governance. Review of Policy Research 33:578-602.

North DW, Stern PC, Webler T, Field P. 2014. Public and stakeholder participation for managing and reducing the risks of shale gas development. Environ Sci Technol 48:8388–8396.

O'Connor CD, Fredericks K. 2018. Citizen perceptions of fracking: The risks and opportunities of natural gas development in Canada. Energy Research & Social Science 42:61-69.

Olive A, Valentine K. 2018. Is anyone out there? Exploring Saskatchewan's civil society involvement in hydraulic fracturing. Energy Research & Social Science 39:192-197.

Palmer RC, Short D, Auch WET. 2018. The Human Right to Water and Unconventional Energy. Int J Environ Res Public Health 15.

Paredes D, Komarek T, Loveridge S. 2015. Income and employment effects of shale gas extraction windfalls: Evidence from the Marcellus region. Energy Economics 47:112–120.

Partridge T, Thomas M, Pidgeon N, Harthorn BH. 2018. Urgency in energy justice: Contestation and time in prospective shale extraction in the United States and United Kingdom. Energy Research & Social Science 42:138-146.

Patterson LA, Maloney KO. 2016. Transport of hydraulic fracturing waste from Pennsylvania wells: A county-level analysis of road use and associated road repair costs. Journal of Environmental Management 181:353-362.

Penningroth SM, Yarrow MM, Figueroa AX, Bowen RJ, Delgado S. 2013. Community-based risk assessment of water contamination from high-volume horizontal hydraulic fracturing. New Solut 23:137–166.

Perry SL. 2012. Development, land use, and collective trauma: the Marcellus Shale gas boom in rural Pennsylvania. Culture, Agriculture, Food and Environment 34:81–92.

Perry SL. 2012. Environmental reviews and case studies: addressing the societal costs of unconventional oil and gas exploration and production: a framework for evaluating short-term, future, and cumulative risks and uncertainties of hydrofracking. Environ Pract 14:352–365.

Perry SL. 2013. Using ethnography to monitor the community health implications of onshore unconventional oil and gas developments: examples from Pennsylvania's Marcellus Shale. New Solut 23:33–53.

Peterson, CJ. 2018. Ambivalent landscapes: energy extraction and farming livelihoods in Weld County, CO (Doctoral dissertation, University of Colorado at Denver).

Phelan A, Jacobs S. 2016. Facing the true cost of fracking; social externalities and the role of integrated valuation. Ecosyst Serv 22:348-358.

Picou JS, Marshall BK, Gill DA. 2004. Disaster, litigation, and the corrosive community. Soc Forces 82:1493–1522.

Popkin JH, Duke JM, Borchers AM, Ilvento T. 2013. Social costs from proximity to hydraulic fracturing in New York State. Energy Policy 62:62–69.

Portney KE. 1991. Siting Hazardous Waste Treatment Facilities: The NIMBY Syndrome. New York:Auburn House.

Powers M, Saberi P, Pepino R, Strupp E, Bugos E, Cannuscio C. 2015. Popular epidemiology and "fracking": citizens' concerns regarding the economic, environmental, health and social impacts of unconventional natural gas drilling operations. J Community Health 40:534–541.

EPA-HQ-2019-460

Rabinowitz P, Slizovskiy I. 2014. Proximity to natural gas wells and reported health status: results of a household survey in Washington County, Pennsylvania. Environ Health Perspect 123:21–26.

Rich JL. 2016. Drilling Is Just the Beginning: Romanticizing Rust Belt identities in the campaign for shale gas. Environmental Communication-a Journal of Nature and Culture 10:292-304.

Resources for the Future. 2014. Shale Gas Development Linked to Traffic Accidents in Pennsylania. 6-7.Resources for the Future, Washington, DC.

Saberi P, Propert KJ, Powers M, Emmett E, Green-McKenzie J. 2014. Field survey of health perception and complaints of Pennsylvania residents in the Marcellus shale region. Int J Environ Res Public Health 11:6517–6527.

Sampson RJ. 1991. Linking the micro-and macrolevel dimensions of community social organization. Soc Forces 70:43–64.

Sampson RJ, Groves WB. 1989. Community structure and crime: testing social-disorganization theory. Am J Sociol 94:774–802.

Sangaramoorthy T, Jamison AM, Boyle MD, Payne-Sturges DC, Sapkota A, Milton DK, Wilson SM. 2016. Place-based perceptions of the impacts of fracking along the Marcellus Shale. Soc Sci Med 151:27–37.

Schafft K, Biddle C. 2015. Opportunity, ambivalence, and youth perspectives on community change in Pennsylvania's Marcellus shale region. Human Organization 74:74–85.

Schafft KA, Borlu Y, Glenna L. 2013. The relationship between Marcellus shale gas development in Pennsylvania and local perceptions of risk and opportunity. Rural Sociol 78:143–166.

Schafft KA, Glenna LL, Green B, Borlu Y. 2014. Local impacts of unconventional gas development within Pennsylvania's Marcellus shale region: gauging boomtown development through the perspectives of educational administrators. Soc Nat Resour 27:389–404.

Scott RP. 2018. Should we call the neighbors? Voluntary deliberation and citizen complaints about oil and gas drilling. Energy Policy 115:258-272.

Slovic P, Layman M, Kraus N, Flynn J, Chalmers J, Gesell G. 1991. Perceived risk, stigma, and potential economic impacts of a high-level nuclear waste repository in Nevada. Risk Anal 11:683–696.

Smith DC, Richards JM. 2015. Social License to Operate: Hydraulic Fracturing-Related Challenges Facing the Oil & Gas Industry. U Denver Legal Studies Research Paper No. 15-13. Westminster, CO:Rocky Mountain Mineral Law Foundation and International Bar Foundation. Available: http://ssrn.com/abstract=2591988.

Smith MD, Krannich RS, Hunter LM. 2001. Growth, decline, stability, and disruption: a longitudinal analysis of social Well-Being in four western rural communities. Rural Sociol 66:425–450.

Smith KR, Frumkin H, Balakrishnan K, Butler CD, Chafe ZA, Fairlie I, Kinney P, Kjellstrom T, Mauzerall DL, McKone TE, McMichael AJ, Schneider M. 2013. Energy and Human Health. Annu Rev Public Health 34:159-188.

Stedman RC, Jacquet JB, Filteau MR, Willits FK, Brasier KJ, McLaughlin DK. 2012. Marcellus shale gas development and new boomtown research: views of New York and Pennsylvania residents. Environ Pract 14:382–393.

Stedman RC, Patriquin MN, Parkins JR. 2012. Dependence, diversity, and the well-being of rural community: building on the Freudenburg legacy. J Environ Stud Sci 2:28–38.

Steinzor N, Subra W, Sumi L. 2012. Gas Patch Roulette: How Shale Gas Development Risks Public Health in Pennsylvania. Washington, DC:Earthworks. Available: https://www.earthworksaction.org/files/publications/Health-Report-Full-FINAL-sm.pdf.

ED_002185_00000045-00090

Steinzor N, Subra W, Sumi L. 2013. Investigating links between shale gas development and health impacts through a community survey project in Pennsylvania. New Solut 23:55–83.

Sumell, A. J. (2015). "Fracturing and foreclosure: A study of shale gas development and foreclosure levels in Pennsylvania." Housing Studies: 1-18.

Summers GF, Evans S, Clemente F, Beck E, Minkoff J. 1976. Industrial Invasion of Nonmetropolitan America. New York:Praeger.

Sumell AJ. 2015. Fracturing and foreclosure: a study of shale gas development and foreclosure levels in Pennsylvania. Hous Stud; doi:101080/0267303720151094031.

Theodori GL, Luloff A. 2015. Perceptions of Oil and Natural Gas Development in the Eagle Ford Shale: a Summary of Findings from a 2015 Survey. The Woodlands, TX:Houston Advanced Research Center. Available: http://efdsystems.org/pdf/Eagle_Ford_Shale_final_research_report.pdf.

Theodori GL, Luloff A, Willits FK, Burnett DB. 2013. Hydraulic Fracturing and the Management, Disposal, and Reuse of Frac Flowback Waters: Views from the General Public in the Pennsylvania Marcellus Shale Region. Final research report for the New York State Energy Research and Development Authority. Huntsville, TX: Center for Rural Studies, Sam Houston State University.

Theodori GL. 2009. Paradoxical perceptions of problems associated with unconventional natural gas development. Southern Rural Sociology 24:97–117.

Theodori GL, Wynveen BJ, Fox WE, Burnett DB. 2009. Public perception of desalinated water from oil and gas field operations: data from Texas. Soc Nat Resour 22:674–685.

Thomas M, Partridge T, Harthorn BH, Pidgeon N. 2017. Deliberating the perceived risks, benefits, and societal implications of shale gas and oil extraction by hydraulic fracturing in the US and UK. Nat Energy 2:7.

Thomas M, Pidgeon N, Evensen D, Partridge T, Hasell A, Enders C, Harthorn BH, Bradshaw M. 2017. Public perceptions of hydraulic fracturing for shale gas and oil in the United States and Canada. Wiley Interdiscip Rev-Clim Chang 8:19.

Veenstra AS, Lyons BA, Fowler-Dawson A. 2016. Conservatism vs. conservationism: differential influences of social identities on beliefs about fracking. Environmental Communication-a Journal of Nature and Culture 10:322-336.

Weber BA, Geigle J, Barkdull C. 2014. Rural North Dakota's oil boom and its impact on social services. Soc Work 59:62–72.

Weber JG. 2012. The effects of a natural gas boom on employment and income in Colorado, Texas, and Wyoming. Energy Economics 34:1580–1588.

Weber JG, Burnett J, Xiarchos IM. 2014. Shale Gas Development and Housing Values over a Decade: Evidence from the Barnett Shale. USAEE Working Paper No. 14-165.

Weigle JL. 2011. Resilience, community, and perceptions of Marcellus Shale development in the Pennsylvania wilds: reframing the discussion. Sociological Viewpoints 27:3.

Weisz R. 1979. Stress and mental health in a boom town. In: Boom Town and Human Services (Davenport III J, Davenport JA, eds). Laramie, WY:University of Wyoming, Department of Social Work.

Weisz R. 1980. Coping with stresses of a boom: mental health alternatives for impacted communities. In: The Boom Town: Problems and Promises of the Energy Vortex (Davenport III J, Davenport JA, eds). Laramie, WY:University of Wyoming, Department of Social Work, 55–69.

Wernham A. 2007. Inupiat health and proposed Alaskan oil development: results of the first integrated health impact assessment/environmental impact statement for proposed oil development on Alaska's North Slope. EcoHealth 4:500–513.

Williamson J, Kolb B. 2011. Marcellus Natural Gas Development's Effect on Housing in Pennsylvania. Williamsport, PA:Center for the Study of Community and the Economy. Available: http://www.marcellus.psu.edu/resources/PDFs/housingreport.pdf.

Willits FK, Filteau MR, McLaughlin DK, Brasier KJ, Ooms T, Tracewski S, et al. Pennsylvania Residents' Perceptions of Natural Gas Development in the Marcellus Shale. 13.Penn State University, Cornell University Institute for Public Policy and Economic Development.

Willow A, Zak R, Vilaplana D, Sheeley D. 2014. The contested landscape of unconventional energy development: a report from Ohio's shale gas country. J Environ Stud Sci 4:56–64.

Worldwatch Institute. 2015. Broken Promises: Impacts of Pennsylvania's Shale Gas Boom on Local Economies. Washington, DC:Worldwatch Institute. Available: http://www.worldwatch.org/broken-promises-impacts-pennsylvania%E2%80%99s-shale-gas-boom-local-economies.

Wrenn DH, Kelsey TW, Jaenicke EC. 2015. Resident vs. nonresident employment associated with Marcellus shale development. Agricultural and Resource Economics Review 44:1–19.

Wynveen BJ. 2011. A thematic analysis of local respondents' perceptions of Barnett Shale energy development. J Rural Soc Sci 26:8–31.

Yonk RM, Simmons RT. 2013. The Role of Oil and Gas and Amenities in County Economic Development. Washington, DC:American Petroleum Institute.

Zilliox S, Smith JM. 2017. Memorandums of understanding and public trust in local government for Colorado's unconventional energy industry. Energy Policy 107:72-81.

Message

From: Konkus, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=555471B2BAA6419E8E141696F4577062-KONKUS, JOH]
Sent: 10/11/2018 3:07:43 PM
To: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: RE: New CASAC appointments

Good thanks

From: Gunasekara, Mandy
Sent: Thursday, October 11, 2018 11:07 AM
To: Woods, Clint <woods.clint@epa.gov>
Cc: Konkus, John <konkus.john@epa.gov>
Subject: Re: New CASAC appointments

Deliberative Process / Ex. 5

Sent from my iPhone

On Oct 11, 2018, at 10:32 AM, Woods, Clint <woods.clint@epa.gov> wrote:

+ Mandy for any additional screening

On Oct 11, 2018, at 10:31 AM, Konkus, John <konkus.john@epa.gov> wrote:

Deliberative Process / Ex. 5

From: Woods, Clint
Sent: Thursday, October 11, 2018 10:28 AM
To: Konkus, John <konkus.john@epa.gov>
Subject: Fwd: New CASAC appointments

Begin forwarded message:

From: Sean Reilly <sreilly@eenews.net>
Date: October 11, 2018 at 10:08:38 AM EDT
To: "Woods.Clint@epa.gov" <Woods.Clint@epa.gov>
Subject: New CASAC appointments

Hi Clint:

Just wanted to check on whether you had any input into the selection process and, if so, how? I'm asking because the three state and local

government appointees (Dr. Lange, Dr. Masuca and Dr. Packham) all work for agencies that are AAPCA members.

If you could let me know, I'd appreciate it. My deadline is 11:45 this morning.

Thanks,
Sean

Sean Reilly
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Twitter: @SeanatGreenwire

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Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/10/2018 10:10:50 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Fwd: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee

FYI - Thanks!

Begin forwarded message:

From: "EPA Press Office" <press@epa.gov>
Date: October 10, 2018 at 5:07:53 PM EDT
To: "woods.Clint@epa.gov" <woods.Clint@epa.gov>
Subject: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee
Reply-To: press@epa.gov

Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee

Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process

WASHINGTON (October 10, 2018) - Today, U.S. Environmental Protection Agency (EPA) Acting Administrator Andrew Wheeler announced the appointment of five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). This seven-member panel, required under Section 109 of the Clean Air Act, provides critical advice related to National Ambient Air Quality Standards (NAAQS), including about how to set standards that protect public health with an adequate margin of safety, the role of background pollution, research needs, and potential adverse effects from strategies to meet these standards. Consistent with the Clean Air Act and CASAC's charter, Acting Administrator Wheeler also tasked this panel with leading the review of science for any necessary changes to the NAAQS for ozone or particulate matter. As outlined in the May 2018 "Back-to-Basics Process for Reviewing NAAQS" memorandum these changes would be finalized by late 2020.

"These experts will provide critical scientific advice to EPA as it evaluates where to set national standards for key pollutants like ozone and particulate matter," said Acting Administrator Wheeler. **"They are highly qualified and have a diverse set of**

backgrounds in fields like toxicology, engineering, medicine, ecology, and atmospheric science. These individuals, including five panelists who work in state, local, or federal environmental agencies, will work hard over the next two years to advise EPA in a manner consistent with the Clean Air Act and the protection of public health."

The seven-member chartered CASAC:

- Dr. Anthony (Tony) Cox, Cox Associates (Chair)
- Dr. James Boylan, Georgia Department of Natural Resources
- Dr. Mark Frampton, University of Rochester Medical Center
- Dr. Sabine Lange, Texas Commission on Environmental Quality
- Dr. Timothy Lewis, U.S. Army Corps of Engineers
- Dr. Corey Masuca, Jefferson County (AL) Department of Health
- Dr. Steven Packham, Utah Department of Environmental Quality

Under the Clean Air Act, CASAC is to provide advice on air quality criteria, recommending any new NAAQS or revisions of existing criteria or standards as may be appropriate as well as advising the Administrator of: areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS; research efforts necessary to provide the required information; the relative contribution to air pollution concentrations of natural as well as anthropogenic activity; and any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.

Following the April 2018 Presidential Memorandum on Job Creation and Domestic Manufacturing, EPA issued a memorandum laying out the following principles to reform the process for setting NAAQS:

- Meet statutory deadlines;
- Address all Clean Air Act provisions for NAAQS reviews;
- Streamline and standardize the process for development and review of key policy-relevant information;
- Differentiate science and policy considerations in the NAAQS review process; and
- Issue timely implementation rules or guidance following the revision of a NAAQS.

CASAC operates pursuant to the Clean Air Act, the Federal Advisory Committee Act, and its charter, which is renewed every two years. Consistent with these authorities, the seven-member chartered CASAC will serve as the body to review key science assessments for the ongoing reviews of the ozone and particulate matter NAAQS (last revised in 2015 and 2012, respectively). In the next two weeks, EPA's Office of Research and Development (ORD) intends to make public the draft Integrated Science Assessment for particulate matter for review and comment by CASAC and the public ahead of an in-person meeting in December. ORD also intends to hold a webinar regarding the Integrated Science Assessment for ozone in late October. EPA will also be releasing a

draft Integrated Review Plan to outline the expected ozone NAAQS review process. These steps will kick off the scientific review process which will result in EPA finalizing any necessary changes to the ozone or particulate matter NAAQS by the end of 2020.

For more information, visit EPA's NAAQS review and CASAC websites.

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Sent: 10/10/2018 9:03:26 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]
CC: Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]
Subject: RE: FOR REVIEW: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee - Preview

We have approval. Let's roll!

From: Block, Molly
Sent: Wednesday, October 10, 2018 4:18 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>
Cc: Abboud, Michael <abboud.michael@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Konkus, John <konkus.john@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Dunlap, David <dunlap.david@epa.gov>
Subject: FOR REVIEW: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee - Preview

Per John's email, here's a mocked up press release to review. Thanks!

Molly

U.S. ENVIRONMENTAL PROTECTION AGENCY
NEWS RELEASE
WWW.EPA.GOV/NEWSROOM

Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee

Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process

WASHINGTON (October 10, 2018) - Today, U.S. Environmental Protection Agency (EPA) Acting Administrator Andrew Wheeler announced the appointment of five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). This seven-member panel, required under Section 109 of the Clean Air Act, provides critical advice related to National Ambient Air Quality Standards (NAAQS), including about how to set standards that protect public health with an adequate margin of safety, the role of background pollution, research needs, and potential adverse effects from strategies to meet these standards. Consistent with the Clean Air Act and CASAC's charter, Acting Administrator Wheeler also tasked this panel with leading the review of science for any necessary changes to the NAAQS for ozone or particulate matter. As outlined in the May 2018 "Back-to-Basics Process for Reviewing NAAQS" memorandum these changes would be finalized by late 2020.

"These experts will provide critical scientific advice to EPA as it evaluates where to set national standards for key pollutants like ozone and particulate matter," said Acting Administrator Wheeler. **"They are highly qualified and have a diverse set of backgrounds in fields like toxicology, engineering, medicine, ecology, and atmospheric science. These individuals, including five panelists who work in state, local, or federal environmental agencies, will work hard over the next two years to advise EPA in a manner consistent with the Clean Air Act and the protection of public health."**

The seven-member chartered CASAC:

- Dr. Anthony (Tony) Cox, Cox Associates (Chair)
- Dr. James Boylan, Georgia Department of Natural Resources
- Dr. Mark Frampton, University of Rochester Medical Center
- Dr. Sabine Lange, Texas Commission on Environmental Quality
- Dr. Timothy Lewis, U.S. Army Corps of Engineers
- Dr. Corey Masuca, Jefferson County (AL) Department of Health
- Dr. Steven Packham, Utah Department of Environmental Quality

Under the Clean Air Act, CASAC is to provide advice on air quality criteria, recommending any new NAAQS or revisions of existing criteria or standards as may be appropriate as well as advising the Administrator of: areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS; research efforts necessary to provide the required information; the relative contribution to air pollution concentrations of natural as well as anthropogenic activity; and any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.

Following the April 2018 Presidential Memorandum on Job Creation and Domestic Manufacturing, EPA issued a memorandum laying out the following principles to reform the process for setting NAAQS:

Meet statutory deadlines;

- Address all Clean Air Act provisions for NAAQS reviews;
- Streamline and standardize the process for development and review of key policy-relevant information;
- Differentiate science and policy considerations in the NAAQS review process; and
- Issue timely implementation rules or guidance following the revision of a NAAQS.

CASAC operates pursuant to the Clean Air Act, the Federal Advisory Committee Act, and its charter, which is renewed every two years. Consistent with these authorities, the seven-member chartered CASAC will serve as the body to review key science assessments for the ongoing reviews of the ozone and particulate matter NAAQS (last revised in 2015 and 2012, respectively). In the next two weeks, EPA's Office of Research and Development (ORD) intends to make public the draft Integrated Science Assessment for particulate matter for review and comment by CASAC and the public ahead of an in-person meeting in December. ORD also intends to hold a webinar regarding the Integrated Science Assessment for ozone in late October. EPA will also be releasing a draft Integrated Review Plan to outline the expected ozone NAAQS review process. These steps will kick off the scientific review process which will result in EPA finalizing any necessary changes to the ozone or particulate matter NAAQS by the end of 2020.

For more information, visit EPA's NAAQS review and CASAC websites.

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U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

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Message

From: Konkus, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=555471B2BAA6419E8E141696F4577062-KONKUS, JOH]
Sent: 10/10/2018 8:11:16 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]
CC: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]
Subject: RE: Draft CASAC Release

Ryan: FYI we are (need to) sending this our this evening as soon as I circle up with Thomas Brennan…Molly will be sending around a draft shortly. We may need you to approve Wheeler's quote as he's in the air until 6pm. By then it will be too late.

From: Woods, Clint
Sent: Tuesday, October 9, 2018 11:55 AM
To: Abboud, Michael <abboud.michael@epa.gov>; Konkus, John <konkus.john@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>
Cc: Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Dunlap, David <dunlap.david@epa.gov>
Subject: Draft CASAC Release

Headline: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee
Sub-Headline: Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

For more information, visit EPA's NAAQS review [link: https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards] and CASAC [link: https://yosemite.epa.gov/sab/sabpeople.nsf/webcommittees/CASAC] websites.

Message

From: Harlow, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B5A9A34E31FC4FE6B2BEADDDA2AFFA44-HARLOW, DAV]
Sent: 10/9/2018 12:44:11 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: FW: For review: PM2.5 Precursor Demonstration Guidance
Attachments: OMB 12866 Review_Precursor Demonstration Guidance -10022018.docx; PM2.5 precursor guidance_summary.docx

Importance: High

Clint,

Deliberative Process / Ex. 5

I will leave it to your assessment, therefore, when you have the opportunity. Thanks.

David S. Harlow
Senior Counsel
Immediate Office of the Assistant Administrator
Office of Air and Radiation, USEPA
WJC-N Room 5409K
1200 Pennsylvania Avenue NW
Washington, DC 20460
202-564-1233
Harlow.David@epa.gov

From: Lewis, Josh
Sent: Thursday, October 4, 2018 3:50 PM
To: Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Harlow, David <harlow.david@epa.gov>; Woods, Clint <woods.clint@epa.gov>
Cc: Dominguez, Alexander <dominguez.alexander@epa.gov>; Atkinson, Emily <Atkinson.Emily@epa.gov>
Subject: For review: PM2.5 Precursor Demonstration Guidance
Importance: High

2nd of the new packages for review. Note this would be signed by Peter after it clears OMB.

Message

From: Clint Woods [clintwoods@gmail.com]
Sent: 8/19/2018 1:52:33 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Attachments: tian_pres.pdf

https://www.epa.gov/sites/production/files/2015-09/documents/tian_pres.pdf

Georgia Wildland Fire Emissions and Their Air Quality Impacts

Di Tian, Tao Zeng, James Boylan
Georgia Department of Natural Resources
Environmental Protection Division, Air Protection Branch

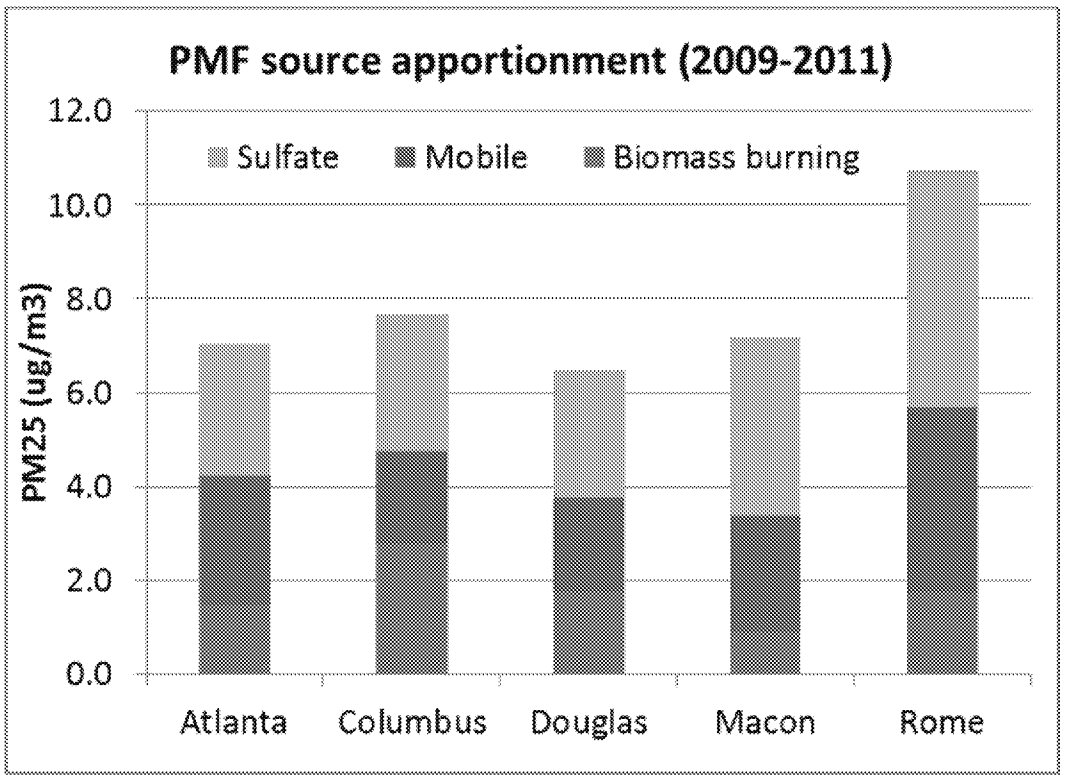
2015 Emissions Inventory Conference, San Diego, CA
April 15, 2015

Contents

- Background
  - Wildland fires in Georgia
  - Georgia wildland fire emission inventories and their impacts on air quality modeling
- Reviewing 2011 SMARTFIREv2 and GAEPD fire inventory
  - Total emissions and comparison with other sources
  - Spatial/temporal distribution
  - Fire size distribution
  - Fuel consumption
  - Emission factors
- Related issues in air quality modeling
  - Need to investigate impacts of high VOC emissions on AQM
  - Definition of emissions during flaming and smoldering and how to use them in air quality modeling
  - Typical wildland fire inventory
- Summary - Suggestions for NEI2014 fire emission inventory development

Wildland Fires in Georgia

- Wildland fires emit large amounts of air pollutants
  - e.g. PM, VOC, NOX, NH3, etc
- Biomass burning has large contribution on $PM_{2.5}$
  - Prescribed fires, wildfires, agriculture burning, land clearing and RWC
  - Mostly prescribed fires (more than 1 million acres of forest land a year in GA)



- Positive Matrix Factorization (PMF) - Multivariate factor analysis tool
- Three years of speciated $PM_{2.5}$ observations at CSN sites in Georgia(2009-2011)
- Three major sources: Biomass burning, Sulfate, and Mobile

Quantifying Emissions from Wildland Fires

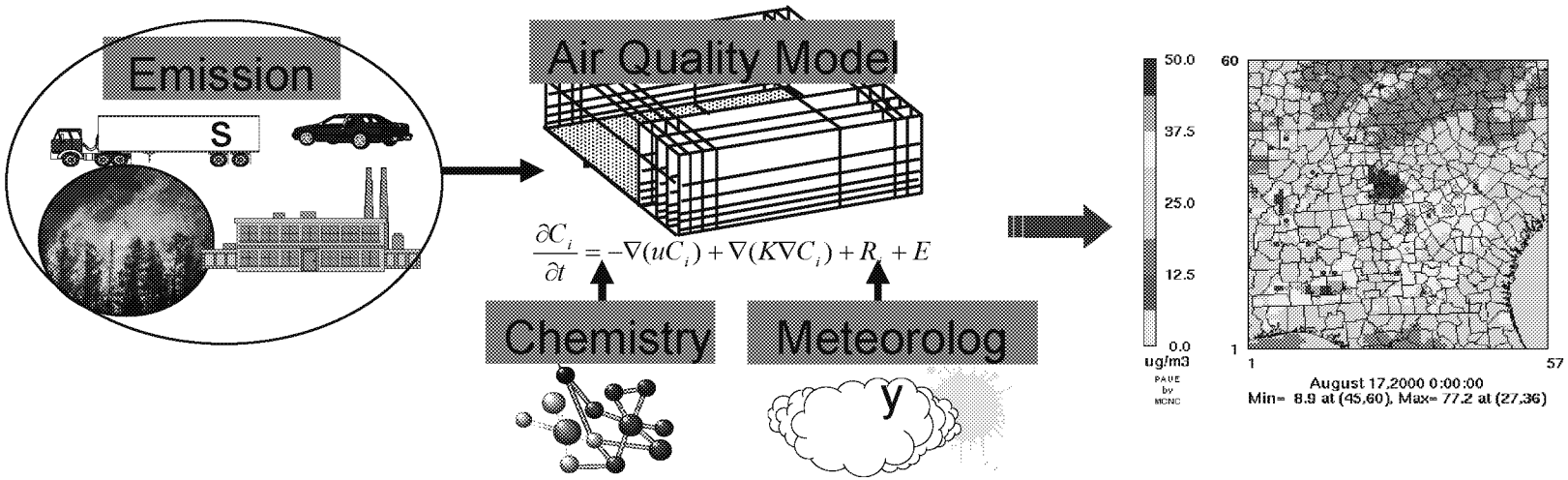
$$E = A \times F_a \times E_f$$

A: burned area (acres)
F_a: fuel consumption (tons/acre)
E_f: emission factor (lbs/ton)

- Georgia Fire emissions inventory
  - Three NEI inventories: 2005, 2008 and 2011 fire emissions developed by GA EPD and submitted to U.S. EPA to include as part of NEI
  - Two SIP fire inventories: VISTAS2002 and SEMAP2007, collaborative efforts in the southeast
- Georgia fire emissions in NEI2011
  - 2011 burned records: by events
    - Georgia Forestry Commission (GFC), military bases, USFS, and FWS (daily burned area for the Okefenokee area fire)
  - Shared these burning records with U.S. EPA and USFS
  - Reviewed SMARTFIRE estimates
  - Developed GA estimates using the same method as used in the SEMAP2007 fire inventory development, no satellite data are used in the GA estimates
    - AMEC, 2012. *Development of the 2007 Base Year and Typical Year Fire Emission Inventory for the Southeastern States Air Resource Managers, Inc.*

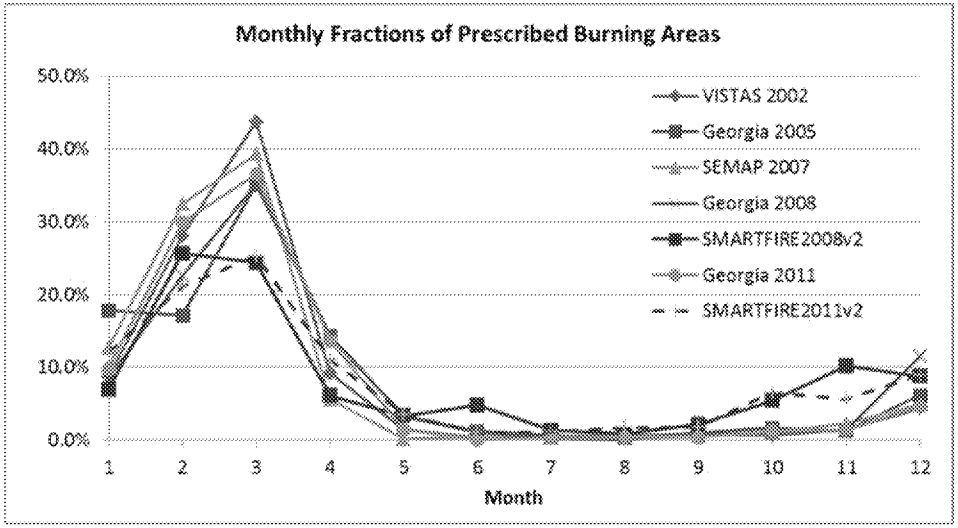
Photochemical Air Quality Modeling

- Meteorological conditions, emissions by hour and modeling grids, physical and chemical processes in the atmosphere (WRF/SMOKE/CMAQ)
- How air pollutant concentrations change with source emissions
- Wildland fire emissions have large impacts on air quality modeling performance
  - Tian, 2009; Garcia-Menendez, 2014
- Quantifying control efficiency to inform control strategy development
- Attainment demonstration
- Forecasting air quality to inform burning permit issuing

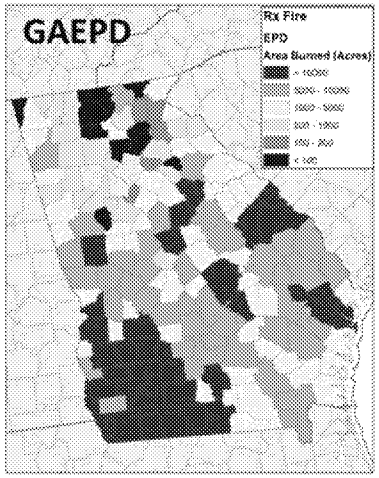


Fire Emissions Have large Impacts on AQM Performance

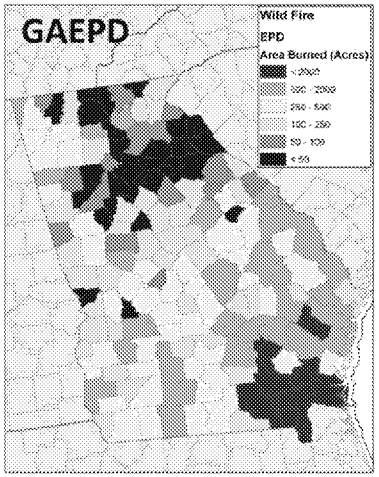
Fire emissions have large temporal and spatial variation



Prescribed Fires

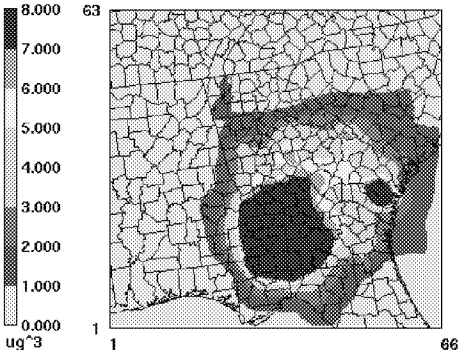


Wildfires

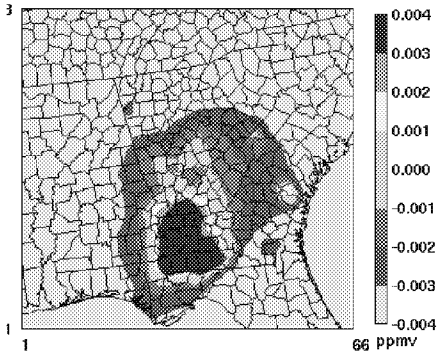


The same fire emissions emitted during different months have different impacts on $PM_{2.5}$ and O_3(Peaks of daily maximum 8-hr ozone)

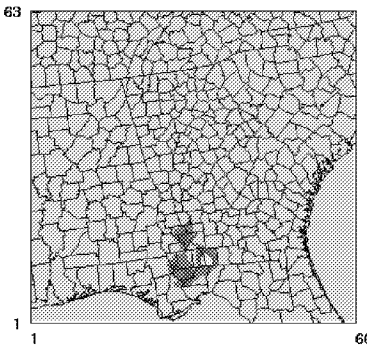
$PM_{2.5}$ Jan: 7.3 μg/m^3



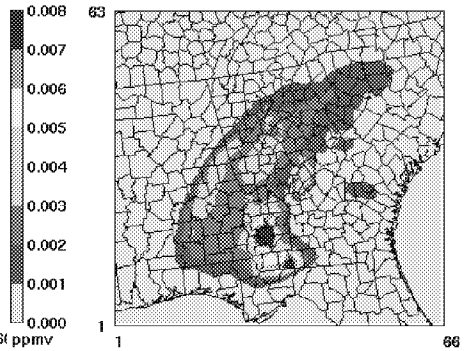
$PM_{2.5}$ May: 3.4 μg/m^3



Ozone Jan: 0.18 ppbv

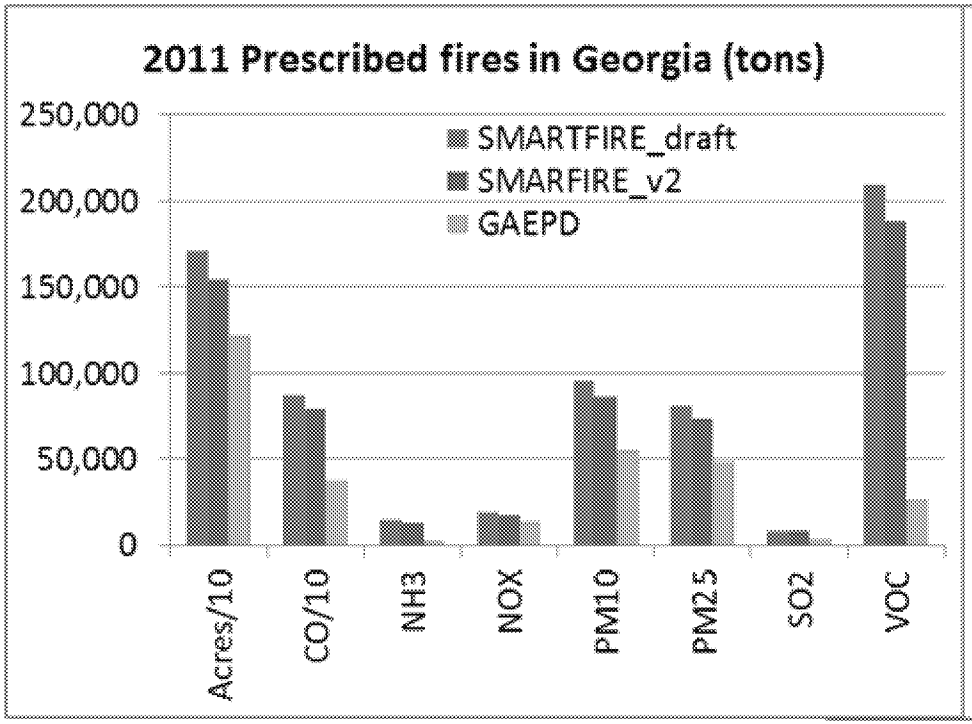


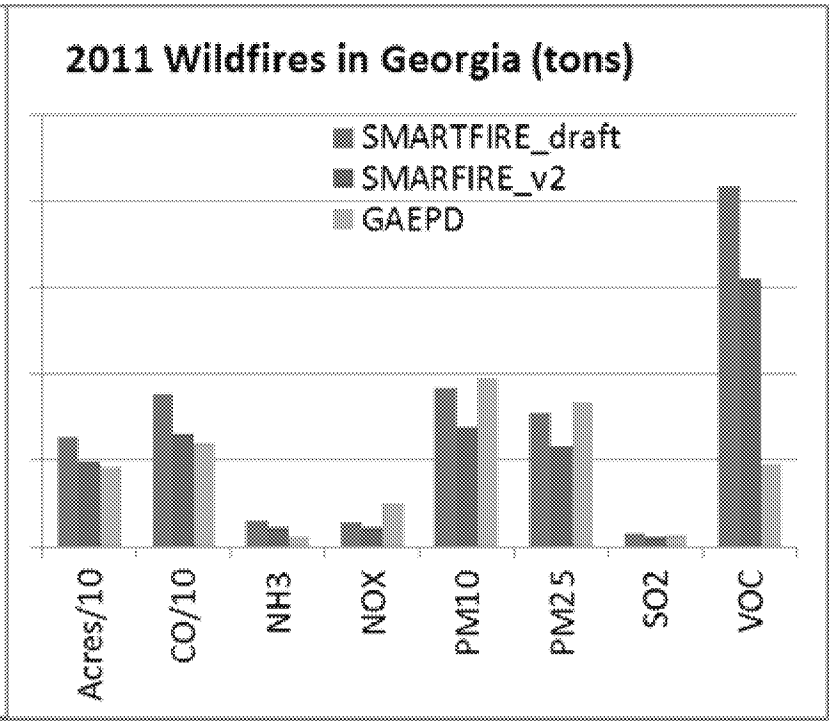
Ozone May: 2.4 ppbv



* $PM_{2.5}$ Values are monthly averages for Georgia, and ozone values are averages for Atlanta metropolitan area.

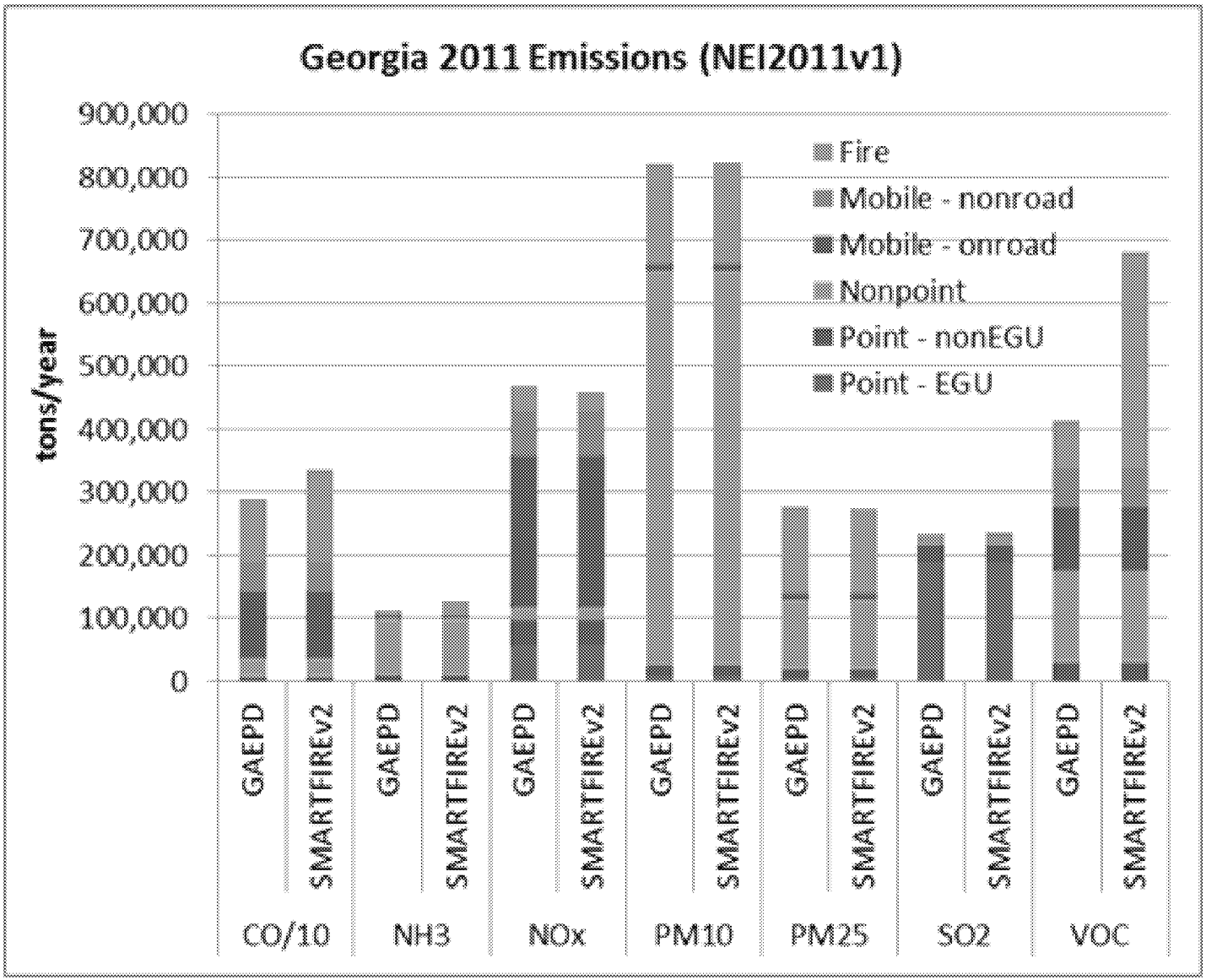
Comparison of SMARTFIRE Estimates and GA EPD Estimates





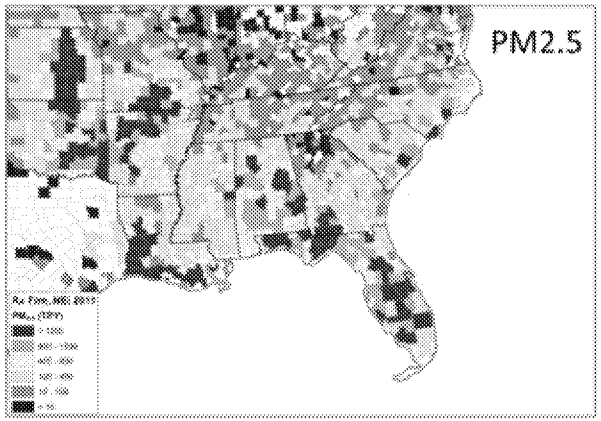
	Emissions (tons/year)			Difference (%)	
	SMARTFIRE_draft	SMARFIRE_v2	GA EPD	SMARTFIRE_draft	SMARFIRE_v2
Acres	2,349,116	2,034,861	1,686,655	39%	21%
CO	1,761,852	1,450,815	981,215	80%	48%
NH3	29,102	23,981	8,154	257%	194%
NOX	33,575	28,530	38,888	-14%	-27%
PM10	187,746	155,390	152,840	23%	2%
PM25	159,107	131,686	132,861	20%	-1%
SO2	16,156	13,574	10,663	52%	27%
VOC	418,337	344,731	74,976	458%	360%

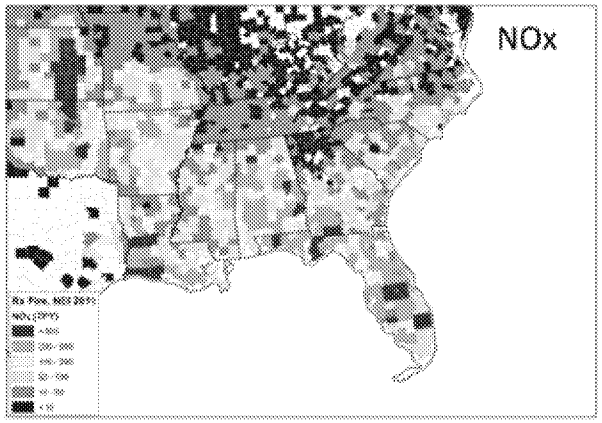
Emissions by Source Categories in Georgia during 2011

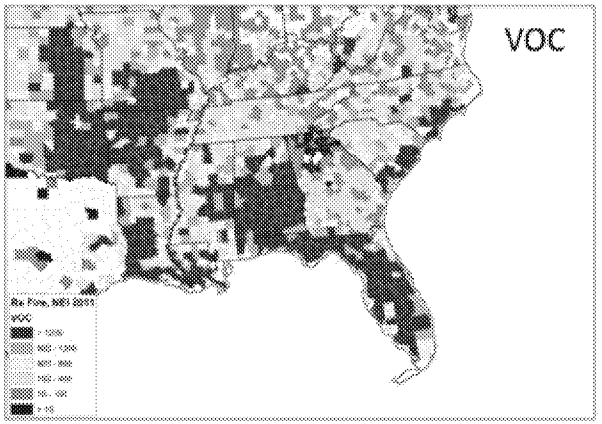


Spatial Distribution of Wildland Fire Emissions in NEI2011v1

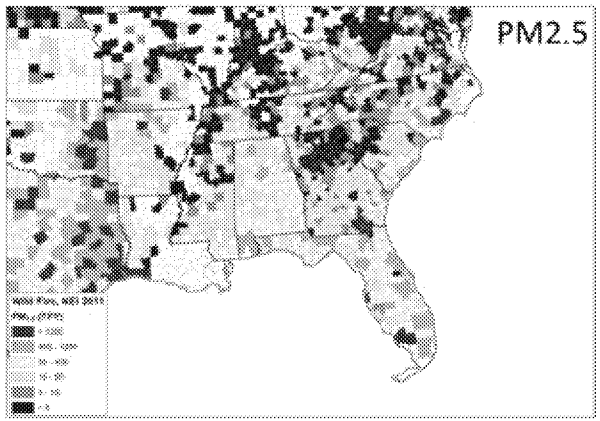
Prescribed fires

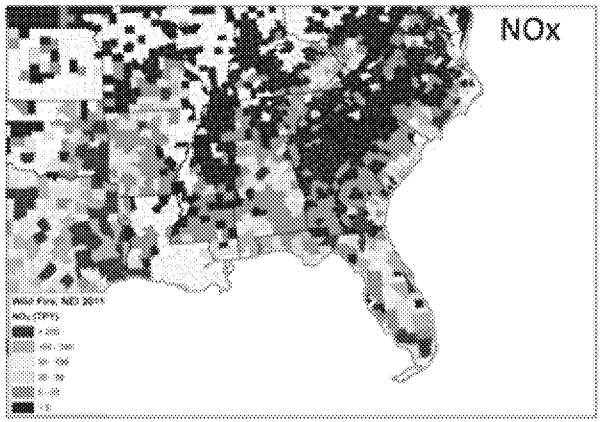


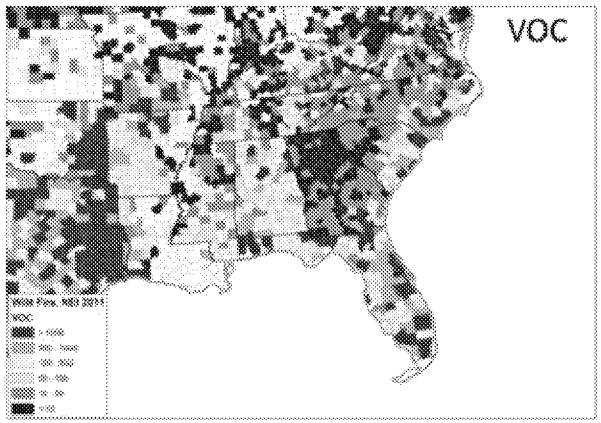




Wildfires



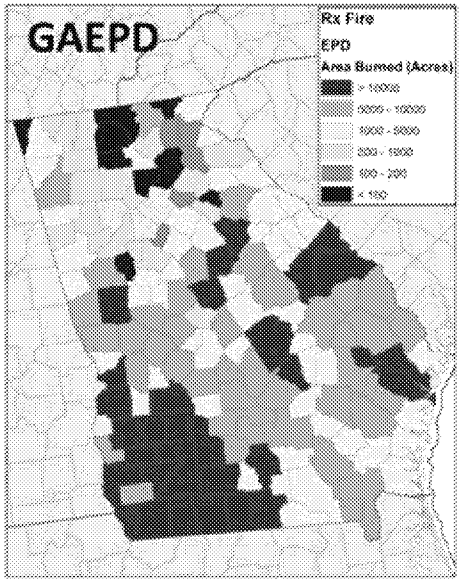


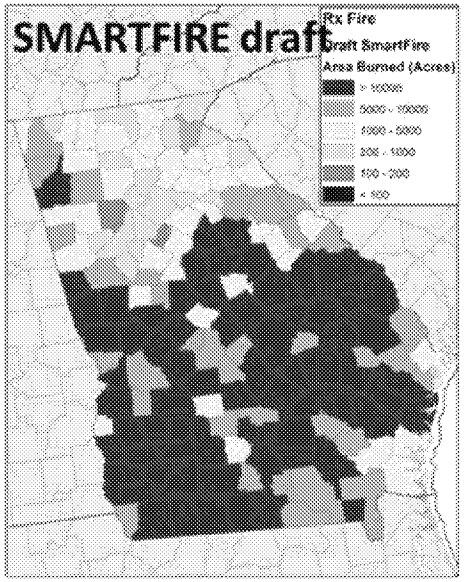


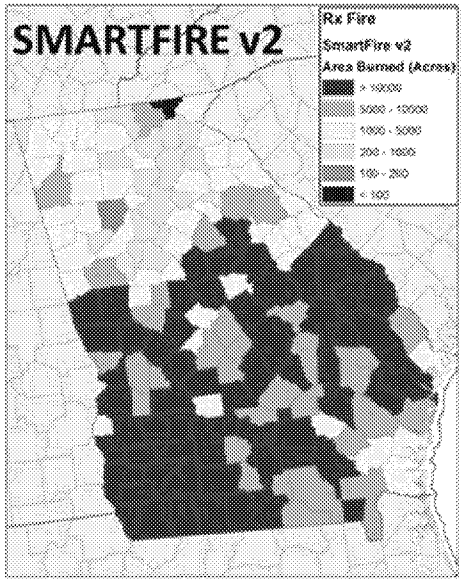
- VOC emissions in NEI2011 look high in all states except Georgia
- Large difference in PM2.5 and NOx emissions between GA and AL/FL
- Low prescribed fire emissions in TX and low wildfire emissions in LA

Spatial Distribution of Burned Area in Georgia during 2011

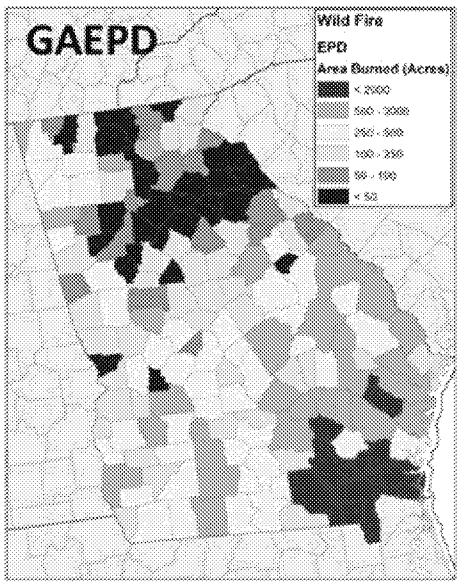
Prescribed fires

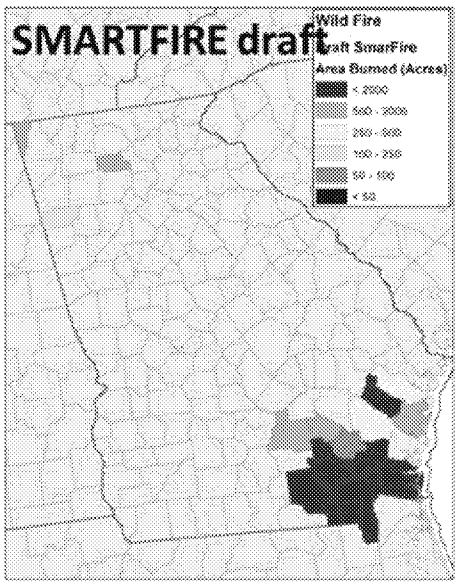


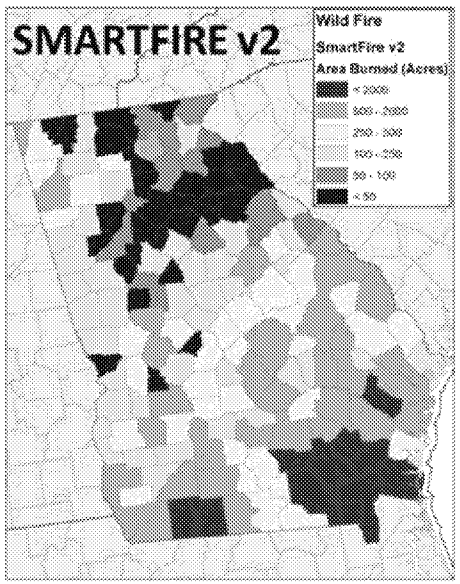




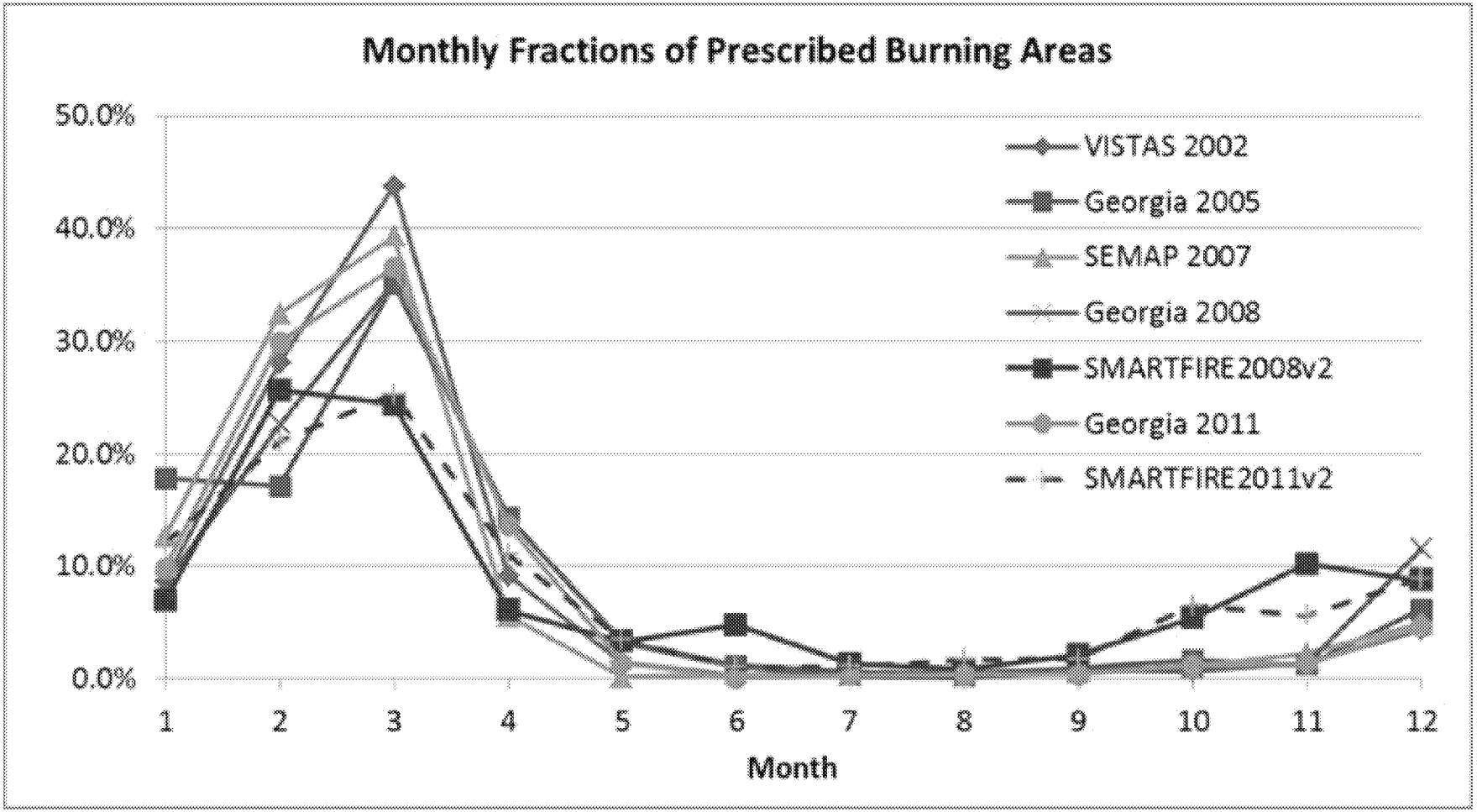
Wildfires





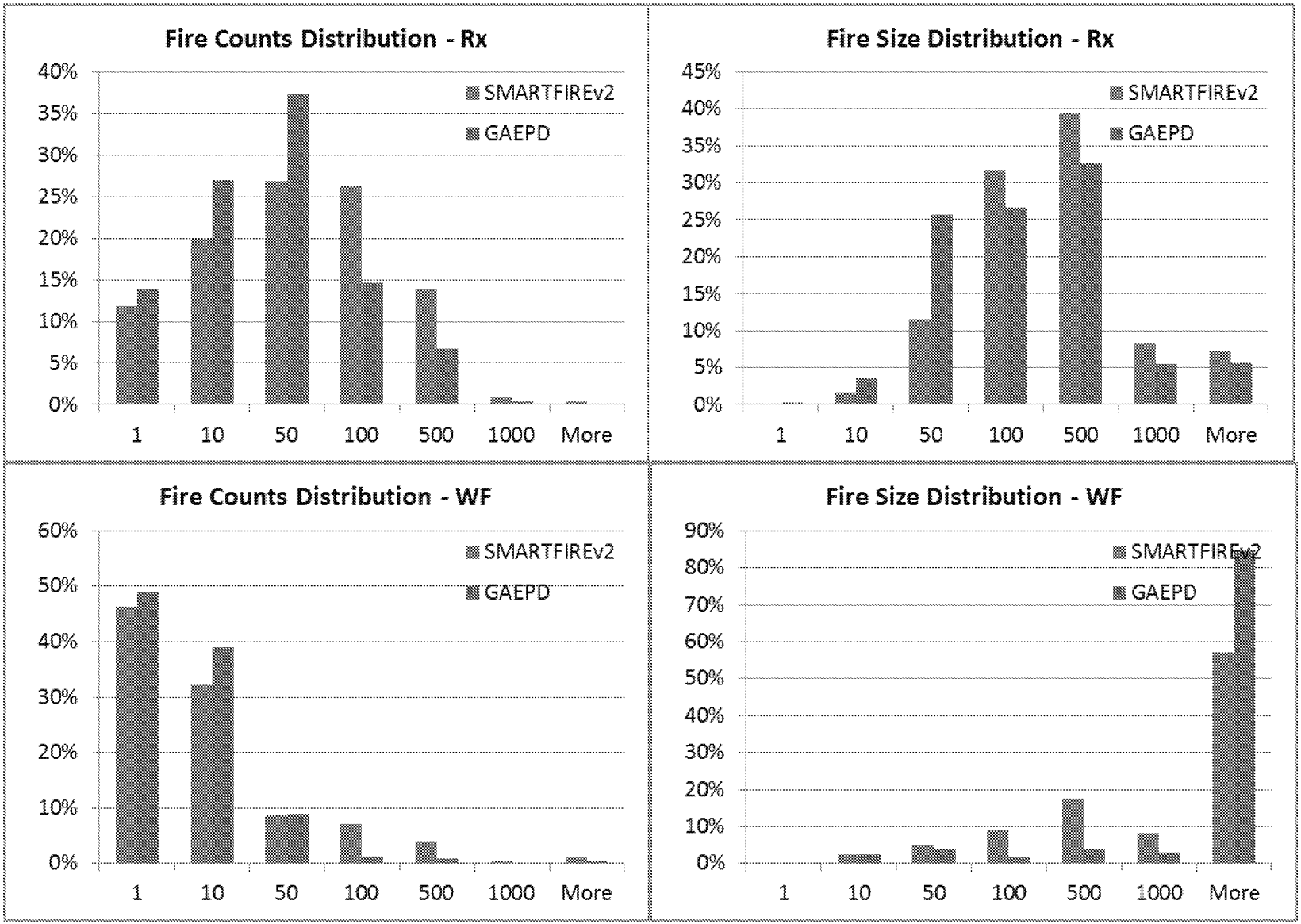


Monthly Fractions of Prescribed Burning Areas



SMARTFIRE_v2 has overestimated prescribed fire activities during October and November and underestimated such activity during March

Fire Counts and Acres Distribution by Fire Size



Southeastern wildland fires are usually small and under canopy prescribed fires with short duration

Fuel Consumption Comparison (1)

Fuel consumption calculation methods in SMATFIREv2 and GAEPD fire inventory

	Fuel Map	Fuel loading	Fuel moisture	Percent of fuel consumption
SMARTFIREv2	FCCS	FCCS fuel bed	Nearby monitors	CONSUME
GAEPD/SEMAP	NFDRS	NFDRS fuel bed	Typical fuel moisture levels for prescribed fires and wildfires. Drier conditions for wildfires.	FEPS and Expert judgments Percent duff consumption for prescribed fires: 0 Percent duff consumption for wildfires: 10% Percent shrub and wood fuel combustion is reduced

Fuel consumption calculation values in SMATFIREv2 and GAEPD fire inventory

	Prescribed fires	Wildfires
SMARTFIREv2	26 FCCS fuel types (0.9 -23.66) tons/acre	27 FCCS fuel types (2.43-196.38) tons/acre
GAEPD	8 NFDRS fuel types (0.6 – 8.1) tons/acre	12 NFDRS fuel types (0.7 – 25) ton/acre

Fuel Consumption Comparison (2)

- Large uncertainties in fuel consumption values due to scarce of data
  - Prescribed fires are usually conducted every 2~5 years in the southeast
  - Typical prescribed fire fuel consumption is about 4 tons/acre
- Improve fuel type assignment
  - Fuel consumption values vary greatly with fuel type
  - Quality of location information in fire records (e.g. “Urban” in SMARTFIREv2)
  - Reviewing assigned fuel type using local knowledge in GAEPD fire inventory
- More representative fuel loading information
  - Collect information such as whether fire is applied to log slash and number of years since last burn for areas under high burning frequency
- Improve fuel consumption estimation
  - Fuel consumption values are sensitive to fuel moisture levels. Should typical fuel moisture level be used in SMARTFIREv2 for prescribed fires?
  - High Duff consumption for some fuel types for prescribed fires
  - Should set maximum fuel consumption value by fuel types with local knowledge

High VOC Emissions from Wildland Fires

- High CO, NH3 and VOC emissions in SMARTFIREv2 than GAEPD fire inventory
  - Separate EFs by combustion phases in SMARTFIREv2 are not available
  - Likely caused by more fuel consumption during smoldering phase
- Comparing EFs in GAEPD Fire Inventory with EFs for Prescribed fire southeast conifer forest in Urbanski 2014
  - CO – Similar, NH3 – lower, VOC – higher
  - VOC: 52 lbs/ton, 32 lbs/ton (without unidentified species), 13-15 lbs/ton (GAEPD/SEMAP). Should VOC for unidentified species in Urbanski 2014 be used in the emission calculation??
  - Much higher emission factors for Stumps and logs or temperate forest duff/organic soil, need to identify such fires
- Investigate impacts of high VOC emissions from fires on AQM
  - Need to update VOC Speciation profiles for wildland fires

Emissions by Flaming and Smoldering (1)

- EPA requires states to submit wildland fire emissions by flaming and smoldering for NEI2014
- Separate fuel combustion and emission factors values by combustion phases
- Percent of fuel consumption values by combustion phases vary with fuel types in SMARTFIREv2
  - Prescribed fires: flaming (36.7%-93.2%), smoldering (6.7%-25.2%), residual smoldering (0.2%-38.1%)
  - Few emissions during residual smoldering for prescribed fires in the southeast
- Lumped emission factors in Urbanski 2014 for both flaming and smoldering phases

Emissions by Flaming and Smoldering (2)

- Using such emissions in AQM depends on the definition of flaming and smoldering (???)
  - Different plume rise
  - Residual smoldering: after strong fire flames
  - Flaming and smoldering: simultaneously occur, often mixed together
- AQM is not sensitive to vertical distribution, but sensitive to emission injection altitude relative to PBL height (Garcia-Menendez, 2014)
  - Prescribed fires usually are not very hot with few emissions during residual smoldering
  - Small wildfires: similar like prescribed fires
  - Large wildfires: very complicated, large uncertainties in emissions

Developing Typical Fire Emissions (1)

- Future year air quality projection and control strategy development using AQMs need fire emissions representing the typical emission and air quality conditions
  - Large year-to-year variation in wildland fire activity, unlike other anthropogenic sources
  - Year-specific inventory might not be representative
- Air quality modeling projections
  - $DV_F = DV_C * RRF$
  - $RRF = Model_{future}/Model_{base}$
  - If the fire emissions inventory includes large wildfires fires near a monitor that last for weeks or months, the relative response factors (RRFs) become unresponsive to anthropogenic emission controls because the base year and future year modeled concentrations are dominated by fire emissions.
  - Air quality responses to emission reductions can't be properly simulated by the AQM.

Developing Typical Fire Emissions (2)

- Consistent with Design Value (DV) calculations
  - Ozone and PM2.5 DVs for attainment with NAAQS
    - Average of 3 years of measurements (e.g., DV2011 based on 2009-2011)
  - Ozone and PM2.5 DVs for model attainment demonstrations
    - Average of 3 DVs (e.g., DV2011, DV2012, DV2013 for base year 2011)
    - (2009 + 2010*2 + 2011*3 + 2012*2 + 2013)/9
  - Regional haze projections for 20% best and 20% worst days
    - 5-year straight average (e.g., 2009-2013 for base year 2011)
- Typical fire emissions should be representative of either 3 years or 5 years for ozone and PM2.5, and 5 years for regional haze
  - Remove fires classified as exceptional events by U.S. EPA
  - Scale county-by-county base year actual emissions by the ratios of multi-year average of acreage burned and base year acreage burned
- Future fire emissions can either be kept constant with the base year typical fire emissions or adjusted for projected growth

SEMAP Example

- Two SEMAP 2007 emission inventories: 2007actual and 2007typical
- SEMAP 2007actual: best estimates for emissions during 2007
  - Used for model performance evaluations
- SEMAP 2007typical: same as 2007 actual emissions, except fires
  - Removed exceptional events and average fire activity during 2006-2008
- Two CMAQ runs were performed with 2007actual or 2007typical fire emissions with emissions from other anthropogenic and natural sources

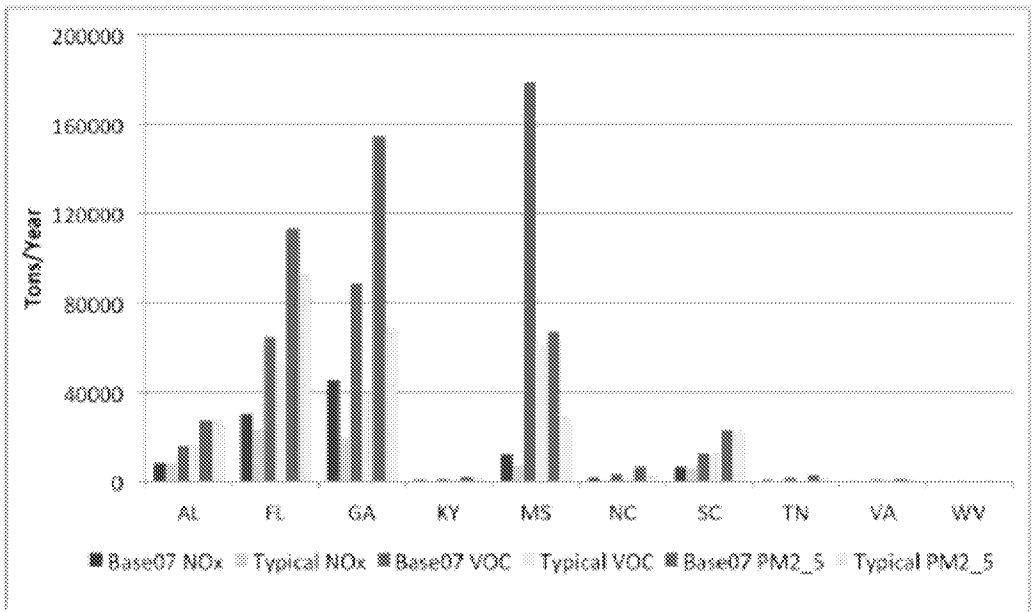
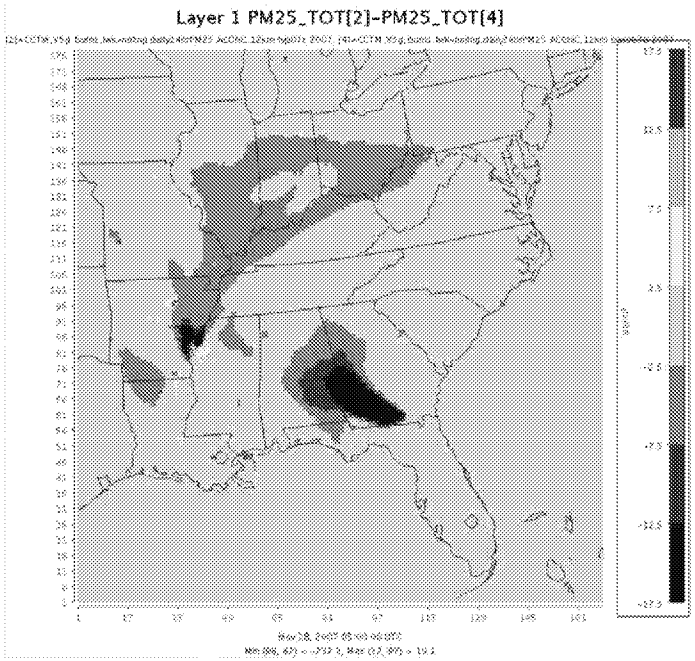


Figure 2-37. SESARM base 2007 and typical annual total fire emissions of NOx, VOC, and PM2.5



Summary

- Reviewed 2011 SMARTFIREv2 and GAEPD fire inventory
- Suggestions for NEI2014 fire emission inventory development
  - Burned area: Satellite data should not be used for the southeast if detailed local fire records are provided in NEI2014
  - Fuel consumption: Local knowledge about fuel consumption should be used in addition to the fuel consumption model results.
  - Emission factors: Updated values in Urbanski 2014 work should be used.
  - Investigate impacts of high VOC emissions on air quality modeling and how to adjust VOC speciation profiles accordingly.
  - Separate emissions by flaming and smoldering: How important to have separate emissions? How to match fuel consumption with emission factors by combustion phases? how to use them in AQM.
  - Need more discussion on how to develop typical fire inventory for AQM.

Message

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Subject: FW: Midwest Ozone Group comments on the proposed Determination Regarding Good Neighbor Obligations for the 2008 Ozone NAAQS
Attachments: Midwest Ozone Group Comments.pdf; Midwest Ozone Group Comments Exhibit A.pdf

---

From: Dave Flannery [mailto:Dave.Flannery@Steptoe-Johnson.com]
Sent: Friday, August 31, 2018 9:05 AM
To: Wheeler, Andrew <wheeler.andrew@epa.gov>
Cc: Wehrum, Bill <Wehrum.Bill@epa.gov>; R3 RA <R3_RA@epa.gov>; Glenn, Trey <Glenn.Trey@epa.gov>; Stepp, Cathy <stepp.cathy@epa.gov>; Wayland, Richard <Wayland.Richard@epa.gov>; Lewis, Josh <Lewis.Josh@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Lopez, Peter <lopez.peter@epa.gov>; Gray, David <gray.david@epa.gov>; R7 Actionline <R7Actionline@epa.gov>
Subject: Midwest Ozone Group comments on the proposed Determination Regarding Good Neighbor Obligations for the 2008 Ozone NAAQS

Dear Acting Administrator Wheeler

Please find attached the comments of the Midwest Ozone Group with respect to EPA's proposed Determination Regarding Good Neighbor Obligations for the 2008 Ozone NAAQS which have been filed in Docket No. EPA-HQ-OAR-2018-0225 today. A copy of the comments can also be found here: http://www.midwestozonegroup.com/files/Midwest_Ozone_Group_Comments.pdf

For all of the reasons stated in these comments, the Midwest Ozone Group supports EPA's proposed determination that the CSAPR Update fully addresses certain states' obligations under CAA section 110(a)(2)(D)(i)(I).

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"Good Neighbor" Modeling for the 2008 8-Hour Ozone State Implementation Plans

Final Modeling Report

Prepared by:
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December 2017
Project Number: TS-510

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1.0 INTRODUCTION

1.1 OVERVIEW

Sections 110(a)(1) and (2) of the Clean Air Act (CAA) require all states to adopt and submit to the U. S. Environmental Protection Agency (EPA) any revisions to their infrastructure State Implementation Plans (SIP) which provide for the implementation, maintenance and enforcement of a new or revised national ambient air quality standard (NAAQS). The EPA revised the ozone NAAQS in March 2008 and completed the designation process to identify nonattainment areas in July 2012. Through final action and rulemaking of the Cross-State Air Pollution Rule (CSAPR) (81 FR 74504), EPA has indicated its intention to issue a Federal Implementation Plan (FIP) to multiple states in the absence of an approved revision to the SIP.

CAA section 110(a)(2)(D)(i)(I) requires each state to prohibit emissions that will significantly contribute to nonattainment of a NAAQS, or interfere with maintenance of a NAAQS, in a downwind state. According to EPA many states' infrastructure certification failed to demonstrate that emissions activities within those states will not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in a neighboring state.

This document serves to provide the air quality modeling results for 8-hour ozone modeling analysis in support of the revision of 2008 8-hour ozone Good Neighbor State Implementation Plan (GNS). The 2008 8-hour ozone NAAQS form is the three year average of the fourth highest daily maximum 8-hour ozone concentrations with a threshold not to be exceeded of 0.075 ppm (75 ppb). On October 26, 2015, the EPA promulgated a new 8-hour ozone NAAQS with a threshold not to be exceeded of 0.070 ppm (70 ppb). Attainment of this new (2015) ozone NAAQS will be addressed in future SIP actions and may use results of this effort to inform that determination.

This document describes the overall modeling activities performed in order to demonstrate that states do not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in a neighboring state. This effort was undertaken working closely with states, other local agencies, and stakeholder groups, including the Midwest Ozone Group which funded this modeling.

A comprehensive draft Modeling Protocol for an 8-hour ozone SIP revision study was prepared and provided to EPA for comment and review relative to Kentucky's Good Neighbor SIP requirements on which this modeling is established. Based on EPA comments, the draft document was revised to include many of the comments and recommendations submitted, most importantly, but not limited to, using EPA's 2023en modeling platform (EPA, 2017a). This 2023en modeling platform represents EPA's estimation of a projected "base case" that demonstrates compliance with final CSAPR update seasonal EGU NOx budgets. A final Modeling Protocol (Alpine, 2017) was prepared and submitted to the Midwest Ozone Group and KYDAQ.

1.2 STUDY BACKGROUND

Section 110(a)(2)(D)(i)(I) of the CAA requires that states address the interstate transport of pollutants and ensure that emissions within the state do not contribute significantly to nonattainment in, or interfere with maintenance by, any other state. The following section is intended to address eastern state interstate transport, or "Good Neighbor," responsibilities for the 2008 ozone NAAQS. Eastern states have many rules and limits currently in place that control ozone precursor pollutants and emissions of these pollutants are decreasing in the state. These facts strengthen the demonstration that no further controls or emission limits may be required to fulfil responsibilities under the Good Neighbor Provisions for the 2008 ozone NAAQS.

On October 26, 2016, EPA published in the Federal Register a final update to the Cross-State Air Pollution Rule (CSAPR) for the 2008 ozone NAAQS. In this final update, EPA outlines its four-tiered approach to addressing the interstate transport of pollution related to the ozone NAAQS, or states' Good Neighbor responsibilities. EPA's approach determines which states contribute significantly to nonattainment areas or significantly interfere with air quality in maintenance areas in downwind states. EPA has determined that if a state's contribution to downwind air quality problems is below one percent of the applicable NAAQS, then it does not consider that state to be significantly contributing to the downwind area's nonattainment or maintenance concerns. EPA's approach to addressing interstate transport has been shaped by public notice and comment and refined in response to court decisions.

As part of the final CSAPR update, EPA released regional air quality modeling to support the 2008 ozone NAAQS attainment date of 2017, indicating which states significantly contribute to nonattainment or maintenance area air quality problems in other states. To make these determinations, the EPA projected future ozone nonattainment and maintenance receptors, then conducted state-level ozone source apportionment modeling to determine which states contributed pollution over a pre-identified "contribution threshold."

Multiple upwind states' contributions to projected downwind nonattainment area air quality was found to be over the one-percent threshold at numerous final CSAPR-identified nonattainment and maintenance ("problem") monitors. The one percent threshold for the 2008 NAAQS is 0.75 parts per billion (ppb). These monitors and their final CSAPR update base period and modeled future year design values are shown in Table 1-1.

Table 1-1. Final CSAPR Update-identified problem monitor base period and modeled future year design values (ppb) .

Monitor ID	State	County	2009-2013 Base Period Average Design Value (ppb)	2009-2013 Base Period Maximum Design Value (ppb)	2017 Base Case Average Design Value (ppb)	2017 Base Case Maximum Design Value (ppb)
Nonattainment Monitors						
90019003	Connecticut	Fairfield	83.7	87	76.5	79.5
90099002	Connecticut	New Haven	85.7	89	76.2	79.2
480391004	Texas	Brazoria	88.0	89	79.9	80.8
484392003	Texas	Tarrant	87.3	90	77.3	79.7
484393009	Texas	Tarrant	86.0	86	76.4	76.4
551170006	Wisconsin	Sheboygan	84.3	87	76.2	78.7
Maintenance Monitors						
90010017	Connecticut	Fairfield	80.3	83	74.1	76.6
90013007	Connecticut	Fairfield	84.3	89	75.5	79.7
211110067	Kentucky	Jefferson	85.0	85	76.9	76.9
240251001	Maryland	Harford	90.0	93	78.8	81.4
260050003	Michigan	Allegan	82.7	86	74.7	77.7
360850067	New York	Richmond	81.3	83	75.8	77.4
361030002	New York	Suffolk	83.3	85	76.8	78.4
390610006	Ohio	Hamilton	82.0	85	74.6	77.4
421010024	Pennsylvania	Philadelphia	83.3	87	73.6	76.9
481210034	Texas	Denton	84.3	87	75.0	77.4
482010024	Texas	Harris	80.3	83	75.4	77.9
482011034	Texas	Harris	81.0	82	75.7	76.6
482011039	Texas	Harris	82.0	84	76.9	78.8

Because upwind state contribution to projected downwind maintenance problems is above the one percent threshold and thus significant, additional analyses are required to fulfil these state responsibilities under the Good Neighbor Provisions for the 2008 ozone NAAQS.

1.2.1 Current Ozone Air Quality at the Problem Monitors

Table 1-2 displays the maximum 8-hour ozone Design Values from 2008-2015 along with the highest fourth highest daily maximum 8-hour ozone concentration at the CSAPR-problem monitors. The fourth highest daily maximum 8-hour ozone concentration at these monitors exhibits high year-to-year variability that is primarily due to meteorological variations that can cause the values to change between successive years. Use of the three-year average of these fourth highest values in the ozone Design Value results in a suppression of this variability so that the differences in the maximum 8-hour ozone Design Value over this period is less pronounced.

Table 1-2. Final CSAPR Update-identified problem monitor design value observations (ppb).

			4th Highest (ppb)								3-yr Avg (ppb)					
Site ID	**State**	**County**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2008-10**	**2009-11**	**2010-12**	**2011-13**	**2012-14**	**2013-15**
Nonattainment Monitors																
90019003	Connecticut	Fairfield	90	73	79	87	89	86	81	87	80	79	85	87	85	84
90099002	Connecticut	New Haven		73	79	92	90	85	69	81		81	87	89	81	78
480391004	Texas	Brazoria	75	91	88	90	87	84	71	86	84	89	88	87	80	80
484392003	Texas	Tarrant	85	90	85	97	79	80	74	76	86	90	87	85	77	76
484393009	Texas	Tarrant	77	86	83	91	86	83	73	79	82	86	86	86	80	78
551170006	Wisconsin	Sheboygan	75	74	85	84	93	78	72	81	78	81	87	85	81	77
Maintenance Monitors																
90010017	Connecticut	Fairfield	88	68	79	81	88	82	78	84	78	76	82	83	82	81
90013007	Connecticut	Fairfield	78	73	79	87	90	90	74	86	76	79	85	89	84	83
211110067	Kentucky	Jefferson			85	82	90	65	70	76			85	79	75	70
240251001	Maryland	Harford	89	83	96	98	86	72	67	74	89	92	93	85	75	71
260050003	Michigan	Allegan	73	76	73	85	95	78	77	72	74	78	84	86	83	75
360850067	New York	Richmond	64	78	85	87	78	71	72	79	75	83	83	78	73	74
361030002	New York	Suffolk	83	79	85	89	83	72	66	78	82	84	85	81	73	72
390610006	Ohio	Hamilton	86	72	80	88	87	69	70	72	79	80	85	81	75	70
421010024	Pennsylvania	Philadelphia	87	72	88	89	85	68	72	79	82	83	87	80	75	73
481210034	Texas	Denton	84	82	74	95	81	85	77	88	80	83	83	87	81	83
482010024	Texas	Harris	83	80	87	83	75	74	68	95	83	83	81	77	72	79
482011034	Texas	Harris	73	79	76	88	83	69	66	88	76	81	82	80	72	74
482011039	Texas	Harris	76	82	85	83	85	69	63	77	81	83	84	79	72	69

1.2.3 Purpose

This document serves to provide air quality modeling results for the 8-hour ozone modeling analysis in support of revisions of 2008 8-hour ozone Good Neighbor State Implementation Plans. This document demonstrates that emissions activities within eastern states will not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in a neighboring state with the four problem monitors identified in the final CSAPR update.

1.3 LEAD AGENCY AND PRINCIPAL PARTICIPANTS

Individual impacted states will be the lead agency in the development of 8-hour ozone SIP revisions. Relevant EPA Regional offices will be the local regional EPA office that will take the lead in the review and approval process for this SIP revision.

1.4 OVERVIEW OF MODELING APPROACH

The GNS 8-Hour ozone SIP modeling documented here includes an ozone simulation study using the 12 km grid based on EPA's 2023en modeling platform and preliminary source contribution assessment (EPA, 2016b).

1.4.1 Episode Selection

Episode selection is an important component of an 8-hour ozone attainment demonstration. EPA guidance recommends that 10 days be used to project 8-hour ozone Design Values at each critical monitor. The May 1 through August 31 2011 ozone season period was selected for the ozone SIP modeling primarily due to the following reasons:

- It is aligned with the 2011 NEI year, which is the latest currently available NEI.
- It is not an unusually low ozone year.
- Ambient meteorological and air quality data are available.
- A 2011 12 km CAMx modeling platform is available from the EPA that can be leveraged for the GNS ozone SIP modeling.

More details of the summer 2011 episode selection and justification using criteria in EPA's modeling guidance are contained in Section 3.

1.4.2 Model Selection

Details on the rationale for model selection are provided in Section 2. The Weather Research Forecast (WRF) prognostic meteorological model was selected for the GNS ozone modeling using a 12 km resolution grid. Additional emission modeling is not required as the 2023en platform was provided to Alpine in pre-merged CAMx ready format. Emissions processing was completed by EPA using the SMOKE emissions model for most source categories. The exceptions are that BEIS model was used for biogenic emissions and there are special processors for fires, windblown dust, lightning and sea salt emissions. The MOVES2014 on-road mobile source emissions model was used with SMOKE-MOVES to generate on-road mobile source emissions with EPA generated vehicle activity data provided in the NAAQS NODA. The CAMx photochemical grid model was also be used. The setup is based on the same WRF/SMOKE/BEIS/CAMx modeling system used in the EPA 2023en platform modeling.

1.4.3 Base and Future Year Emissions Data

The 2023 future year was selected for the attainment demonstration modeling based on OAQPS Director Steven Page's October 27, 2017 memo (Page, 2017, page 4) to Regional Air Directors. In this memo, Director Page identified the two primary reasons the EPA selected 2023 for their 2008 NAAQS modeling; (1) the D.C. Circuit Court's response to *North Carolina v. EPA* in considering downwind attainment dates for the 2008 NAAQS, and (2) EPA's consideration of the timeframes that may be required for implementing further emission reductions as expeditiously as possible. The 2011 base case and 2023 future year emissions will be based on EPA's "en" inventories with no adjustment. This platform has been identified by EPA as the base case for compliance with the final CSAPR update seasonal EGU NOx emission budgets.

1.4.4 Input Preparation and QA/QC

Quality assurance (QA) and quality control (QC) of the emissions datasets are some of the most critical steps in performing air quality modeling studies. Because emissions processing is tedious, time consuming and involves complex manipulation of many different types of large databases, rigorous QA measures are a necessity to prevent errors in emissions processing from occurring. The GNS 8-Hour ozone modeling study utilized EPA's pre-QA/QC'd emissions platform that followed a multistep emissions QA/QC approach.

1.4.5 Meteorology Input Preparation and QA/QC

The CAMx 2011 12 km meteorological inputs are based on WRF meteorological modeling conducted by EPA. Details on the EPA 2011 WRF application and evaluation are provided by EPA (EPA 2014d).

1.4.6 Initial and Boundary Conditions Development

Initial concentrations (IC) and Boundary Conditions (BCs) are important inputs to the CAMx model. We ran 15 days of model spin-up before the first high ozone days occur in the modeling domain so the ICs are washed out of the modeling domain before the first high ozone day of the May-August 2011 modeling period. The lateral boundary and initial species concentrations are provided by a three dimensional global atmospheric chemistry model, GEOS-Chem (Yantosca, 2004) standard version 8-03-02 with 8-02-01 chemistry.

1.4.7 Air Quality Modeling Input Preparation and QA/QC

Each step of the air quality modeling was subjected to QA/QC procedures. These procedures included verification of model configurations, confirmation that the correct data were used and processed correctly, and other procedures.

1.4.8 Model Performance Evaluation

The Model Performance Evaluation (MPE) relied on the CAMx MPE from EPA's associated modeling platforms. EPA's MPE recommendations in their ozone modeling guidance (EPA, 2007; 2014e) were followed in this evaluation. Many of EPA's MPE procedures have already been performed by EPA in their CAMx 2011 modeling database being used in the GNS ozone SIP modeling.

1.4.9 Diagnostic Sensitivity Analyses

Since no issues were identified in confirming Alpine's CAMx runs compared to EPA's using the same modeling platform and configuration, additional diagnostic sensitivity analyses were not required.

2.0 MODEL SELECTION

This section documents the models used in the 8-hour ozone GNS SIP modeling study. The selection methodology presented in this chapter mirrors EPA's regulatory modeling in support of the 2008 Ozone NAAQS Preliminary Interstate Transport Assessment (Page, 2017; EPA, 2016b).

Unlike some previous ozone modeling guidance that specified a particular ozone model (e.g., EPA, 1991 that specified the Urban Airshed Model; Morris and Myers, 1990), the EPA now recommends that models be selected for ozone SIP studies on a "case-by-case" basis. The latest EPA ozone guidance (EPA, 2014) explicitly mentions the CMAQ and CAMx PGMs as the most commonly used PGMs that would satisfy EPA's selection criteria but notes that this is not an exhaustive list and does not imply that they are "preferred" over other PGMs that could also be considered and used with appropriate justification. EPA's current modeling guidelines lists the following criteria for model selection (EPA, 2014e):

- It should not be proprietary;
- It should have received a scientific peer review;
- It should be appropriate for the specific application on a theoretical basis;
- It should be used with data bases which are available and adequate to support its application;
- It should be shown to have performed well in past modeling applications;
- It should be applied consistently with an established protocol on methods and procedures;
- It should have a user's guide and technical description;
- The availability of advanced features (e.g., probing tools or science algorithms) is desirable; and
- When other criteria are satisfied, resource considerations may be important and are a legitimate concern.

For the GNS 8-hour ozone modeling, we used the WRF/SMOKE/MOVES2014/BEIS/CAMx-OSAT/APCA modeling system as the primary tool for demonstrating attainment of the ozone NAAQS at downwind monitors at downwind problem monitors. The utilized modeling system satisfies all of EPA's selection criteria. A description of the key models to be used in the GNS ozone SIP modeling follows.

WRF/ARW: The Weather Research and Forecasting (WRF)[1] Model is a mesoscale numerical weather prediction system designed to serve both operational forecasting and atmospheric research needs (Skamarock, 2004; 2006; Skamarock et al., 2005). The Advanced Research WRF (ARW) version of WRF was used in this ozone modeling study. It features multiple dynamical cores, a 3-dimensional variational (3DVAR) data assimilation system, and a software architecture allowing for computational parallelism and system extensibility. WRF is suitable for a broad spectrum of applications across scales ranging from meters to thousands of

1 http://www.wrf-model.org/index.php

kilometers. The effort to develop WRF has been a collaborative partnership, principally among the National Center for Atmospheric Research (NCAR), the National Oceanic and Atmospheric Administration (NOAA), the National Centers for Environmental Prediction (NCEP) and the Forecast Systems Laboratory (FSL), the Air Force Weather Agency (AFWA), the Naval Research Laboratory, the University of Oklahoma, and the Federal Aviation Administration (FAA). WRF allows researchers the ability to conduct simulations reflecting either real data or idealized configurations. WRF provides operational forecasting a model that is flexible and efficient computationally, while offering the advances in physics, numerics, and data assimilation contributed by the research community.

SMOKE: The Sparse Matrix Operator Kernel Emissions (SMOKE)[2] modeling system is an emissions modeling system that generates hourly gridded speciated emission inputs of mobile, non-road, area, point, fire and biogenic emission sources for photochemical grid models (Coats, 1995; Houyoux and Vukovich, 1999). As with most 'emissions models', SMOKE is principally an emission processing system and not a true emissions modeling system in which emissions estimates are simulated from 'first principles'. This means that, with the exception of mobile and biogenic sources, its purpose is to provide an efficient, modern tool for converting an existing base emissions inventory data into the hourly gridded speciated formatted emission files required by a photochemical grid model. SMOKE was used by EPA to prepare 2023en emission inputs for non-road mobile, area and point sources. These files were adopted and used as-is for this analysis.

SMOKE-MOVES: SMOKE-MOVES uses an Emissions Factor (EF) Look-Up Table from MOVES, gridded vehicle miles travelled (VMT) and other activity data and hourly gridded meteorological data (typically from WRF) and generates hourly gridded speciated on-road mobile source emissions inputs.

MOVES2014: MOVES2014[3] is EPA's latest on-road mobile source emissions model that was first released in July 2014 (EPA, 2014a,b,c). MOVES2014 includes the latest on-road mobile source emissions factor information. Emission factors developed by EPA were used in this analysis.

BEIS: Biogenic emissions were modeled by EPA using version 3.61 of the Biogenic Emission Inventory System (BEIS). First developed in 1988, BEIS estimates volatile organic compound (VOC) emissions from vegetation and nitric oxide (NO) emissions from soils. Because of resource limitations, recent BEIS development has been restricted to versions that are built within the Sparse Matrix Operational Kernel Emissions (SMOKE) system.

CAMx: The Comprehensive Air quality Model with Extensions (CAMx[4]) is a state-of-science "One-Atmosphere" photochemical grid model capable of addressing ozone, particulate matter (PM), visibility and acid deposition at regional scale for periods up to one year (ENVIRON, 2015[5]). CAMx is a publicly available open-source computer modeling system for the integrated assessment of gaseous and particulate air pollution. Built on today's understanding that air

2 http://www.smoke-model.org/index.cfm
3 http://www.epa.gov/otaq/models/moves/
4 http://www.camx.com
5 http://www.camx.com/files/camxusersguide_v6-20.pdf

quality issues are complex, interrelated, and reach beyond the urban scale, CAMx is designed to (a) simulate air quality over many geographic scales, (b) treat a wide variety of inert and chemically active pollutants including ozone, inorganic and organic $PM_{2.5}$ and PM_{10} and mercury and toxics, (c) provide source-receptor, sensitivity, and process analyses and (d) be computationally efficient and easy to use. The U.S. EPA has approved the use of CAMx for numerous ozone and PM State Implementation Plans throughout the U.S., and has used this model to evaluate regional mitigation strategies including those for most recent regional rules (e.g., Transport Rule, CAIR, NO_X SIP Call, etc.). The current version of CAMx is Version 6.40 that was used in this study.

OSAT/APCA: Ozone Source Apportionment Technique/Anthropogenic Precursor Culpability Assessment (OSAT/APCA) tool of CAMx was selected to develop source contribution and significant contribution calculations and was not required for this analysis.

3.0 EPISODE SELECTION

EPA's most recent 8-hour ozone modeling guidance (EPA, 2014e) contains recommended procedures for selecting modeling episodes The GNS ozone SIP revision modeling used the May through end of August 2011 modeling period because it satisfies the most criteria in EPA's modeling guidance episode selection discussion.

EPA guidance recommends that 10 days be used to project 8-hour ozone Design Values at each critical monitor. The May through August 2011 period has been selected for the ozone SIP modeling primarily due to being aligned with the 2011 NEI year, not being an unusually low ozone year and availability of a 2011 12 km CAMx modeling platform from the EPA NAAQS NODA.

4.0 MODELING DOMAIN SELECTION

This section summarizes the modeling domain definitions for the GNS 8-hour ozone modeling, including the domain coverage, resolution, and map projection. It also discusses emissions, aerometric, and other data available for use in model input preparation and performance testing.

4.1 HORIZONTAL DOMAIN

The GNS ozone SIP modeling used a 12 km continental U.S. (12US2) domain. The 12 km nested grid modeling domain configuration is shown in Figure 4-1. The 12 km domain shown in Figure 4-1 represents the CAMx 12km air quality and SMOKE/BEIS emissions modeling domain. The WRF meteorological modeling was run on larger 12 km modeling domains than used for CAMx as demonstrated in EPA's meteorological model performance evaluation document (EPA, 2014d). The WRF meteorological modeling domains are defined larger than the air quality modeling domains because meteorological models can sometimes produce artifacts in the meteorological variables near the boundaries as the prescribed boundary conditions come into dynamic balance with the coupled equations and numerical methods in the meteorological model.

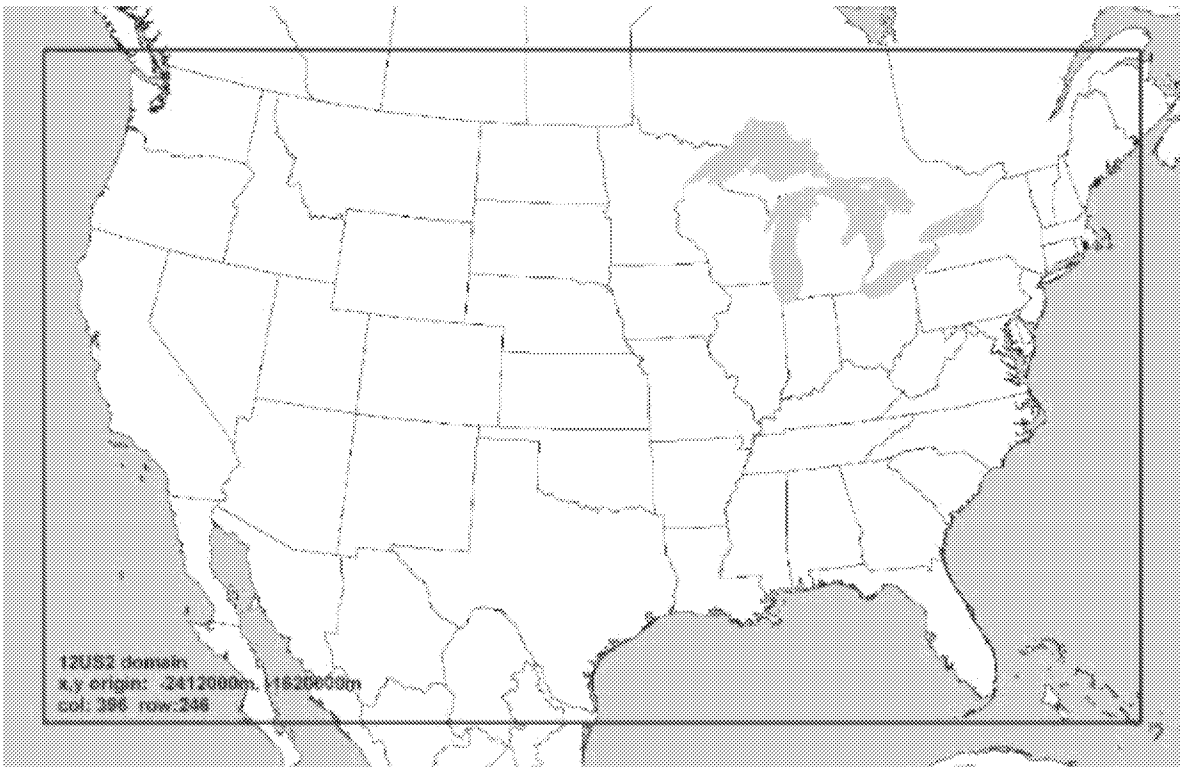

Figure 4-1. Map of 12km CAMx modeling domains. Source: EPA NAAQS NODA.

4.2 VERTICAL MODELING DOMAIN

The CAMx vertical structure is primarily defined by the vertical layers used in the WRF meteorological modeling. The WRF model employs a terrain following coordinate system defined by pressure, using multiple layer interfaces that extend from the surface to 50 mb (approximately 19 km above sea level). EPA ran WRF using 35 vertical layers. A layer averaging scheme is adopted for CAMx simulations whereby multiple WRF layers are combined into one CAMx layer to reduce the air quality model computational time. Table 4-1 displays the approach for collapsing the WRF 35 vertical layers to 25 vertical layers in CAMx.

Table 4-1. WRF and CAMx layers and their approximate height above ground level.

CAMx Layer	WRF Layers	Sigma P	Pressure (mb)	Approx. Height (m AGL)
25	35	0.00	50.00	17,556
	34	0.05	97.50	14,780
24	33	0.10	145.00	12,822
	32	0.15	192.50	11,282
23	31	0.20	240.00	10,002
	30	0.25	287.50	8,901
22	29	0.30	335.00	7,932
	28	0.35	382.50	7,064
21	27	0.40	430.00	6,275
	26	0.45	477.50	5,553
20	25	0.50	525.00	4,885
	24	0.55	572.50	4,264
19	23	0.60	620.00	3,683
18	22	0.65	667.50	3,136
17	21	0.70	715.00	2,619
16	20	0.74	753.00	2,226
15	19	0.77	781.50	1,941
14	18	0.80	810.00	1,665
13	17	0.82	829.00	1,485
12	16	0.84	848.00	1,308
11	15	0.86	867.00	1,134
10	14	0.88	886.00	964
9	13	0.90	905.00	797
	12	0.91	914.50	714
8	11	0.92	924.00	632
	10	0.93	933.50	551
7	9	0.94	943.00	470
	8	0.95	952.50	390
6	7	0.96	962.00	311
5	6	0.97	971.50	232
4	5	0.98	981.00	154
	4	0.99	985.75	115
3	3	0.99	990.50	77
2	2	1.00	995.25	38
1	1	1.00	997.63	19

4.3 DATA AVAILABILITY

The CAMx modeling systems requires emissions, meteorology, surface characteristics, initial and boundary conditions (IC/BC), and ozone column data for defining the inputs.

4.3.1 Emissions Data

Without exception, the 2011 base year and 2023 base case emissions inventories for ozone modeling for this analysis were based on emissions obtained from the EPA's "en" modeling platform. This platform was obtained from EPA, via LADCO, in late September of 2017 and represents EPA's best estimate of all promulgated national, regional, and local control strategies, including final implementation of the seasonal EGU NOx emission budgets outlined in CSAPR.

4.3.2 Air Quality

Data from ambient monitoring networks for gas species are used in the model performance evaluation. Table 4-2 summarizes routine ambient gaseous and PM monitoring networks available in the U.S.

4.3.4 Meteorological Data

Meteorological data were generated by EPA using the WRF prognostic meteorological model (EPA, 2014d). WRF was run on a continental U.S. 12 km grid for the NAAQS NODA platform.

4.3.5 Initial and Boundary Conditions Data

The lateral boundary and initial species concentrations are provided by a three dimensional global atmospheric chemistry model, GEOS-Chem (Yantosca, 2004) standard version 8-03-02 with 8-02-01 chemistry. The global GEOS-Chem model simulates atmospheric chemical and physical processes driven by assimilated meteorological observations from the NASA's Goddard Earth Observing System (GEOS-5; additional information available at: http://gmao.gsfc.nasa.gov/GEOS/ and http://wiki.seas.harvard.edu/geos-chem/index.php/GEOS-5). This model was run for 2011 with a grid resolution of 2.0 degrees x 2.5 degrees (latitude-longitude). The predictions were used to provide one-way dynamic boundary concentrations at one-hour intervals and an initial concentration field for the CAMx simulations. The 2011 boundary concentrations from GEOS-Chem will be used for the 2011 and 2023 model simulations.

Table 4-2. Overview of routine ambient data monitoring networks.

Monitoring Network	Chemical Species Measured	Sampling Period	Data Availability/Source
The Interagency Monitoring of Protected Visual Environments (IMPROVE)	Speciated PM25 and PM10 (see species mappings)	1 in 3 days; 24 hr average	http://vista.cira.colostate.edu/improve/Data/IMPROVE/improve_data.htm
Clean Air Status and Trends Network (CASTNET)	Speciated PM25, Ozone (see species mappings)	Approximately 1-week average	http://www.epa.gov/castnet/data.html
National Atmospheric Deposition Program (NADP)	Wet deposition (hydrogen (acidity as pH), sulfate, nitrate, ammonium, chloride, and base cations (such as calcium, magnesium, potassium and sodium)), Mercury	1-week average	http://nadp.sws.uiuc.edu/
Air Quality System (AQS) or Aerometric Information Retrieval System (AIRS)	CO, NO2, O3, SO2, PM25, PM10, Pb	Typically hourly average	http://www.epa.gov/air/data/
Chemical Speciation Network (CSN)	Speciated PM	24-hour average	http://www.epa.gov/ttn/amtic/amticpm.html
Photochemical Assessment Monitoring Stations (PAMS)	Varies for each of 4 station types.		http://www.epa.gov/ttn/amtic/pamsmain.html
National Park Service Gaseous Pollutant Monitoring Network	Acid deposition (Dry; SO4, NO3, HNO3, NH4, SO2), O3, meteorological data	Hourly	http://www2.nature.nps.gov/ard/gas/netdata1.htm

5.0 MODEL INPUT PREPARATION PROCEDURES

This section summarizes the procedures used in developing the meteorological, emissions, and air quality inputs to the CAMx model for the GNS 8-hour ozone modeling on the 12 km grid for the May through August 2011 period. The 12 km CAMx modeling databases are based on the EPA "en" platform (EPA, 2017a; Page, 2017) databases. While some of the data prepared for this platform are new, many of the files are largely based on the NAAQS NODA platform. More details on the NAAQS NODA 2011 CAMx database development are provided in EPA documentation as follows:

- Technical Support Document (TSD) Preparation of Emissions Inventories for the Version 6.3, 2011 Emissions Modeling Platform (EPA, 2016a).
- Meteorological Model Performance for Annual 2011 WRF v3.4 Simulation (EPA, 2014d).
- Air Quality Modeling Technical Support Document for the 2015 Ozone NAAQS Preliminary Interstate Transport Assessment (EPA, 2016b).

The modeling procedures used in the modeling are consistent with over 20 years of EPA ozone modeling guidance documents (e.g., EPA, 1991; 1999; 2005a; 2007; 2014), other recent 8-hour ozone modeling studies conducted for various State and local agencies using these or other state-of-science modeling tools (see, for example, Morris et al., 2004a,b, 2005a,b; 2007; 2008a,b,c; Tesche et al., 2005a,b; Stoeckenius et al., 2009; ENVIRON, Alpine and UNC, 2013; Adelman, Shanker, Yang and Morris, 2014; 2015), as well as the methods used by EPA in support of the recent Transport analysis (EPA, 2010; 2015b, 2016b).

5.1 METEOROLOGICAL INPUTS

5.1.1 WRF Model Science Configuration

Version 3.4 of the WRF model, Advanced Research WRF (ARW) core (Skamarock, 2008) was used for generating the 2011 simulations. Selected physics options include Pleim-Xiu land surface model, Asymmetric Convective Model version 2 planetary boundary layer scheme, KainFritsch cumulus parameterization utilizing the moisture-advection trigger (Ma and Tan, 2009), Morrison double moment microphysics, and RRTMG longwave and shortwave radiation schemes (Gilliam and Pleim, 2010). The WRF model configuration was prepared by EPA (EPA, 2014d).

5.1.2 WRF Input Data Preparation Procedures

A summary of the WRF input data preparation procedures that were used are listed in EPA's documentation (EPA, 2014d).

5.1.3 WRF Model Performance Evaluation

The WRF model evaluation approach was based on a combination of qualitative and quantitative analyses. The quantitative analysis was divided into monthly summaries of 2-m temperature, 2-m mixing ratio, and 10-m wind speed using the boreal seasons to help generalize the model bias and error relative to a set of standard model performance benchmarks. The qualitative approach was to compare spatial plots of model estimated

monthly total precipitation with the monthly PRISM precipitation. The WRF model performance evaluation for the 12km domain is provided in EPA's documentation (EPA, 2014d).

5.1.3 WRFCAMx/MCIP Reformatting Methodology

The WRF meteorological model output data was processed to provide inputs for the CAMx photochemical grid model. The WRFCAMx processor maps WRF meteorological fields to the format required by CAMx. It also calculates turbulent vertical exchange coefficients (Kz) that define the rate and depth of vertical mixing in CAMx. A summary of the methodology used by EPA to reform the meteorological data into CAMx format is provided in EPA's documentation (EPA, 2014d).

5.2 EMISSION INPUTS

5.2.1 Available Emissions Inventory Datasets

The base year and future year base case emission inventories used for the GNS 8-hour ozone modeling study were based on EPA's "en" modeling platform (EPA, 2017a) without exception.

5.2.2 Development of CAMx-Ready Emission Inventories

CAMx-ready emission inputs were generated by EPA mainly by the SMOKE and BEIS emissions models. CAMx requires two emission input files for each day: (1) low level gridded emissions that are emitted directly into the first layer of the model from sources at the surface with little or no plume rise; and (2) elevated point sources (stacks) with plume rise calculated from stack parameters and meteorological conditions. For this analysis, CAMx will be operated using version 6 revision 4 of the Carbon Bond chemical mechanism (CB6r4).

EPA's 2011 base year and 2023 future year inventories from the "en" platform were used for all categories.

5.2.2.1 Episodic Biogenic Source Emissions

Biogenic emissions were generated by EPA using the BEIS biogenic emissions model within SMOKE. BEIS uses high resolution GIS data on plant types and biomass loadings and the WRF surface temperature fields, and solar radiation (modeled or satellite-derived) to develop hourly emissions for biogenic species on the 12 km grids. BEIS generates gridded, speciated, temporally allocated emission files

5.2.2.2 Point Source Emissions

2011 point source emissions were from the 2011 "en" modeling platform. Point sources were developed in two categories: (1) major point sources with Continuous Emissions Monitoring (CEM) devices; and (2) point sources without CEMs. For point sources with continuous emissions monitoring (CEM) data, day-specific hourly NOX and SO2 emissions were used for the 2011 base case emissions scenario. The VOC, CO and PM emissions for point sources with CEM data were based on the annual emissions temporally allocated to each hour of the year using the CEM hourly heat input. The locations of the point sources were converted to the LCP coordinate system used in the modeling. They were processed by EPA using SMOKE to generate the temporally varying (i.e., day-of-week and hour-of-day) speciated emissions needed by CAMx, using profiles by source category from the EPA "en" modeling platform.

5.2.2.3 Area and Non-Road Source Emissions

2011 area and non-road emissions were from the 2011 "en" modeling platform. The area and non-road sources were spatially allocated to the grid using an appropriate surrogate distribution (e.g., population for home heating, etc.). The area sources were temporally allocated by month and by hour of day using the EPA source-specific temporal allocation factors. The SMOKE source-specific CB6 speciation allocation profiles were also used.

5.2.2.4 Wildfires, Prescribed Burns, Agricultural Burns

Fire emissions in 2011NEIv2 were developed based on Version 2 of the Satellite Mapping Automated Reanalysis Tool for Fire Incident Reconciliation (SMARTFIRE) system (Sullivan, et al., 2008). SMARTFIRE2 was the first version of SMARTFIRE to assign all fires as either prescribed burning or wildfire categories. In past inventories, a significant number of fires were published as unclassified, which impacted the emissions values and diurnal emissions pattern. Recent updates to SMARTFIRE include improved emission factors for prescribed burning.

5.2.2.5 QA/QC and Emissions Merging

EPA processed the emissions by major source category in several different "streams", including area sources, on-road mobile sources, non-road mobile sources, biogenic sources, non-CEM point sources, CEM point sources using day-specific hourly emissions, and emissions from fires. Separate Quality Assurance (QA) and Quality Control (QC) were performed for each stream of emissions processing and in each step following the procedures utilized by EPA. SMOKE includes advanced quality assurance features that include error logs when emissions are dropped or added. In addition, we generated visual displays that included spatial plots of the hourly emissions for each major species (e.g., NOX, VOC, some speciated VOC, SO2, NH3, PM and CO).

Scripts to perform the emissions merging of the appropriate biogenic, on-road, non-road, area, low-level, fire, and point emission files were written to generate the CAMx-ready two-dimensional day and domain-specific hourly speciated gridded emission inputs. The point source and, as available elevated fire, emissions were processed into the day-specific hourly speciated emissions in the CAMx-ready point source format.

The resultant CAMx model-ready emissions were subjected to a final QA using spatial maps to assure that: (1) the emissions were merged properly; (2) CAMx inputs contain the same total emissions; and (3) to provide additional QA/QC information.

5.2.3 Use of the Plume-in-Grid (PiG) Subgrid-Scale Plume Treatment

Consistent with the EPA 2011 modeling platform, no PiG subgrid-scale plume treatment will be used.

5.2.4 Future-Year Emissions Modeling

Future-year emission inputs were generated by processing the 2023 emissions data provided with EPA's "en" modeling platform without exception.

5.3 PHOTOCHEMICAL MODELING INPUTS

5.3.1 CAMx Science Configuration and Input Configuration

This section describes the model configuration and science options used in the GNS 8-hour ozone modeling effort.

The latest version of CAMx (Version 6.40) was used in the GNS ozone modeling. The CAMx model setup used is defined by EPA in its air quality modeling technical support document (EPA, 2016b, 2017).

6.0 MODEL PERFORMANCE EVALUATION

The CAMx 2011 base case model estimates are compared against the observed ambient ozone and other concentrations to establish that the model is capable of reproducing the current year observed concentrations so it is likely a reliable tool for estimating future year ozone levels.

6.1 EPA MODEL PERFORMACE EVALUATION

6.1.1 Overview of EPA Model Performance Evaluation Recommendations

EPA current (EPA, 2007) and draft (EPA, 2014e) ozone modeling guidance recommendations for model performance evaluation (MPE) describes a MPE framework that has four components:

- Operation evaluation that includes statistical and graphical analysis aimed at determining how well the model simulates observed concentrations (i.e., does the model get the right answer).
- Diagnostic evaluation that focuses on process-oriented evaluation and whether the model simulates the important processes for the air quality problem being studied (i.e., does the model get the right answer for the right reason).
- Dynamic evaluation that assess the ability of the model air quality predictions to correctly respond to changes in emissions and meteorology.
- Probabilistic evaluation that assess the level of confidence in the model predictions through techniques such as ensemble model simulations.

EPA's guidance recommends that *"At a minimum, a model used in an attainment demonstration should include a complete operational MPE using all available ambient monitoring data for the base case model simulations period"* (EPA, 2014, pg. 63). And goes on to say *"Where practical, the MPE should also include some level of diagnostic evaluation.* EPA notes that there is no single definite test for evaluation model performance, but instead there are a series of statistical and graphical MPE elements to examine model performance in as many ways as possible while building a *"weight of evidence"* (WOE) that the model is performing sufficiently well for the air quality problem being studied.

Because this 2011 ozone modeling is using a CAMx 2011 modeling database developed by EPA, we include by reference the air quality modeling performance evaluation as conducted by EPA (EPA, 2016b) on the national 12km domain and will include any additional documentation provided in the future on the use of the 2011en modeling configuration.

In summary, EPA conducted an operational model performance evaluation for ozone to examine the ability of the CAMx v6.32 and v.6.40 modeling systems to simulate 2011 measured concentrations. This evaluation focused on graphical analyses and statistical metrics of model predictions versus observations. Details on the evaluation methodology, the calculation of performance statistics, and results are provided in Appendix A of that report.

Overall, the ozone model performance statistics for the CAMx v6.32 2011 simulation are similar to those from the CAMx v6.20 2011 simulation performed by EPA for the final CSAPR Update. The 2011 CAMx model performance statistics are within or close to the ranges found in other

recent peer-reviewed applications (e.g., Simon et al, 2012). As described in Appendix A of the AQ TSD, the predictions from the 2011 modeling platform correspond closely to observed concentrations in terms of the magnitude, temporal fluctuations, and geographic differences for 8-hour daily maximum ozone. We fully anticipate that the MPE performed for the 2011en platform will demonstrate similar results and will document final evaluation metrics in the documentation associated with the final SIP revision. Thus, the current model performance results demonstrate the scientific credibility of the 2011 modeling platform chosen and used for this analysis. These results provide confidence in the ability of the modeling platform to provide a reasonable projection of expected future year ozone concentrations and contributions.

7.0 FUTURE YEAR MODELING

This chapter discusses the future year modeling used in the GNS 8-hour ozone modeling effort.

7.1 FUTURE YEAR TO BE SIMULATED

As discussed in Section 1, to support the 2008 ozone NAAQS preliminary interstate transport assessment, EPA conducted air quality modeling to project ozone concentrations at individual monitoring sites to 2023 and to estimate state-by-state contributions to those 2023 concentrations. The projected 2023 ozone concentrations were used to identify ozone monitoring sites that are projected to be nonattainment or have maintenance problems for the 2008 ozone NAAQS in 2023.

7.2 FUTURE YEAR GROWTH AND CONTROLS

In September 2017, EPA released the revised "en" modeling platform that was the source for the 2023 future year emissions in this analysis. This platform has been identified by EPA as the base case for compliance with the final CSAPR update seasonal EGU NOx emission budgets. Additionally, there were several emission categories and model inputs/options that were held constant at 2011 levels as follows:

- Biogenic emissions.
- Wildfires, Prescribed Burns and Agricultural Burning (open land fires).
- Windblown dust emissions.
- Sea Salt.
- 36 km CONUS domain Boundary Conditions (BCs).
- 2011 12 km meteorological conditions.
- All model options and inputs other than emissions.

The effects of climate change on the future year meteorological conditions were not accounted. It has been argued that global warming could increase ozone due to higher temperatures producing more biogenic VOC and faster photochemical reactions (the so called climate penalty). However, the effects of inter-annual variability in meteorological conditions will be more important than climate change given the 12 year difference between the base (2011) and future (2023) years. It has also been noted that the level of ozone being transported into the U.S. from Asia has also increased.

7.3 FUTURE YEAR BASELINE AIR QUALITY SIMULATIONS

A 2023 future year base case CAMx simulation was conducted and 2023 ozone design value projection calculations were made based on EPA's latest ozone modeling guidance (EPA, 2014).

7.4 CONCLUSIONS FROM 2023 CAMX MODELING

All sites identified in the final CSAPR update are predicted to be well below the 2008 ozone standard by 2023. Table 7-1 provides the GNS 2023 future year average and maximum design value modeling results from this analysis for the eastern state problem monitors identified in Section 1.

Based on these calculations, none of the problem monitors are predicted to be in nonattainment or have issues with maintenance in 2023 and therefore no states are required to estimate their contribution to these monitors.

Table 7-1. GNS Modeling results at Final CSAPR Update-identified problem monitors (ppb).

Monitor ID	State	County	2009-2013 Base Period Average Design Value (ppb)	2009-2013 Base Period Maximum Design Value (ppb)	2023 Base Case Average Design Value (ppb)	2023 Base Case Maximum Design Value (ppb)
Nonattainment Monitors						
90019003	Connecticut	Fairfield	83.7	87	72.7	75.6
90099002	Connecticut	New Haven	85.7	89	71.2	73.9
480391004	Texas	Brazoria	88.0	89	74.0	74.9
484392003	Texas	Tarrant	87.3	90	72.5	74.8
484393009	Texas	Tarrant	86.0	86	70.6	70.6
551170006	Wisconsin	Sheboygan	84.3	87	70.8	73.1
Maintenance Monitors						
90010017	Connecticut	Fairfield	80.3	83	69.8	72.1
90013007	Connecticut	Fairfield	84.3	89	71.2	75.2
211110067	Kentucky	Jefferson	85.0	85	70.1	70.1
240251001	Maryland	Harford	90.0	93	71.4	73.8
260050003	Michigan	Allegan	82.7	86	69.0	71.8
360850067	New York	Richmond	81.3	83	71.9	73.4
361030002	New York	Suffolk	83.3	85	72.5	74.0
390610006	Ohio	Hamilton	82.0	85	65.0	67.4
421010024	Pennsylvania	Philadelphia	83.3	87	67.3	70.3
481210034	Texas	Denton	84.3	87	69.7	72.0
482010024	Texas	Harris	80.3	83	70.4	72.8
482011034	Texas	Harris	81.0	82	70.8	71.6
482011039	Texas	Harris	82.0	84	71.8	73.6

Through this modeling analysis, has all upwind states identified in the final CSAPR Update demonstrated compliance with CAA Section 110(a)(2)(D)(i)(I) for the 2008 Ozone National Ambient Air Quality Standard.

8.0 MODELING DOCUMENTATION AND DATA ARCHIVE

EPA recommends that certain types of documentation be provided along with a photochemical modeling attainment demonstration. Alpine Geophysics is committed to supplying the material needed to ensure that the technical support for this SIP revision is understood by all stakeholders, EPA and states.

Alpine Geophysics plans to archive all documentation and modeling input/output files generated as part of the 8-hour modeling analysis and will maintain a copy for additional internal use. Key participants in this modeling effort will be given data access to the archived modeling information.

9.0 REFERENCES

Abt. 2014. Modeled Attainment Test Software – Users Manual. Abt Associates Inc., Bethesda, MD. April. (http://www.epa.gov/ttn/scram/guidance/guide/MATS_2-6-1_manual.pdf).

Alpine Geophysics, LLC. 2017. ""Good Neighbor" Modeling for the Kentucky 2008 8-Hour Ozone State Implementation Plan - Final Modeling Protocol." October 2017. (http://midwestozonegroup.com/files/Interstate_Transport_Model_Protocol_to_address_Kentucky_SIP_obligations2.pdf)

Arnold, J.R., R.L. Dennis, and G.S. Tonnesen. 2003. "Diagnostic Evaluation of Numerical Air Quality Models with Specialized Ambient Observations: Testing the Community Multiscale Air Quality Modeling System (CMAQ) at Selected SOS 95 Ground Sites", *Atmos. Environ.*, Vol. 37, pp. 1185-1198.

Arnold, J.R.; R.L. Dennis, and G.S. Tonnesen. 1998. Advanced techniques for evaluating Eulerian air quality models: background and methodology. In: Preprints of the 10th Joint Conference on the Applications of Air Pollution Meteorology with the Air & Waste Management Association, January, Phoenix, Arizona. American Meteorological Society, Boston, Massachusetts, paper no. 1.1, pp. 1-5.

Arunachalam, S. 2009. Peer Review of Source Apportionment Tools in CAMx and CMAQ. University of North Carolina Institute for the Environment, Chapel Hill, NC. August 31. (http://www.epa.gov/scram001/reports/SourceApportionmentPeerReview.pdf).

Boylan, J. W. 2004. "Calculating Statistics: Concentration Related Performance Goals", paper presented at the EPA PM Model Performance Workshop, Chapel Hill, NC. 11 February.

Byun, D.W., and J.K.S. Ching. 1999. "Science Algorithms of the EPA Models-3 Community Multiscale Air Quality (CMAQ) Modeling System", EPA/600/R-99/030.

Carter, W.P.L. 1999. Documentation of the SAPRC-99 Chemical Mechanism for VOC Reactivity Assessment, Draft report to the California Air Resources Board, Contracts 92-329 and 95-308, 9/13/99.

Coats, C.J. 1995. Sparse Matrix Operator Kernel Emissions (SMOKE) Modeling System, MCNC Environmental Programs, Research Triangle Park, NC.

Colella, P., and P.R. Woodward. 1984. The Piecewise Parabolic Method (PPM) for Gas-dynamical Simulations. *J. Comp. Phys.*, **54**, 174201.

Emery, C., E. Tai, and G. Yarwood. 2001. "Enhanced Meteorological Modeling and Performance Evaluation for Two Texas Episodes", report to the Texas Natural Resources Conservation Commission, prepared by ENVIRON, International Corp, Novato, CA.

Emery, C.A., E. Tai, E., R. E. Morris, G. Yarwood. 2009a. Reducing Vertical Transport Over Complex Terrain in CMAQ and CAMx; AWMA Guideline on Air Quality Models Conference, Raleigh, NC, October 26-30, 2009.

Emery, C.A., E. Tai, R.E. Morris, G. Yarwood. 2009b. Reducing Vertical Transport Over Complex Terrain in Photochemical Grid Models; 8th Annual CMAS Conference, Chapel Hill, NC, October 19-21, 2009.

Emery, C., E. Tai, G. Yarwood and R. Morris. 2011. Investigation into approaches to reduce excessive vertical transport over complex terrain in a regional photochemical grid model. *Atmos. Env.*, Vol. 45, Issue 39, December 2011, pp. 7341-7351. (http://www.sciencedirect.com/science/article/pii/S1352231011007965).

ENVIRON and UCR. 2004. "Modeling Protocol for the CENRAP 2002 Annual Emissions and Air Quality Modeling." ENVIRON International Corporation and University of California at Riverside. November.

ENVIRON and Alpine. 2005. CONCEPT Emissions Modeling User's Guide. ENVIRON International Corporation, Novato, CA. Alpine Geophysics, LLC, Arvada, CO. May 27 (http://www.ladco.org/reports/rpo/emissions/new_emissions_model_concept_introduction_alpine_environ.pdf)

ENVIRON. 2015. User's Guide Comprehensive Air-quality Model with extensions Version 6.3. ENVIRON International Corporation, Novato, CA. March. (http://www.camx.com/files/camxusersguide_v6-3.pdf).

EPA. 1991. "Guidance for Regulatory Application of the Urban Airshed Model (UAM), "Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, N.C.

EPA. 1999. "Draft Guidance on the Use of Models and Other Analyses in Attainment Demonstrations for the 8-hr Ozone NAAQS". Draft (May 1999), U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, N.C

EPA. 2001. "Guidance Demonstrating Attainment Air Quality Goals for PM2.5 and Regional Haze". Draft Final (17 February 2005), U.S. Environmental Protection Agency, Atmospheric Sciences Modeling Division, Research Triangle Park, N.C.

EPA. 2003a. A Conceptual Model to Adjust Fugitive Dust Emissions to Account for Near Source Particle Removal in Grid Model Applications, prepared by Tom Pace, U.S. EPA, August. http://www.epa.gov/ttn/chief/emch/invent/statusfugdustemissions_082203.pdf.

EPA. 2003b. National Emission Inventory QA and Augmentation Memo, prepared by Anne Pope, U.S. EPA, June. http://www.epa.gov/ttn/chief/emch/invent/qaaugmementationmemo_99nei_60603.pdf

EPA. 2005a. Guidance on the Use of Models and Other Analyses in Attainment Demonstrations for the 8-hr Ozone NAAQS -- Final. U.S. Environmental Protection Agency, Atmospheric Sciences Modeling Division, Research Triangle Park, N.C. October.

EPA. 2005b. Technical Support Document for the Final Clean Air Interstate Rule – Air Quality Modeling. U.S. Environmental Protection Agency, Office of Air Quality and Planning Standards, Research Triangle Park, North Carolina, 27711. March.

EPA. 2005c. "Regional Haze Regulations and Guidelines for Best Available Technology (BART) Determinations". Fed. Reg./Vol. 70, No. 128/Wed. July, Rules and Regulations, pp. 39104-39172. 40 CFR Part 51, FRL-7925-9, RIN AJ31.

EPA. 2007. Guidance on the Use of Models and Other Analyses for Demonstrating Attainment of Air Quality Goals for Ozone, PM2.5 and Regional Haze. U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-454/B-07-002. April. (http://www.epa.gov/ttn/scram/guidance/guide/final-03-pm-rh-guidance.pdf).

EPA. 2010. Technical Support Document for the Transport Rule. Docket ID No. EPA-HQ-OAR-2009-0491. Air Quality Modeling. U.S. Environmental Protection Agency, Office of Pair Quality Planning and Standards, Air Quality Assessment Division, Research Triangle Park, NC. June.

EPA. 2014a. Motor Vehicle Emissions Simulator (MOVES) – User Guide for MOVES2014. Assessment and Standards Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency. (EPA-420-B-14-055). July. (http://www.epa.gov/oms/models/moves/documents/420b14055.pdf).

EPA. 2014b. Motor Vehicle Emissions Simulator (MOVES) –MOVES2014 User Interface Manual. Assessment and Standards Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency. (EPA-420-B-14-067). July. (http://www.epa.gov/oms/models/moves/documents/420b14057.pdf).

EPA. 2014c. Motor Vehicle Emissions Simulator (MOVES) –MOVES2014 Software Design Reference Manual. Assessment and Standards Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency. (EPA-420-B-14-058). December. (http://www.epa.gov/oms/models/moves/documents/420b14056.pdf).

EPA. 2014d. Meteorological Model Performance for Annual 2011 WRF v3.4 Simulation, U.S. Environmental Protection Agency. November 2014.

EPA. 2014e. Draft Modeling Guidance for Demonstrating Attainment of Air Quality Goals for Ozone, PM2.5, and Regional Haze, U.S. Environmental Protection Agency. December 2014.

EPA. 2015b. Air Quality Modeling Technical Support Document for the 2008 Ozone NAAQS Transport Assessment. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. January. (http://www.epa.gov/airtransport/O3TransportAQModelingTSD.pdf).

EPA. 2016a. Technical Support Document (TSD) Preparation of Emissions Inventories for the Version 6.3, 2011 Emissions Modeling Platform. U.S. Environmental Protection Agency. August 2016.

EPA. 2016b. Air Quality Modeling Technical Support Document for the 2015 Ozone NAAQS Preliminary Interstate Transport Assessment. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. December 2016.

EPA. 2017a. Technical Support Document (TSD) Additional Updates to Emissions Inventories for the Version 6.3, 2011 Emissions Modeling Platform for the Year 2023. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. October 2017. https://www.epa.gov/sites/production/files/2017-11/documents/2011v6.3_2023en_update_emismod_tsd_oct2017.pdf

EPA. 2017b. Use of Photochemical Grid Models for Single-Source Ozone and secondary PM2.5 impacts for Permit Program Related Assessments and for NAAQS Attainment

Demonstrations for Ozone, PM2.5 and Regional Haze. Memorandum from Tyler Fox, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. August 2017. https://www3.epa.gov/ttn/scram/guidance/clarification/20170804-Photochemical_Grid_Model_Clarification_Memo.pdf

Gery, M. W., G.Z. Whitten, J.P. Killus, and M.C. Dodge. 1989. A photochemical mechanism for urban and regional-scale computer modeling. *J. Geophys. Res.* 94, 12925-12956.

Gilliam, R. 2010. Evaluation of Multi-Annual CONUS 12 km WRF Simulations. U.S. Environmental Protection Agency, NREL, Atmospheric Modeling and Analysis Division. (http://epa.gov/scram001/adhoc/gilliam2010.pdf).

Kemball-Cook, S., Y. Jia, C. Emery, R. Morris, Z. Wang and G. Tonnesen. 2004. Comparison of CENRAP, VISTAS and WRAP 36 km MM5 Model Runs for 2002, Task 3: Meteorological Gatekeeper Report. http://pah.cert.ucr.edu/aqm/cenrap/ppt_files/CENRAP_VISTAS_WRAP_2002_36km_MM5_eval.ppt. December.

Michalakes, J., J. Dudhia, D. Gill, J. Klemp and W. Skamarock. 1998. Design of a Next-Generation Regional Weather Research and Forecast Model. Mesoscale and Microscale Meteorological Division, National Center for Atmospheric Research, Boulder, CO. (http://www.mcs.anl.gov/~michalak/ecmwf98/final.html).

Michalakes, J., S. Chen, J. Dudhia, L. Hart, J. Klemp, J. Middlecoff and W. Skamarock. 2001. Development of a Next-Generation Regional Weather Research and Forecast Model. Developments in Teracomputing: Proceedings of the 9th ECMWF Workshop on the Use of High Performance Computing in Meteorology. Eds. Walter Zwieflhofer and Norbet Kreitz. World Scientific, Singapore. Pp. 269-276. (http://www.mmm.ucar.edu/mm5/mpp/ecmwf01.htm).

Michalakes, J., J. Dudhia, D. Gill, T. Henderson, J. Klemp, W. Skamarock and W. Wang. 2004. The Weather Research and Forecast Model: Software Architecture and Performance. Proceedings of the 11th ECMWF Workshop on the Use of High Performance Computing in Meteorology. October 25-29, 2005, Reading UK. Ed. George Mozdzynski. (http://wrf-model.org/wrfadmin/docs/ecmwf_2004.pdf).

Moore, C.T. et al. 2011. "Deterministic and Empirical Assessment of Smoke's Contribution to Ozone – Final Report. Western Governors' Association, Denver, CO. (https://wraptools.org/pdf/11-1-6-6_final_report_DEASCO3_project.pdf)

Morris, R. E. and T. C. Myers. 1990. "User's Guide for the Urban Airshed Model. Volume I: User's Manual for UAM (CB-IV)" prepared for the U.S. Environmental Protection Agency (EPA-450/4-90-007a), Systems Applications International, San Rafael, CA.

Page. S. (October 27, 2017). *Supplemental Information on the Interstate Transport State Implementation Plan Submissions for the 2008 Ozone national Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I)* [Memorandum]. Research Triangle Park, NC: U.S. EPA, Office of Air Quality Planning and Standards. Retrieved from https://www.epa.gov/sites/production/files/2017-10/documents/final_2008_o3_naaqs_transport_memo_10-27-17b.pdf

Simon, H., K. Baker and S. Phillips. 2012. Compilations and Interpretation of Photochemical Model Performance Statistics Published between 2006 and 2012. *Atmos. Env.* 61 (2012) 124-139. December. (http://www.sciencedirect.com/science/article/pii/S135223101200684X).

Skamarock, W. C. 2004. Evaluating Mesoscale NWP Models Using Kinetic Energy Spectra. *Mon. Wea. Rev.*, Volume 132, pp. 3019-3032. December. (http://www.mmm.ucar.edu/individual/skamarock/spectra_mwr_2004.pdf).

Skamarock, W. C., J. B. Klemp, J. Dudhia, D. O. Gill, D. M. Barker, W. Wang and J. G. Powers. 2005. A Description of the Advanced Research WRF Version 2. National Center for Atmospheric Research (NCAR), Boulder, CO. June. (http://www.mmm.ucar.edu/wrf/users/docs/arw_v2.pdf)

Skamarock, W. C. 2006. Positive-Definite and Monotonic Limiters for Unrestricted-Time-Step Transport Schemes. *Mon. Wea. Rev.*, Volume 134, pp. 2241-2242. June. (http://www.mmm.ucar.edu/individual/skamarock/advect3d_mwr.pdf).

Sullivan D.C., Raffuse S.M., Pryden D.A., Craig K.J., Reid S.B., Wheeler N.J.M., Chinkin L.R., Larkin N.K., Solomon R., and Strand T. (2008) Development and applications of systems for modeling emissions and smoke from fires: the BlueSky smoke modeling framework and SMARTFIRE: 17th International Emissions Inventory Conference, Portland, OR, June 2-5. Available at: http://www.epa.gov/ttn/chief/conferences.html.

UNC. 2008. Atmospheric Model Evaluation Tool (AMET) User's Guide. Institute for the Environment, University of North Carolina at Chapel Hill. May 30. (https://www.cmascenter.org/amet/documentation/1.1/AMET_Users_Guide_V1.1.pdf).

UNC and ENVIRON, 2014a. Three-State Air Quality Modeling Study (3SAQS) – Draft Modeling Protocol 2011 Emissions & Air Quality Modeling. University of North Carolina at Chapel Hill and ENVIRON International Corporation, Novato, CA. July. (http://vibe.cira.colostate.edu/wiki/Attachments/Modeling/3SAQS_2011_Modeling_Protocol_Finalv2.pdf).

UNC. 2015. SMOKE v3.6.5 User's Manual. University of North Carolina at Chapel Hill, Institute for the Environment. (https://www.cmascenter.org/smoke/documentation/3.6.5/html/).

UNC and ENVIRON, 2015a. Three-State Air Quality Modeling Study (3SAQS) – Weather Research Forecast 2011 Meteorological Model Application/Evaluation. University of North Carolina at Chapel Hill and ENVIRON International Corporation, Novato, CA. March 5. (http://vibe.cira.colostate.edu/wiki/Attachments/Modeling/3SAQS_2011_WRF_MPE_v05Mar2015.pdf).

Wesely, M.L. 1989. Parameterization of Surface Resistances to Gaseous Dry Deposition in Regional-Scale Numerical Models. *Atmos. Environ.*, 23, 1293-1304.

Xiu, A. and J.E. Pleim. 2000. Development of a land surface model. Part I: application in a mesoscale meteorology model. *J. App. Met.*, 40, pp. 192-209.

Yantosca, B. 2004. GEOS-CHEMv7-01-02 User's Guide, Atmospheric Chemistry Modeling Group, Harvard University, Cambridge, MA.

Yarwood, G., J. Jung, G. Z. Whitten, G. Heo, J. Mellberg and M. Estes. 2010. Updates to the Carbon Bond Mechanism for Version 6 (CB6). 2010 CMAS Conference, Chapel Hill, NC. October. (http://www.cmascenter.org/conference/2010/abstracts/emery_updates_carbon_2010.pdf)

Zhang, L., S. Gong, J. Padro, L. Barrie. 2001. A size-segregated particle dry deposition scheme for an atmospheric aerosol module. *Atmos. Environ.*, **35**, 549-560.

Zhang, L., J. R. Brook, and R. Vet. 2003. A revised parameterization for gaseous dry deposition in air-quality models. *Atmos. Chem. Phys.*, **3**, 2067–2082.

Message

From: Clint Woods [clintwoods@gmail.com]
Sent: 7/23/2018 9:38:12 AM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Attachments: CASAC FY 2019 List of Candidates-web.pdf

https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/0E5EAA136A4666D28525824A0074280A/$File/CASAC%20FY%202019%20List%20of%20Candidates-web.pdf

Message

From: Ted Steichen [SteichenT@api.org]
Sent: 8/30/2018 1:21:44 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
CC: Howard Feldman [Feldman@api.org]
Subject: CFI - NAAQS Ozone
Attachments: CFI Ozone.pdf; Exhibit A.pdf; Exhibit B.pdf; Exhibit C Embedded File.pdf; Exhibit C.pdf

Hi Clint,

For your information, please see a copy of API comments filed to the docket on the Call for Information – NAAQS Ozone.

Section II provides suggestions on meeting the October 2020 schedule.

If you or others at EPA would like to discuss our public input, please let me now.

Thank you,

Ted Steichen
202 682 8568
stecihent@api.org

From: Ted Steichen
Sent: Wednesday, August 29, 2018 4:40 PM
To: Sasser, Erika (Sasser.Erika@epa.gov) <Sasser.Erika@epa.gov>
Subject: CFI - NAAQS Ozone

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August 27, 2018

Via www.regulations.gov

Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, D.C. 20460

Re: **Review of the National Ambient Air Quality Standards for Ozone—Call for Scientific and Policy-Relevant Information; June 26, 2018; 83 Fed. Reg. 29,785; Docket ID: EPA–HQ–ORD–2018–0274**

The American Petroleum Institute (API) offers the following comments on the Environmental Protection Agency's (EPA) Call for Scientific and Policy-Relevant Information: Review of the National Ambient Air Quality Standards (NAAQS) for Ozone.

API is the only national trade association representing all facets of the oil and natural gas industry, which supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. API's more than 620 members include large integrated companies, as well as exploration and production, refining, marketing, pipeline, and marine businesses, and service and supply firms. They provide most of the nation's energy and are backed by a growing grassroots movement of more than 40 million Americans. Regulations and the required emission control requirements to attain the NAAQS can have an impact on all aspects of API member operations.

The members of API are dedicated to continuous efforts to improve the compatibility of their operations with the environment while economically developing energy resources and supplying high quality products and services to consumers. Our members recognize their responsibility to work with the public, the government, and others to develop and to use natural resources in an environmentally sound manner while protecting the health and safety of our employees and the public.

This call for information is the initial step in the NAAQS ozone review, which the Agency has stated will be complete by October 2020.[1] Of course, API supports compliance with the Clean Air Act (CAA) and its schedule requirements and this challenging schedule is in the forefront of this 5-year NAAQS ozone review. Getting this review planned out is urgent and is arguably the first step the Agency should undertake. With this priority in mind, the API comments first address how the Back-to-Basics memorandum could be incorporated into this review.

[1] May 9, 2018 E. Scot Pruitt to Assistant Administrators Back-to-Basics Process for reviewing National Ambient Air Quality Standards, page 2. https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf (accessed August 24, 2018).

An equal opportunity employer

API finds that an emphasis on a robust and comprehensive Integrated Review Plan (IRP) is perhaps the best path forward to meet the Agency's challenging deadline. A focused "one draft process" with clear roles and responsibilities will be key. Please find suggestions on how the Agency can meet the timeframe in the attached comments. The challenge of this schedule cannot overemphasize. The number of issues underway, not least of which is the NAAQS $PM_{2.5}$ review process, risk delaying this central objective to meet NAAQS statutory deadlines.

In this call for information EPA requests materials regarding significant new ozone research and policy-relevant issues for consideration in this review. The API comments contain input on both the research and policy-relevant issues and discuss the importance of properly characterizing background ozone as a policy relevant issue during the NAAQS ozone review.

API appreciates the opportunity to provide these comments and looks forward to remaining an engaged and supportive stakeholder as the Agency moves forward with the NAAQS ozone review. If you have any questions about these comments, please contact me at (202) 682-8568 or steichent@api.org.

Sincerely,

/s/

Ted Steichen

Comments on the

U. S. Environmental Protection Agency's

Review of the National Ambient Air Quality Standards for Ozone

Call for Scientific and Policy-Relevant Information

Docket ID: EPA–HQ–ORD–2018–0274

June 26, 2018

83 Fed. Reg. 29,785

Submitted by the

American Petroleum Institute

August 27, 2018

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Exhibit C Embedded File	INTERNATIONAL CONTRIBUTIONS TO OZONE ACROSS UNITED STATES Maria Zatko, Ramboll Environ November 2, 2017 (Reference: Zatko_PNWIS_NoIntlEmis_2017-10-11_v6.pdf)

I. Introduction

A. Scope of the Call for Information on Ozone NAAQS

EPA called for the submittal of information regarding significant new ozone research and policy-relevant issues for consideration in this review of the primary (health-based) and secondary (welfare-based) ozone standards.

B. Organization of these Comments

This call for information is the initial step in the NAAQS ozone review, which the Agency has stated will be complete by October 2020.[2] Of course, API supports compliance with the Clean Air Act and its schedule requirements and this challenging schedule is in the forefront of this NAAQS ozone review. Getting this review planned out is urgent and is arguably the first step the Agency should undertake. With this priority in mind, the API comments first address how the Back-to-Basic memorandum could be incorporated into this review.

API finds that an emphasis on a robust and comprehensive Integrated Review Plan (IRP) is perhaps the best path forward to meet the Agency's challenging deadline. A focused "one draft process" with clear roles and responsibilities will be key. Please find in Section II suggestions on how the Agency could meet the timeframe established in the Back-to-Basics memorandum.

In this call for information EPA requests materials regarding significant new ozone research and policy-relevant issues for consideration in this review.[3] The API research input is organized in Sections III and IV, and associated Exhibits A and B.

Section III provides an example list of studies that could form a "pivotal list" of studies that the ISA could cover. This list contains examples of recent information, some of which API anticipates EPA's Office of Research and Development (ORD) would likely select as pivotal. Please note the studies listed are not an endorsement of these studies but are listed for illustration. Exhibit A of the comments provide more detail and suggestions for how these studies could be summarized in the ISA.

Section IV and Exhibit B deal with ozone research that API suggests the Agency consider as the "pivotal list" is developed.

API comments discuss the importance of properly characterizing background ozone as a policy-relevant issue during the NAAQS ozone review in Section V and Exhibit C. Comments on adverse impacts on the NAAQS setting process will follow in response to that separate call for information.

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[2] E. Scot Pruitt memorandum to: EPA Assistant Administrators, May 9, 2018, page 2. https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf (accessed August 24, 2018).

[3] 83 Fed. Reg. 29,785 (June 26, 2018).

II. Toward a Final Ozone Rule by October 2020

In thinking about how the challenging deadline can be met API reviewed materials created by the Administration relevant to the NAAQS review process.

A. Recent Memoranda on the NAAQS Review Process

The NAAQS ozone review began with this July 2018 call for information. This upcoming review has been the subject of memoranda from the President and the EPA Administrator.

1. Presidential Memorandum of April 12, 2018 Promoting Domestic Manufacturing and Job Creation—Policies and Procedures Relating to Implementation of Air Quality Standards[4]

A key excerpt from this memo referenced future NAAQS reviews:

> *"Sec. 7. Future NAAQS Reviews. The Administrator shall evaluate whether EPA is complying fully with the requirements of section 109(d)(2)(C) of the CAA (42 U.S.C. 7409(d)(2)(C)) relating to the scope and characterization of advice provided by its Clean Air Act Scientific Advisory Committee, including requirements that the Committee advise the Administrator regarding background concentrations and adverse public health or other effects that may result from implementation of revised air quality standards. In addition, the Administrator shall examine the current NAAQS review process and develop criteria to ensure transparency in the evaluation, assessment, and characterization of scientific evidence in such reviews. The Administrator shall also develop clear guidance for differentiating the role of science and policy considerations in establishing NAAQS."*[5]

2. Administrators Back-to-Basics Process for reviewing National Ambient Air Quality Standards[6]

In this document there is substantial detail on how the Agency should refocus and reimagine the review process. In this memorandum, the Administrator set out the following five principles for EPA to observe in future NAAQS reviews:

- Meet statutory deadlines;
- Address all CAA provisions for NAAQS reviews;
- Streamline and standardize the process for development and review of key policy-relevant information;
- Differentiate science and policy judgments in the NAAQS review process; and
- Issue timely implementation regulations and guidance.

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[4] 83 Fed. Reg. 16,761 (April 12, 2018).
[5] 83 Fed. Reg. 16,764 (April 16, 2018).
[6] E. Scot Pruitt memorandum to: EPA Assistant Administrators, May 9, 2018.

The memorandum discusses each of the five principles and builds on early improvements to the NAAQS review process, memoranda issued December 7, 2006,[7] and May 21, 2009.[8]

Meet Statutory Deadlines is the first principle in the memorandum. The Administrator states "[f]or the next review of the ozone NAAQS, EPA shall seek efficiencies through replacing the kick-off workshop with a more robust request for information, and shall consider combining its integrated science, risk and exposure, and policy assessment into a single review.

As EPA implements this memo API encourages the Agency to look to the first document, the Integrated Review Plan (IRP) to provide the outline for this efficient review. In Part G. of this Section, API provides more detail on how the IRP and the Clean Air Scientific Advisory Committee (CASAC) review of the IRP will allow the Agency to adhere to this first principle.

Address All CAA Provisions for NAAQS Reviews is the second principle, and these provisions are specified in Section 109(d)(2) of the Act on the roles and responsibilities of CASAC. Some of these responsibilities have not been completed in past reviews and the reasons given were that EPA did not provide within the science documents material for review on all the topics mentioned in Section 109(d)(2) and that CASAC panel did not include members to address all these areas[9]. In the recent request for nominations the need for members across all the relevant disciplines was highlighted. API anxiously awaits the list of nominated panelists and intends to comment on whether or not the needed expertise will be provided on the panel. The task remains for EPA to determine how they will address all the topics that require review and if that is best incorporated in the ISA. EPA should address this issue in the IRP as to the plan to develop the needed materials for a CASAC review in the IRP.

Of note, these NAAQS topic specific panels have been constituted by the EPA Science Advisory Board (SAB) Staff Office, as compared to the statutory CASAC membership that is determined by the Administrator. Since the previous process has not provided for panels to address all the provisions, for at least this ozone panel API recommends the Administrator takes an active role to ensure this principle is fully addressed.

Streamline and standardize the process for development and review of key policy-relevant information is the third principle. The IRP should include details on how the Agency intends to meet this requirement.

Differentiate science and policy judgments in the NAAQS review process is the fourth principle. These expectations need to be enumerated and provide to the ozone NAAQS review panel as soon as it is formed. In attending many review meetings in the past API staff sensed that the CASAC panel members did not always have a common understanding of this distinction. Written expectations to the CASAC review panel would greatly improve the chances the ozone review will adhere to this principle.

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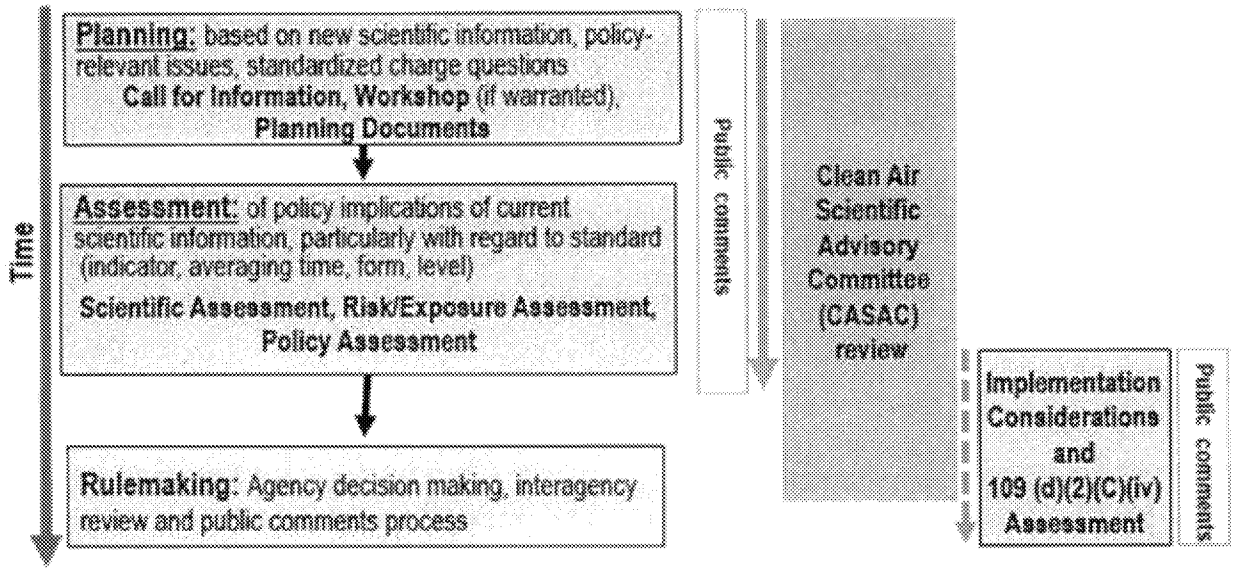
[7] Marcus Peacock: memorandum to George Gray, and Bill Wehrum, December 7, 2006. https://www3.epa.gov/ttn/naaqs/pdfs/memo_process_for_reviewing_naaqs.pdf (accessed August 24, 2018).
[8] Lisa Jackson: memorandum to Elizabeth Craig and Lek Kadeli, May 21, 2009. https://www3.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf (accessed August 24, 2018).
[9] Dr. H. Christopher Frey: letter to The Honorable Gina McCarthy, June 26, 2014. https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/$File/EPA-CASAC-14-004+unsigned.pdf (accessed August 24, 2018).

Issue timely implementation regulations and guidance is the fifth principle. This principle is important, but the challenging schedule to complete this NAAQS ozone review by October 2020 elevates the prior four principles over this one.

Within the Back-to-Basics memorandum a schematic of the steps associated with a streamlined and efficient NAAQS review is illustrated as Figure 1:[10]

Figure 1. Schematic of the steps associated with a streamlined and efficient NAAQS review.

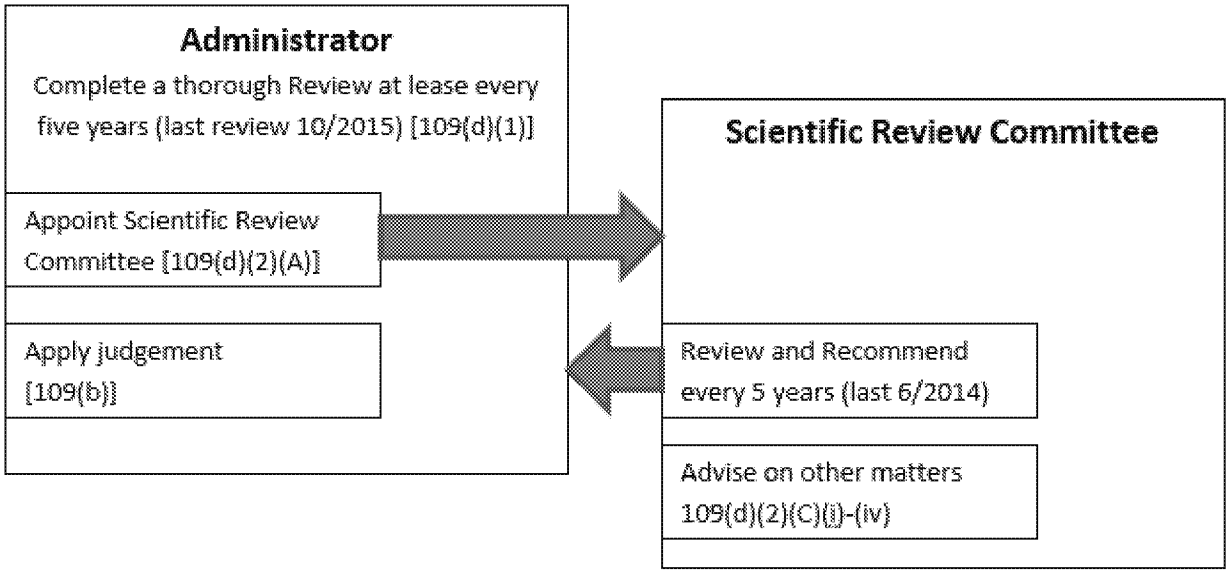


[10] E. Scot Pruitt memorandum to: EPA Assistant Administrators, May 9, 2018, page 10.

To pare this down to the minimum statutory requirements, the following illustration is provided:

Review of National Ambient Air Quality Standards

Statutory Requirements



The Administrator (EPA) prepares documents that the Scientific Review Committee, known as CASAC, review and provide recommendations. For ozone, prior to the 2015 review a Criteria Document was developed and reviewed by CASAC.[11] For the 2015 ozone review an Integrated Review Plan, Risk and Exposure Assessment Scope and Methods Plans (otherwise referred to as the Risk and Exposure Assessment Planning Documents), an Integrated Science Assessment, Risk and Exposure Assessments and a Policy Assessment were completed.

The schematic from the Back-to-Basics references all the documents that were part of the 2015 review. API recommends EPA consider whether all of these documents are necessary to produce and review. The need to do no more than necessary is critical within the timeline the Administrator has established. Please see Part B of this Section for further discussion on what API views as an aggressive timeline and provides a suggested alternative schematic in Part F of this Section.

On page 9 of the memorandum the Administrator states:

> *"EPA should strive to ensure that initial drafts of all documents are sufficiently robust and complete to serve as adequate vehicles for review from both the CASAC and the public, and CASAC should strive to focus on significant comments for these drafts to avoid multiple draft reviews whenever possible. EPA focus on providing CASAC with assessments and chapters succinctly reflect the most salient information, and CASAC focus on providing clear scientific, not editorial, advice, will prevent the inefficiency of what one former CASAC Chair called a "ping-pong" review process with review of multiple drafts. The Agency should seek additional*

[11] U.S. EPA. Air Quality Criteria for Ozone and Related Photochemical Oxidants (Second External Review Draft). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-05/004aB-cB, 2005. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=137307 (accessed August 24, 2018).

efficiencies in each step in the review process ..., redesigning those steps as needed, and utilizing, in the most efficient manner possible, only those steps that add value in a particular review."

API strongly supports this expectation and suggests that it is best accomplished by a robust IRP that already outlines which new science may be most pivotal to review to accomplish the review. The CASAC and the public, at that point in the process, can provide feedback to the Agency to inform the development of a focused ISA. Please see Part G of this Section for further suggestions on the development of more robust IRP.

B. Aggressive Timeline

Within this call for information EPA provides a deadline to complete this review by October 2020.[12] The task before the EPA is challenging and the need to establish clear expectations and timelines for the Agency staff and CASAC is critical.

To highlight the challenge, in the last Integrated Review Plan the Call for Information (this request) was documented as being made September 2008 with a target final rule in February 2014 in the draft of the IRP,[13] and June 2014 in the final document.[14] The rule was actually finalized in October 2015[15]. The final IRP plan projected was almost 6 years, and it ended up being 7 years. The time between this Call for Information in July 2018 and the date the Administrator intends the review to be complete, October 2020, is little more than two years. Clearly to meet this new timeline will require a sweeping change in the NAAQS review process.

To add to the workload, EPA will likely need to gather additional materials that directly apply to the advice the scientific review committee (CASAC) has not traditionally provided, most especially that required in Section 109(d)(2)(C)(iv).

In considering how to implement a sweeping change, API starts with the statutory requirements and looks how to incorporate all the elements from the latest NAAQS ozone review into the minimum number of documents that require review. For example, assume the documents to be prepared are:

- Integrated Review Plan
- Integrated Science Assessment
- Materials for Section 109(d)(2)(C)(iv) (from existing materials)
- Advanced Notice of Proposed Rulemaking
- Proposed Rule
- Final Rule

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[12] E. Scot Pruitt memorandum to: EPA Assistant Administrators, May 9, 2018, page 2.
[13] U.S. EPA. Integrated Review Plan for the Ozone National Ambient Air Quality Standards Review - External Review Draft. U.S. Environmental Protection Agency, Washington, DC, EPA/452/D-09-001, 2009, page 14. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1005B09.txt (accessed August 24, 2018)
[14] U.S. EPA. Integrated Review Plan for the Ozone National Ambient Air Quality Standards. U.S. Environmental Protection Agency, Washington, DC, EPA/452/R-11-006, 2011, page 2-2. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100AUZO.txt (accessed August 24, 2018)
[15] 80 Fed. Reg. 65,292 (October 26, 2015).

For illustration, please see the following possible timeline to meet the challenging schedule:

Potential NAAQS Ozone Review Milestones

Milestone	Date	Notes
Call for Information	July 2018	30-day comment period
Draft IRP	March 2019	60-day comment period
CASAC Review of IRP	April 2019	
Final IRP (becomes an element of the ISA)	July 2019	
Draft ISA & Materials for 109(d)(2)(C)(iv)	September 2019	30-day comment period
CASAC Review of ISA & Materials for 109(d)(2)(C)(iv)	October 2019	
Final ISA	December 2019	
ANPRM	February 2020	30-day comment period
Proposed Rule	May 2020	60-day comment period
Final Rule	October 2020	

The timeline allows for the development of the much more robust IRP including significant detail on the science to be reviewed and any already identified potential new risks and exposures that might need to be evaluated. Close coordination between the Office of Research and Development and the Office of Air Quality Policy and Standards within the Office of Air and Radiation would likely be the necessary to complete this draft robust IRP.

For the 2015 ozone review CASAC did not hold a meeting to discuss the draft IRP, it was discussed on a consultation conference call; CASAC provided no consensus report for the Administrator.[16] This illustrates that, in the current process, the planning phase (IRP) is not elevated to the same level as the assessment phase.

The key suggestion to EPA is to elevate the planning phase to receive the informed recommendations from the CASAC following a full review of a more robust draft IRP. The review of the ISA could then be focused on how well the IRP was followed. In Part G of this Section is a further discussion on the IRP while Part H provides discussion of the other review steps.

C. Full Requirements of the Review (CAA requirements)

Section 109(d)(2) of the Act requires appointment of an independent scientific review committee that is to periodically review the existing air quality criteria and NAAQS and to recommend any new standards and revisions of existing criteria and standards as may be appropriate. Since the early 1980s, the requirement for an independent scientific review committee has been fulfilled by the Clean Air Scientific Advisory Committee (CASAC).

Section 109(d)(2)(C) of the Act additionally requires the independent scientific review committee to advise the EPA Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS; describe the research efforts necessary to provide the required information; advise the EPA Administrator on the relative contribution to air

[16] Dr. Jonathan M. Samet: letter to The Honorable Lisa P. Jackson, December 3, 2009 https://yosemite.epa.gov/sab/sabproduct.nsf/8A8B1D042C07DE5185257681007B7D85/$File/EPA-CASAC-10-004-unsigned.pdf (accessed August 24, 2018).

pollution concentrations of natural as well as anthropogenic activity; and, advise the EPA Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS. To ensure this final statutory requirement is fully met, EPA further published in the Federal Register a call for information that would facilitate the committee's consideration of these issues.

Within this call for information Federal Register Notice the CASAC requirements include:

> *"advise the EPA Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity; and, advise the EPA Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS."*

The CASAC panel will need to include experts to address these issues and EPA will need to provide materials for CASAC review to ultimately address the noted requirements. Furthermore, API suggests that EPA prepare materials to highlight to CASAC exactly what is expected to provide this policy relevant information that can inform rule development of any new ozone NAAQS. API also suggests the Administrator identify an office within EPA to be responsible for assembling or preparing the needed documents for CASAC review on these issues.

D. Relationship with Call for Information on Adverse Impacts

The Administrator is already calling for information to evaluate the element of these CASAC review requirements dealing with adverse impacts.[17] API will comment on that call for information but strongly suggests the Agency work this issue now, before those comments are provided, to give the CASAC panel clear expectations on this task.

E. Request for Nominations for CASAC Ozone Panel

In a July 27, 2018 Notice[18] the SAB Staff Office requested public nominations for scientific experts to form a CASAC ad hoc panel to provide advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the NAAQS for ozone.

The SAB Staff Office sought nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone as they select the panel. Experts solicited include:

- Air quality,
- atmospheric science and chemistry,
- causal inference,
- dosimetry,
- toxicology,
- controlled clinical exposure,
- epidemiology,
- biostatistics,

[17] 83 Fed. Reg. 29,784 (June 26, 2018).
[18] 83 Fed Reg 35,635 (July 27, 2018).

- human exposure modeling,
- risk assessment/modeling, uncertainty analysis,
- ecology and effects on welfare and the environment, and
- environmental economics.

The approved policy[19] delegates the decision on this panel to the SAB Staff Office.

The recent request for nominations for the CASAC ozone panel[20] included the need to address the full range of the statutory CASAC duties, including an analysis of background and adverse effects. However, it did not fully highlight the needed experts to handle the full requirements of the review. In other efforts the Agency has begun to address the formation of CASAC,[21] and API recommends the Administrator continue to prioritize making further improvements in canvasing for and selecting the CASAC and the specific NAAQS review panels.

The Administrator could improve the NAAQS ozone review by guiding and supporting CASAC directly, at least as the NAAQS review process is streamlined. The repeated inability for the process to be completed within 5-years, that the full scope of the statutory advice has not been provided in recent reviews, that enhanced coordination will be necessary between ORD and OAQPS within OAR to accomplish a review redesign, and the documented substantial benefits to public health attributed to the NAAQS all argue for the Administrator's direct attention. While the SAB Staff Office has the expertise and supports numerous science panels, CASAC is pivotal to the NAAQS review process. The efficiencies of maintaining this role within the existing SAB framework could be weighed against the attention that is needed by the Administrator to ensure the advice required by the CAA is developed.

At a minimum the Administrator should update the CASAC panel formation approval policy to provide guidance to SAB Staff Office regarding CASAC. API would also suggest the Administrator ensure the CASAC panel members are provided with clear requirements and expectations of their service.

F. Overview of Possible Streamlined Process

The example schematic API provides in these comments is simplified to assist in clarifying the recommendations. These recommendations assume the same level of public interaction with the Agency and the CASAC that has historically been the case. API appreciates EPA's track record on soliciting public comment throughout the NAAQS review process. EPA's schematic provided in the recent Back-to-Basics memorandum demonstrates again its commitment to public engagement.

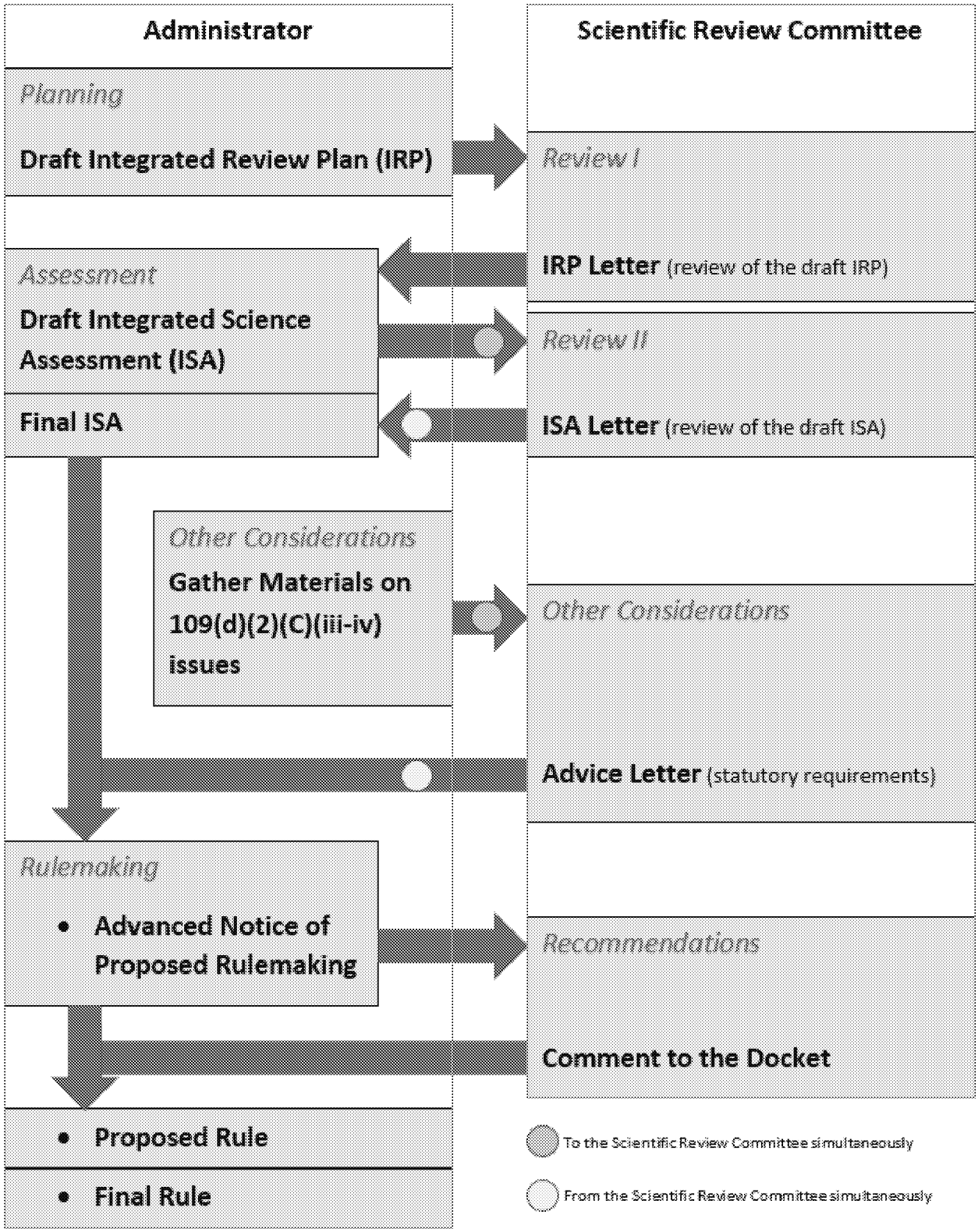
As with the potential scheduled provided in Part B. of this Section, API starts with the statutory requirements and examines how to incorporate all the elements from the latest NAAQS ozone review into

[19] U.S. EPA. Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board. U.S. Environmental Protection Agency, Washington, DC, EPA–SAB–EC– 02–010, 2002. https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf (accessed August 24, 2018).
[20] 83 Fed Reg 35,635 (July 27, 2018).
[21] E. Scott Pruitt: letter to EPA Assistant Administrators, October 31, 2017. https://www.epa.gov/sites/production/files/2017-10/documents/final_draft_fac_memo-10.30.2017.pdf (accessed August 24, 2018).

the minimum number of documents that require review. For purposes of this example the documents will be prepared:

- Integrated Review Plan
- Integrated Science Assessment
- Materials for Section 109(d)(2)(C)(iv) (these are anticipated to be existing materials)
- Advanced Notice of Proposed Rulemaking
- Proposed Rule
- Final Rule

Example Review of National Ambient Air Quality Standards



The example would require two reviews by the Science Review Committee, known as CASAC. The first would be on the more robust draft IRP, the second would be for the draft ISA as well as the areas CASAC has not traditionally focused, the 109(d)(2)(C)(iv) issues discussed in Part C. of this Section.

Following those reviews the Administrator (EPA) would incorporate the recommendations from CASAC and the public and publish an Advance Notice of Proposed Rulemaking (ANPRM). Any needed materials that relate to a risk and exposure assessment that are not already incorporated in the final ISA could be included within the ANPRM or provided separately to the Docket and referenced in the ANPRM. CASAC, as a key stakeholder, would be asked to comment on the ANPRM to provide any additional advice to the Administrator prior to the proposed rule.

G. Integrated Review Plan

1. Key Review Document

As previously stated the challenging schedule requires a substantial reevaluation of the work needed on each identified step in the review process. API suggests EPA focus heavily on developing an IRP that is detailed and provides not only the process to complete the review but also identifies by name the pivotal studies the Agency will review, and how the interpretation of those studies might require further analysis of risk and exposure.

For several cycles the ozone NAAQS review process has extensively evaluated new studies to inform the level and form of the standards, though reviews have been refinements built on the existing record. In more recent years EPA staff have developed data systems that track recent research[22] so it is reasonable to assume the EPA staff experts are generally familiar with the state of the science.

To meet the challenging timeline, yet clearly meet the requirements of the CAA, API recommends EPA assemble a list of "pivotal" studies that will be investigated and discussed in the ISA. This list can and should be thoroughly reviewed by CASAC. Many of these experts, which by definition are "nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone",[23] can review the EPA list and identify more "pivotal" studies that should replace one on the EPA draft list. This determination of the scope of the review seems to be the highest and best use of the time committed by the CASAC ozone panel.

With the list of studies provided in the final IRP, the scope of the ISA is set and then the review can be primarily on whether the Agency had fulfilled the review as planned in the IRP.

In a similar fashion, the IRP could include the known key elements of what are now separate planning documents. Perhaps the experts at EPA can review the final REA from the last review and, in consultation with those developing the "pivotal" studies table provide at least some detail on how to address the possible need and scope of any risk or exposure assessments within the draft IRP. Again, the CASAC panelists, with their extensive knowledge are likely able to review and provide key guidance on the likely planning elements of such potential assessments by reviewing such a chapter within the draft

[22] https://hero.epa.gov/hero

[23] 83 Fed Reg 35,635 (July 27, 2018).

IRP. Inclusion of planning material about these potential assessments in the IRP will allow even more refinement of a potential plan for potential risk and exposure assessments within the draft ISA.

In both cases this robust IRP could rely on "expert elicitation" by both EPA staff and CASAC. This is a departure from prior reviews that can be made given the body of knowledge already evaluated regarding ozone and the rapid improvement in information handling capabilities. The measure of the efficacy of this approach is: does it fulfill the requirements of the statutory CASAC review. Based on the historic inability to complete the review within 5-years and the failure to address all the elements specified within the CAA, this is an example of the fresh thinking EPA should consider.

Traditionally the IRP has contained information from the prior review, summary information on new available materials and some detail on how that information will be evaluated. Each IRP has been tailored to the pollutant, but it remained very much about process and not content. In fairness, the traditional IRP content clearly does meet the definition of a review plan, but the suggestions above would make the review plan much more specific to the pollutant and the research to be reviewed in the current cycle.

More specificity earlier in the process would allow the best use of the expertise of CASAC in finalizing the IRP, as well as provide a clear framework for CASAC to ultimately judge if EPA completed what they indicated within the plan. In this approach the ISA review can be focused on evaluating the quality of the EPA effort in implementing the "plan" without needing to address the "mission creep" that API staff have observed in prior reviews where multiple ISA drafts were prepared and reviewed by CASAC. To highlight where the work has typically been focused, in the 2015 ozone review the IRP was 77 pages,[24] while the ISA was 1,251 pages.[25] In the 2008 ozone review the IRP was 22 pages,[26] while the final ISA was in three volumes with a total page count of 2,118.[27]

2. The IRP Sets the Scope of the Review

The NAAQS review process must be timely and meet the statutory requirements. An improved process should start with a detailed plan with a clear scope. Since any review is not starting from scratch and those developing the materials are already familiar with the current state of science, EPA should strongly consider focusing on developing a detailed scope of the entire NAAQS ozone review and move away from a sequential process of document development, reviews, rework of those documents and then further reviews.

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[24] U.S. EPA. Integrated Review Plan for the Ozone National Ambient Air Quality Standards. U.S. Environmental Protection Agency, Washington, DC, EPA/452/R-11-006, 2011. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100AUZO.txt (accessed August 24, 2018)

[25] U.S. EPA. Integrated Science Assessment (ISA) of Ozone and Related Photochemical Oxidants (Final Report, Feb 2013). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-10/076F, 2013. https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=247492 (accessed August 24, 2018).

[26] U.S. EPA. Plan for Review of the National Ambient Air Quality Standards for Ozone. U.S. Environmental Protection Agency, Washington, DC. https://www3.epa.gov/ttn/naaqs/standards/ozone/data/o3_review_plan_march05.pdf. (accessed August 24, 2018).

[27] U.S. EPA. Air Quality Criteria for Ozone and Related Photochemical Oxidants (Final Report, 2006). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-05/004aF-cF, 2006. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=149923. (Accessed August 24, 2018).

One of the key roles of the CASAC is to describe the research efforts necessary to provide the required information. This is often done in the final letter to the Administrator on the PA.[28] Ultimately, as this NAAQS ozone review proceeds, if unexpected information comes to light it should be flagged by CASAC to investigate for the next review cycle.

3. CASAC Identified Shortcomings in Recent Integrated Review Plans

To illustrate that the current draft IRP is not necessarily sufficient within the current review process, API notes the CASAC review of EPA's Draft Integrated Review Plan for the Secondary National Ambient Air Quality Standard for Oxides of Nitrogen and Oxides of Sulfur. The then Chair of CASAC highlighted, among other items:

- Lack of Specificity in the Plan: The CASAC is concerned that providing just preliminary ideas in the draft IRP does not constitute a plan that could be put into action.[29]

- Uncertainty: A more in-depth consideration of uncertainty is needed[30]

The IRP has not always been fully reviewed by CASAC. For example, in the last review for ozone the Draft Review was a "consultation" and no consensus report was provided[31]

Using substantial EPA resources to create a more robust and specific IRP could provide the best opportunity to meet the Administrator's schedule. A more robust and specific IRP could also allow for a more substantive CASAC review of this key document. Details about how EPA will address uncertainties and highlighting the degree of transparency in the science reviewed will ultimately give the Administrator key information to evaluate any potential change in the NAAQS.

4. Charge Questions

The IRP should include charge questions that are specific to this review, perhaps directed at individual key studies and setting the expectation that the ISA identify the specific evidence within those study results that argues for a change in a NAAQS. Further charge questions can build on the identified evidence to address if the degree of uncertainty of that substantiation is more or less robust than the prior evidence used to set the existing NAAQS. All charge questions would be subject to both public and CASAC input as part of the draft IRP review defining the task in front of EPA as it develops the ISA.

5. Request for Comment by Public and CASAC

The roles and responsibilities of the Chartered CASAC and the CASAC ozone panel should be established before the first meeting. All stakeholders should be encouraged to comment on the IRP. A clear IRP can then be implemented in the ISA and the rulemaking phase.

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[28] Dr. H. Christopher Frey: letter to The Honorable Gina McCarthy, EPA-CASAC-14-004, June 26, 2014.
[29] Dr. Ana V. Diez Roux: letter to The Honorable Gina McCarthy, EPA-CASAC-16-001, April 1, 2016.
[30] Ibid, page 2
[31] Dr. John M. Samet: letter to The Honorable Lisa P. Jackson, EPA-CASAC-10-004, December 3, 2009.

6. Finalizing the IRP

EPA should incorporate, as they are able, the comments of the Public and CASAC when finalizing the IRP. An IRP specific to the pivotal science will facilitate the completion of an ISA that documents any new key evidence including a discussion of uncertainty and transparency. The finalized IRP could be incorporated in the final ISA as an appendix.

H. Other Review Steps

1. Integrated Science Assessment

Were the IRP developed as suggested, the ISA would have a clear format and would answer the specific charge questions raised by the pivotal studies indicated in the IRP to be addressed in the review. The CASAC review of the ISA would be clear. Did EPA adequately review the pivotal research identified in the IRP and complete the risk and exposure review as laid out in the IRP?

If CASAC does identify a needed improvement in the ISA, EPA could then address that in the final ISA. CASAC would also work on answering the full scope of their statutory requirements, which would be included in an advice letter to the Administrator. This letter could end the formal role of the CASAC panel, however CASAC could be encouraged to comment on the ANPRM

2. Risk and Exposure Assessment

A separate document detailing the risk and exposure assessment is not a statutory requirement. In earlier reviews the Criteria Document did not contain risk and exposure information. That information was subsequently prepared as technical documents for use by the Administrator.[32]

Incorporating risk and exposure assessments within the review process could be addressed by including these issues in both the more robust IRP and the ISA. Any available early (preliminary) results of any needed risk and exposure assessment could be included in the draft ISA. If additional risk and exposure assessments are identified, then the results could be included within the final ISA if complete at that time. If such assessments are conducted, another option would be to include the results in their entirety or by reference and place them into the Docket at the time the ANPRM is issued. CASAC could be encouraged to comment on the ANPRM.

3. Policy Assessment as an Advanced Notice of Proposed Rulemaking

The Policy Assessment (PA) could be issued as an Advanced Notice of Proposed Rulemaking (ANPRM) as outlined in the 2006 Memorandum from the Deputy Administrator Marcus Peacock.[33] The ANPRM should have a relatively short comment period and not be held up by the practice of waiting for a CASAC meeting to be held to review the PA. At the time of the ANPRM the CASAC ozone panel could review the ANPRM and update their recommendations to the Administrator via the Docket.

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[32] One of the documents: A Probabilistic Assessment of Health Risks Associated with Short-Term Exposure to Tropospheric Ozone; R,G,Whitfield, W.F. Biller, M.J. Jusko, and J.M. Keisler, ANL/DOS-3, June 1996. https://www3.epa.gov/ttn/naaqs/standards/ozone/data/riskrep.pdf (accessed August 24, 2018).

[33] Marcus Peacock: memorandum to George Gray, and Bill Wehrum, December 7, 2006. https://www3.epa.gov/ttn/naaqs/pdfs/memo_process_for_reviewing_naaqs.pdf (accessed August 24, 2018).

4. Proposed and Final Rulemaking

The release of the ANPRM could provide the opportunity to then release a proposed rule with a preferred option moving forward. After public comment, the final rule could move on to that preferred or perhaps an alternate option as laid out in the proposed rule.

III. Identify Pivotal Studies and List in the IRP

EPA should identify a limited number of truly pivotal studies that will be further evaluated in the Integrated Review Plan (IRP). The much shorter review period will require a streamlined process and EPA should fully utilize the technical expertise of EPA staff and CASAC members to establish the scope of the Integrated Science Assessment (ISA) within the IRP.

Here is an example of studies that might be included in such a focused list:

1. Long-term (chronic) effects

- **Ambient PM2.5, O_3, and NO_2 Exposures and Associations with Mortality over 16 Years of Follow-Up in the Canadian Census Health and Environment Cohort (CanCHEC);** Crouse DL, Peters PA, Hystad P, Brook JR, van Donkelaar A, Martin RV, Villeneuve PJ, Jerrett M, Goldberg MS, Pope CA 3rd, Brauer M, Brook RD, Robichaud A, Menard R, Burnett RT. *Environ Health Perspect.* 2015 Nov;123(11):1180-6.

- **Long-Term Ozone Exposure and Mortality in a Large Prospective Study;** Turner MC, Jerrett M, Pope CA 3rd, Krewski D, Gapstur SM, Diver WR, Beckerman BS, Marshall JD, Su J, Crouse DL, Burnett RT. *Am J Respir Crit Care Med.* 2016 May15;193(10):1134-42.

- **Associations between long-term PM2.5 and ozone exposure and mortality in the Canadian Census Health and Environment Cohort (CANCHEC), by spatial synoptic classification zone;** Cakmak S, Hebbern C, Pinault L, Lavigne E, Vanos J, Crouse DL, Tjepkema M. *Environ Int.* 2018 Feb;111:200-211.

- **Has reducing fine particulate matter and ozone caused reduced mortality rates in the United States?** Cox LA Jr, Popken DA. *Ann Epidemiol.* 2015 Mar;25(3):162-73.

- **Mortality associations with long-term exposure to outdoor air pollution in a national English cohort;** Carey IM, Atkinson RW, Kent AJ, van Staa T, Cook DG, Anderson HR. *Am J Respir Crit Care Med.* 2013 Jun 1;187(11):1226-33.

- **Long-term exposure to ambient ozone and mortality: a quantitative systematic review and meta-analysis of evidence from cohort studies;** Atkinson RW, Butland BK, Dimitroulopoulou C, Heal MR, Stedman JR, Carslaw N, Jarvis D, Heaviside C, Vardoulakis S, Walton H, Anderson HR. *BMJ Open.* 2016 Feb23;6(2):e00949.

- **Ambient ozone and incident diabetes: A prospective analysis in a large cohort of African American women;** Jerrett M, Brook R, White LF, Burnett RT, Yu J, Su J, Seto E, Marshall J, Palmer JR, Rosenberg L, Coogan PF. *Environ Int.* 2017 May;102:42-47.

2. Short-term (acute) effects

- **Association of Short-term Exposure to Air Pollution with Mortality in Older Adults;** Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD, Dominici F. *JAMA*. 2017 Dec 26;318(24):2446-2456

- **Characterization of the concentration-response curve for ambient ozone and acute respiratory morbidity in 5 US cities;** Barry V, Klein M, Winquist A, Chang HH, Mulholland JA, Talbott EO, Rager JR, Tolbert PE, Sarnat SE. *J Expo Sci Environ Epidemiol*. 2018 Jun 19

- **Acute effects of ambient ozone on mortality in Europe and North America: results from the APHENA study;** Peng RD, Samoli E, Pham L, Dominici F, Touloumi G, Ramsay T, Burnett RT, Krewski D, Le Tertre A, Cohen A, Atkinson RW, Anderson HR, Katsouyanni K, Samet JM. *Air Qual Atmos Health*. 2013 Jun 1;6(2):445-453

- **Air quality and acute deaths in California, 2000-2012;** Young SS, Smith RL, Lopiano KK. Air quality and acute deaths in California,2000-2012. *Regul Toxicol Pharmacol*. 2017 Aug;88:173-184

3. Respiratory Function

- **Effects of Policy-Driven Air Quality Improvements on Children's Respiratory Health;** Gilliland F, Avol E, McConnell R, Berhane K, Gauderman WJ, Lurmann FW, et al. 2017. The Effects of Policy-Driven Air Quality Improvements on Children's Respiratory Health. Research Report 190. Boston, MA:Health Effects Institute.

4. Toxicological literature

- **The perpetuation of the misconception that rats receive a 3-5 times lower lung tissue dose than humans at the same ozone concentration;** McCant D, Lange S, Haney J, Honeycutt M. *Inhal Toxicol*. 2017 Apr;29(5):187-196. doi: 10.1080/08958378.2017.1323982.

In Exhibit A to these comments is further information briefly discussing the study, conclusions and other relevant information. Also included for each of these studies is a quick strengths / limitations reference. As an example, below is the table for the first item on this list, **Ambient PM2.5, O_3, and NO_2 Exposures and Associations with Mortality over 16 Years of Follow-Up in the Canadian Census Health and Environment Cohort (CanCHEC):**

Strengths	Limitations
Large (2.5M) national 20% sample from long form Census	Lack of smoking data
Cause-specific mortality, not just all-cause	Associative, not causal modeling; standard limitations
2- and 3-p models with PM2.5 & NO2 with stable results	Hard to statistically separate pollutants' effects

IV. Additional Studies to Consider in Developing a Pivotal List

As EPA develops the list of pivotal studies to present to CASAC in the draft IRP, API offers further material in Exhibit B. In this exhibit API has included original research, methods & recommended practices, reviews, critiques, weight of evidence and commentary that can inform on the policy relevant issues associated with reviewing the ozone NAAQS.

V. Policy Relevance of Background Ozone

EPA has both the ability and legal obligation to consider the impacts of background levels of ozone on the achievability of the NAAQS. Although the U.S. Supreme Court's decision in *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001) is often cited for the proposition that EPA cannot consider the costs of implementation, EPA still can and must consider other contextual factors. Notably, in order to determine the levels of ozone that are "sufficient, but not more than necessary" to protect the public health and welfare, EPA must conduct an assessment of the extent to which the risks from exposure to the pollutant are unacceptable, which requires EPA to take into account contextual considerations. *Id.* at 473. The contextual risk assessment factors were described by Justice Breyer in *Whitman* as including "the public's ordinary tolerance of the particular health risk," "comparative health consequences," and the "acceptability of small risks to health." *Id.* At 494-95 (Breyer, J., concurring in part and concurring in the judgment). These contextual factors can all be influenced by the overall adverse economic, social, and energy impacts that could result from a revised NAAQS. For example, the public's "tolerance" and "acceptability" or a particular level of risk can be affected by the standard's adverse impacts on the public that could occur through reductions in economic growth and job loss.

Furthermore, the text of the Clean Air Act shows that Congress intended the NAAQS to be achievable by regulation of U.S. sources through State Implementation Plans (SIPs). The requirements in Section 107(a) that SIPs specify the manner in which the NAAQS "will be achieved and maintained" and the requirements in Section 110(a)(2)(C) call for an enforcement and regulation program "as necessary to assure that [NAAQS] are achieved." Furthermore, Sections 172(a)(2),181, 186, 188 and 192 specify deadlines for achieving attainment. Additionally, Section 109(b) itself links the setting of "requisite" NAAQS to their "attainment and maintenance." These attainment requirements help demonstrate that Congress did not intend NAAQS to address pollution that is beyond the control of the States or EPA. It follows that, in revising NAAQS, EPA must consider whether the standards can be achieved through the regulations provided for by the Clean Air Act – which means taking background ozone into account – and cannot set a standard that is unachievable on a nationwide basis through these regulations.

A. EPA's Identification of the Issue

As EPA states in this call for information, the EPA Administrator is to be advised on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity as part of his deliberations in setting a NAAQS.

In the ISA and the PA for the 2015 NAAQS review a summary of studies regarding background ozone and its contribution to total ambient ozone levels were provided.

B. Summarize the Key Background Studies in the IRP

EPA should start the update of background studies to include in the IRP by reviewing a key paper by Jaffe et al., 2018, *Scientific assessment of background ozone over the U.S.: Implications for air quality management*[34]. This paper considered over a 100 background ozone studies as part of an assessment of the spatial and temporal distribution, trends, and sources of background ozone over the continental U.S.

[34] Jaffe, DA, et al. 2018. Scientific assessment of background ozone over the U.S.: Implications for air quality management. Elem Sci Anth, 6:56. https://www.elementascience.org/article/10.1525/elementa.309/

Many of the referenced studies were published subsequent to the 2015 NAAQS review and should be considered as part of the current review.

The Jaffe et al. (2018) assessment found that spring and summer seasonal mean U.S. background ozone (i.e., ozone from other than U.S. anthropogenic sources) was greatest at high elevation locations in the western U.S., with monthly mean maximum daily 8-hour average (MDA8) mole fractions approaching 50 parts per billion (ppb) and annual 4th highest MDA8s exceeding 60 ppb at some locations.

C. Further Input into the Background Study Summary for the IRP

Within these comments are a list of recent studies (Exhibit C) that included information about the contribution of internationally transported ozone to U.S. background ozone. Most of these studies are included as references in the Jaffe paper; the attached list summarizes the studies' key findings.

Background ozone levels can and should be considered in setting of the NAAQS. In the previous ozone PA, EPA acknowledged that "The Administrator, when evaluating the range of possible standards that are supported by the scientific evidence, could consider proximity to background O_3 concentrations as one factor in selecting the appropriate standard."[35]

Studies listed in the previous 2015 NAAQS review, as well as those considered in the Jaffe et al. (2018) assessment show that in certain locations a significant fraction of observed ozone is due to background sources, which includes ozone derived from natural sources and international transport of ozone and its precursors. Previous studies have shown that peak background ozone exceeds 60 ppb, contributes to NAAQS exceedances, and comprises a significant fraction of seasonal mean and integrated ozone across the US. Background events are not infrequent and peak background concentrations are near the current ozone NAAQS.

EPA has historically sought to account for uncontrollable sources of ozone via implementation rules. However, in some cases the available tools and guidance to address background ozone issues may not be fully developed or functional, and states' resources to utilize the tools may be limited. While EPA should continue to improve upon implementation tools to address event-driven background ozone, it should also utilize its authority under the CAA to consider background ozone levels in setting the NAAQS.

[35] Policy Assessment for the Review of the Ozone National Ambient Air Quality Standard, Final Report , August 2014, Pg 1-27

Exhibit A

EXAMPLE OF ASSESSMENT OF KEY/PIVOTAL HEALTH EFFECTS RESEARCH AS SUGGESTED TO BE LISTED IN THE INTEGRATED REVIEW PLAN

OBSERVATIONAL EPIDEMIOLOGY

Long-term (chronic) effects

Ambient PM2.5, O_3, and NO_2 Exposures and Associations with Mortality over 16 Years of Follow-Up in the Canadian Census Health and Environment Cohort (CanCHEC)

Crouse DL, Peters PA, Hystad P, Brook JR, van Donkelaar A, Martin RV, Villeneuve PJ, Jerrett M, Goldberg MS, Pope CA 3rd, Brauer M, Brook RD, Robichaud A, Menard R, Burnett RT. *Environ Health Perspect*. 2015 Nov;123(11):1180-6.

BACKGROUND: Few studies examining the associations between long-term exposure to ambient air pollution and mortality have considered multiple pollutants when assessing changes in exposure due to residential mobility during follow-up.

OBJECTIVE: We investigated associations between cause-specific mortality and ambient concentrations of fine particulate matter (≤ 2.5 µm; PM2.5), ozone (O3), and nitrogen dioxide (NO2) in a national cohort of about 2.5 million Canadians.

METHODS: We assigned estimates of annual concentrations of these pollutants to the residential postal codes of subjects for each year during 16 years of follow-up. Historical tax data allowed us to track subjects' residential postal code annually. We estimated hazard ratios (HRs) for each pollutant separately and adjusted for the other pollutants. We also estimated the product of the three HRs as a measure of the cumulative association with mortality for several causes of death for an increment of the mean minus the 5th percentile of each pollutant: 5.0 µg/m3 for PM2.5, 9.5 ppb for O3, and 8.1 ppb for NO2.

RESULTS: **PM2.5, O3, and NO2 were associated with nonaccidental and cause-specific mortality in single-pollutant models.** Exposure to PM2.5 alone was not sufficient to fully characterize the toxicity of the atmospheric mix or to fully explain the risk of mortality associated with exposure to ambient pollution. Assuming additive associations, the estimated HR for nonaccidental mortality corresponding to a change in exposure from the mean to the 5th percentile for all three pollutants together was 1.075 (95% CI: 1.067, 1.084). Accounting for residential mobility had only a limited impact on the association between mortality and PM2.5 and O3, but increased associations with NO2.

CONCLUSIONS: In this large, national-level cohort, we found positive associations between several common causes of death and exposure to PM2.5, O3, and NO2.

Strengths	Limitations
Large (2.5M) national 20% sample from long form Census	Lack of smoking data
Cause-specific mortality, not just all-cause	Associative, not causal modeling; standard limitations
2- and 3-p models with PM2.5 & NO2 with stable results	Hard to statistically separate pollutants' effects

Average ambient concentration: 40 ppb
No information on funding, but likely Canadian government funded.
Transparency: By US policies, the cause of death information would be protected, although available by application if administrative data extraction and processing methods/codes are shared with other approved researchers.

Long-Term Ozone Exposure and Mortality in a Large Prospective Study

Turner MC, Jerrett M, Pope CA 3rd, Krewski D, Gapstur SM, Diver WR, Beckerman BS, Marshall JD, Su J, Crouse DL, Burnett RT. *Am J Respir Crit Care Med*. 2016 May15;193(10):1134-42.

RATIONALE: Tropospheric ozone (O3) is potentially associated with cardiovascular disease risk and premature death. Results from long-term epidemiological studies on O3 are scarce and inconclusive.

OBJECTIVES: In this study, we examined associations between chronic ambient O3 exposure and all-cause and cause-specific mortality in a large cohort of U.S. adults.

METHODS: Cancer Prevention Study II participants were enrolled in 1982. A total of 669,046 participants were analyzed, among whom 237,201 deaths occurred through 2004. We obtained estimates of O3 concentrations at the participant's residence from a hierarchical Bayesian space-time model. Estimates of fine particulate matter (particulate matter with an aerodynamic diameter of up to 2.5 µm [PM2.5]) and NO2 concentrations were obtained from land use regression. Cox proportional hazards regression models were used to examine mortality associations adjusted for individual- and ecological-level covariates.

MEASUREMENTS AND MAIN RESULTS: In single-pollutant models, we observed significant positive associations between O3, PM2.5, and NO2 concentrations and all-cause and cause-specific mortality. **In two-pollutant models adjusted for PM2.5, significant positive associations remained between O3 and all-cause (hazard ratio [HR] per 10 ppb, 1.02; 95% confidence interval [CI], 1.01-1.04), circulatory (HR, 1.03; 95% CI, 1.01-1.05), and respiratory mortality (HR, 1.12; 95% CI, 1.08-1.16) that were unchanged with further adjustment for NO2.** We also observed positive mortality associations with both PM2.5 (both near source and regional) and NO2 in multipollutant models.

CONCLUSIONS: Findings derived from this large-scale prospective study suggest that **long-term ambient O3 contributes to risk of respiratory and circulatory mortality**. Substantial health and environmental benefits may be achieved by implementing further measures aimed at controlling O3 concentrations.

Strengths	Limitations
Large national sample (670K) from ACS Cohort	Convenience sample of volunteers and social network
Cause-specific mortality, not just all-cause	Associative, not causal modeling; standard limitations
2- and 3-p models with PM2.5 & NO2 with stable results	Each pollutant measured at different times
Sophisticated exposure modeling	Residential location from 1982-83 → exposure misclassification
Ecological covariates included in analysis	Individual-level confounder data not updated since 1982-83
	Unexplained regional heterogeneity of effect

Average ambient concentration: 38 ppb
Funders: Government of Canada, US CDC, NIH, ACS
Transparency: None

Assuming that lung cancer is an unlikely a priori target for the ozone NAAQS, and given the null findings from the Cakmak et al (2018) study listed further below, the following study might be 'discounted'.

Ozone exposure and cardiovascular-related mortality in the Canadian Census Health and Environment Cohort (CANCHEC) by spatial synoptic classification zone

Cakmak S, Hebbern C, Vanos J, Crouse DL, Burnett R. *Environ Pollut*. 2016 Jul;214:589-599.

Our objective is to analyse the association between long term ozone exposure and cardiovascular related mortality while accounting for climate, location, and socioeconomic factors. We assigned subjects with 16 years of follow-up in the Canadian Census Health and Environment Cohort (CanCHEC) to one of seven regions based on spatial synoptic classification (SSC) weather types and examined the interaction of exposure to both fine particulate matter (PM2.5) and ground level ozone and cause of death using survival analysis, while adjusting for socioeconomic characteristics and individual confounders. Correlations between ozone and PM2.5 varied across SSC zones from -0.02 to 0.7. Comparing zones using the most populated SSC zone as a reference, a 10 ppb increase in ozone exposure was associated with increases in hazard ratios (HRs) that ranged from 1.007 (95% CI 0.99, 1.015) to 1.03 (95% CI 1.02, 1.041) for cardiovascular disease, 1.013 (95% CI 0.996, 1.03) to 1.058 (95% CI 1.034, 1.082) for cerebrovascular disease, and 1.02 (95% CI 1.006, 1.034) for ischemic heart disease. HRs remained significant after adjustment for PM2.5**. Long term exposure to ozone is related to an increased risk of mortality from cardiovascular and cerebrovascular diseases; the risk varies by location across Canada and is not attenuated by adjustment for PM2.5.** This research shows that the SSC can be used to define geographic regions and it **demonstrates the importance of accounting for that spatial variability when studying the long term health effects of air pollution**.

Strengths	Limitations
Large (3.6M) national 20% sample from long form Census)	Lack of smoking data
Cause-specific mortality, not just all-cause	Associative, not causal modeling; standard limitations
2- pollutant models with PM, stable results	Spatial ecological confounders not available
Assessed spatial variability via climate zone	

Average ambient concentrations ranged from 14 – 41 over the 7 climate zones
Funder: Health Canada Clean Air Regulatory Agenda
Transparency: By US policies, the cause of death information would be protected, although available by application if administrative data extraction and processing methods/codes are shared with other approved researchers.

Note: The following study is largely a repeat of the study above. Follow-up was extended from 2006 in the above study to 2011. Exposures were estimated and assigned somewhat differently, and the impact of that is uncertain. Covariates/confounders were obtained from different sources: the long-form Census in the former and the Canadian Community Health Survey (a US NHANES analog) in the latter. The study below, however, did assess lung cancer mortality and did not find an association with ozone.

Associations between long-term PM2.5 and ozone exposure and mortality in the Canadian Census Health and Environment Cohort (CANCHEC), by spatial synoptic classification zone

Cakmak S, Hebbern C, Pinault L, Lavigne E, Vanos J, Crouse DL, Tjepkema M. *Environ Int*. 2018 Feb;111:200-211

Studies suggest that long-term chronic exposure to fine particulate matter air pollution can increase lung cancer mortality. We analyzed the association between long term PM2.5 and ozone exposure and mortality due to lung cancer, ischemic heart disease, and chronic obstructive pulmonary disease, accounting for geographic location, socioeconomic status, and residential mobility. Subjects in the 1991 Canadian Census Health and Environment Cohort (CanCHEC) were followed for 20 years, and assigned to regions across Canada based on spatial synoptic classification weather types. Hazard ratios (HR) for mortality, were related to PM2.5 and ozone using Cox proportional hazards survival models, adjusting for socioeconomic characteristics and individual confounders. An increase of 10µg/m3 in long term PM2.5 exposure resulted in an HR for lung cancer mortality of 1.26 (95% CI 1.04, 1.53); the inclusion in the model of SSC zone as a stratum increased the risk estimate to HR 1.29 (95% CI 1.06, 1.57). After adjusting for ozone, HRs increased to 1.49 (95% CI 1.23, 1.88), and HR 1.54 (95% CI 1.27, 1.87), with and without zone as a model stratum. HRs for ischemic heart disease fell from 1.25 (95% CI 1.21, 1.29) for exposure to PM2.5, to 1.13 (95% CI 1.08, 1.19) when PM2.5 was adjusted for ozone. For COPD, the 95% confidence limits included 1.0 when climate zone was included in the model. HRs for all causes of death showed spatial differences when compared to zone 3, the most populated climate zone. Exposure to PM2.5 was related to an increased risk of mortality from lung cancer, and **both ozone and PM2.5 exposure were related to risk of mortality from ischemic heart disease, and the risk varied spatially by climate zone.**

Strengths	Limitations
Large (3.6M) national 20% sample from long form Census	Lack of smoking data
Cause-specific mortality, not just all-cause	Associative, not causal modeling; standard limitations
2- pollutant models with PM, stable results	Spatial ecological confounders not available
Assessed spatial variability via climate zone	

Average ambient concentrations ranged from 15 – 43 over the 7 climate zones; overall 39 ppb
Funder: Health Canada Clean Air Regulatory Agenda
Transparency: By US policies, the cause of death information would be protected, although available by application if administrative data extraction and processing methods/codes are shared with other approved researchers.

Has reducing fine particulate matter and ozone caused reduced mortality rates in the United States?

Cox LA Jr, Popken DA. *Ann Epidemiol*. 2015 Mar;25(3):162-73.

PURPOSE: Between 2000 and 2010, air pollutant levels in counties throughout the United States changed significantly, with fine particulate matter (PM2.5) declining over 30% in some counties and ozone (O3) exhibiting large variations from year to year. This history provides an opportunity to compare county-level changes in average annual ambient pollutant levels to corresponding changes in all-cause (AC) and cardiovascular disease (CVD) mortality rates over the course of a decade. Past studies have demonstrated associations and subsequently either interpreted associations causally or relied on subjective judgments to infer causation. This article applies more quantitative methods to assess causality.

METHODS: This article examines data from these "natural experiments" of changing pollutant levels for 483 counties in the 15 most populated US states using quantitative methods for causal hypothesis testing, such as conditional independence and Granger causality tests. We assessed whether changes in historical pollution levels helped to predict and explain changes in CVD and AC mortality rates.

RESULTS: A causal relation between pollutant concentrations and AC or CVD mortality rates cannot be inferred from these historical data, although a statistical association between them is well supported. **There were no significant positive associations between changes in PM2.5 or O3 levels and corresponding changes in disease mortality rates between 2000 and 2010, nor for shorter time intervals of 1 to 3 years.**

CONCLUSIONS: **These findings suggest that predicted substantial human longevity benefits resulting from reducing PM2.5 and O3 may not occur or may be smaller than previously estimated.** Our results highlight the potential for heterogeneity in air pollution health effects across regions, and the high potential value of accountability research comparing model-based predictions of health benefits from reducing air pollutants to historical records of what actually occurred.

Strengths	Limitations
Causal modeling within a natural experiment	Unconventional modeling poorly understood
Large number of counties	Ecological in design (i.e., not individual)

Average ambient concentration not given.
Funder: API
Study meets transparency provisions

Mortality associations with long-term exposure to outdoor air pollution in a national English cohort

Carey IM, Atkinson RW, Kent AJ, van Staa T, Cook DG, Anderson HR. *Am J Respir Crit Care Med.* 2013 Jun 1;187(11):1226-33.

RATIONALE: Cohort evidence linking long-term exposure to outdoor particulate air pollution and mortality has come largely from the United States. There is relatively little evidence from nationally representative cohorts in other countries.

OBJECTIVES: To investigate the relationship between long-term exposure to a range of pollutants and causes of death in a national English cohort.

METHODS: A total of 835,607 patients aged 40-89 years registered with 205 general practices were followed from 2003-2007. Annual average concentrations in 2002 for particulate matter with a median aerodynamic diameter less than 10 (PM(10)) and less than 2.5 µm (PM(2.5)), nitrogen dioxide (NO(2)), ozone, and sulfur dioxide (SO(2)) at 1 km(2) resolution, estimated from emission-based models, were linked to residential postcode. Deaths (n = 83,103) were ascertained from linkage to death certificates, and hazard ratios (HRs) for all- and cause-specific mortality for pollutants were estimated for interquartile pollutant changes from Cox models adjusting for age, sex, smoking, body mass index, and area-level socioeconomic status markers.

MEASUREMENTS AND MAIN RESULTS: **Residential concentrations of all pollutants *except ozone* were positively associated with all-cause mortality** (HR, 1.02, 1.03, and 1.04 for PM(2.5), NO(2), and SO(2), respectively). Associations for PM(2.5), NO(2), and SO(2) were larger for respiratory deaths (HR, 1.09 each) and lung cancer (HR, 1.02, 1.06, and 1.05) but nearer unity for cardiovascular deaths (1.00, 1.00, and 1.04).

CONCLUSIONS: These results strengthen the evidence linking long-term ambient air pollution exposure to increased all-cause mortality. However, the stronger associations with respiratory mortality are not consistent with most US studies in which associations with cardiovascular causes of death tend to predominate.

Strengths	Limitations
Large cohort (830K) from 205 English medical practices	Linear (Cox PH) modeling; no nonlinearity assessment
Electronic medical records	Exposure model validation had inconsistent results
Cluster (by practice) analysis conducted	. . . but 10% not recorded (no history before 20073)
Enhanced exposure concentration modeling	Single-pollutant analysis
	SES (Deprivation Index) measured ecologically

Average ambient concentration: 52 ppb
Funder: United Kingdom Department of Health
Transparency: By US policies, the mortality information would be protected, although available by application if administrative data extraction and processing methods/codes are shared with other approved researchers.

Long-term exposure to ambient ozone and mortality: a quantitative systematic review and meta-analysis of evidence from cohort studies

Atkinson RW, Butland BK, Dimitroulopoulou C, Heal MR, Stedman JR, Carslaw N, Jarvis D, Heaviside C, Vardoulakis S, Walton H, Anderson HR. *BMJ Open*. 2016 Feb23;6(2):e009493

OBJECTIVES: While there is good evidence for associations between short-term exposure to ozone and a range of adverse health outcomes, the evidence from narrative reviews for long-term exposure is suggestive of associations with respiratory mortality only. We conducted a systematic, quantitative evaluation of the evidence from cohort studies, reporting associations between long-term exposure to ozone and mortality.

METHODS: Cohort studies published in peer-reviewed journals indexed in EMBASE and MEDLINE to September 2015 and PubMed to October 2015 and cited in reviews/key publications were identified via search strings using terms relating to study design, pollutant and health outcome. Study details and estimate information were extracted and used to calculate standardised effect estimates expressed as HRs per 10 ppb increment in long-term ozone concentrations.

RESULTS: 14 publications from 8 cohorts presented results for ozone and all-cause and cause-specific mortality. **We found no evidence of associations between long-term annual O3 concentrations and the risk of death from all causes, cardiovascular or respiratory diseases, or lung cancer**. 4 cohorts assessed ozone concentrations measured during the warm season. Summary HRs for cardiovascular and respiratory causes of death derived from 3 cohorts were 1.01 (95% CI 1.00 to 1.02) and 1.03 (95% CI 1.01 to 1.05) per 10 ppb, respectively.

CONCLUSIONS: Our quantitative review revealed a paucity of independent studies regarding the associations between long-term exposure to ozone and mortality. The potential impact of climate change and increasing anthropogenic emissions of ozone precursors on ozone levels worldwide suggests further studies of the long-term effects of exposure to high ozone levels are warranted.

Strengths	Limitations
Sufficient number of original studies	Literature included only through 2015
Analyzed all-year and warm season separately	

No funding agency grant
Fully transparent

The following study could be included under the EPA's susceptible subpopulation section for the following reasons:

1. *Toxicological support already exists (according to the author)*
2. *This is the first study to epidemiologically assess the link between type 2 diabetes and ozone in humans*
3. *Study population is African-American women, one of the many susceptible/sensitive sub-groups*
4. *Type 2 diabetes is a significant public health problem, particularly for this segment of the population*

Ambient ozone and incident diabetes: A prospective analysis in a large cohort of African American women

Jerrett M, Brook R, White LF, Burnett RT, Yu J, Su J, Seto E, Marshall J, Palmer JR, Rosenberg L, Coogan PF.
Environ Int. 2017 May;102:42-47.

BACKGROUND: Ozone is a ubiquitous air pollutant with increasing concentrations in many populous regions. Toxicological studies show that ozone can cause oxidative stress and increase insulin resistance. These pathways may contribute to metabolic changes and diabetes formation. In this paper, we investigate the association between ozone and incident type 2 diabetes in a large cohort of African American women.

METHODS: We used Cox proportional hazards models to calculate hazard ratios (HRs) for incident type 2 diabetes associated with exposure to ozone in a cohort of 45,231 African American women living in 56 metropolitan areas across the United States. Ozone levels were estimated using the U.S. EPA Models-3/Community Multiscale Air Quality (CMAQ) predictions fused with ground measurements at a resolution of 12km for the years 2007-2008.

RESULTS: The HR per interquartile range increment of 6.7ppb of ozone was 1.18 (95% CI 1.04-1.34) for incident diabetes in adjusted models. This association was unaltered in models that controlled for fine particulate matter with diameter <2.5μm (PM2.5). Associations were modified by nitrogen dioxide (NO2) levels, such that HRs for ozone levels were larger in areas of lower NO2.

CONCLUSIONS: Our results provide **initial evidence of a positive association between O3 and incident diabetes in African American women**. Given the ubiquity of ozone exposure and the importance of diabetes on quality of life and survival, these results may have important implications for the protection of public health.

Strengths	Limitations
Prospective cohort, well-designed	High selection bias (higher SES levels); low generalizability
Good follow-up on individual factors and addresses	Address at diagnosis used for exposure assignment, ignores past
Solid analysis, albeit regression-based	No causal modeling; linear regression assumptions
Good exposure modeling validated against monitor values	12x12 km exposure grids too large for ozone modeling?

Average ambient concentration: 35 ppb
Funders: NIEHS, NCI, CDC
Questionable transparency. Data from a prospective cohort study. Although we have not ascertained investigators' willingness to share data with other researchers, this study had authors from 6 different universities, indicating such.

Short-term (acute) effects

Association of Short-term Exposure to Air Pollution with Mortality in Older Adults

Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD, Dominici F. *JAMA*. 2017 Dec 26;318(24):2446-2456

Importance: The US Environmental Protection Agency is required to reexamine its National Ambient Air Quality Standards (NAAQS) every 5 years, but evidence of mortality risk is lacking at air pollution levels below the current daily NAAQS in unmonitored areas and for sensitive subgroups.

Objective: To estimate the association between short-term exposures to ambient fine particulate matter (PM2.5) and ozone, and at levels below the current daily NAAQS, and mortality in the continental United States.

Design, Setting, and Participants: Case-crossover design and conditional logistic regression to estimate the association between short-term exposures to PM2.5 and ozone (mean of daily exposure on the same day of death and 1 day prior) and mortality in 2-pollutant models. The study included the entire Medicare population from January 1, 2000, to December 31, 2012, residing in 39 182 zip codes.

Exposures: Daily PM2.5 and ozone levels in a 1-km × 1-km grid were estimated using published and validated air pollution prediction models based on land use, chemical transport modeling, and satellite remote sensing data. From these gridded exposures, daily exposures were calculated for every zip code in the United States. Warm-season ozone was defined as ozone levels for the months April to September of each year.

Main Outcomes and Measures: All-cause mortality in the entire Medicare population from 2000 to 2012.

Results: During the study period, there were 22 433 862 million case days and 76 143 209 control days. Of all case and control days, 93.6% had PM2.5 levels below 25 μg/m3, during which 95.2% of deaths occurred (21 353 817 of 22 433 862), and 91.1% of days had ozone levels below 60 parts per billion, during which 93.4% of deaths occurred (20 955 387 of 22 433 862). The baseline daily mortality rates were 137.33 and 129.44 (per 1 million persons at risk per day) for the entire year and for the warm season, respectively. **Each short-term increase of** 10 μg/m3 in PM2.5 (adjusted by ozone) and **10 parts per billion (10-9) in warm-season ozone (adjusted by PM2.5) were statistically significantly associated with a relative increase of** 1.05% (95% CI, 0.95%-1.15%) and **0.51% (95% CI, 0.41%-0.61%) in daily mortality rate**, respectively. Absolute risk differences in daily mortality rate were 1.42 (95% CI, 1.29-1.56) and 0.66 (95% CI, 0.53-0.78) per 1 million persons at risk per day. There was no evidence of a threshold in the exposure-response relationship.

Conclusions and Relevance**: In the US Medicare population from 2000 to 2012, short-term exposures to PM2.5 and warm-season ozone were significantly associated with increased risk of mortality. This risk occurred at levels below current national air quality standards**, suggesting that these standards may need to be reevaluated.

Strengths	Limitations
Case cross-over study design	Administrative data lacking individual confounder information
2-p exposure modeling with PM.5 in 1 km x 1 km grids	No specific cause of death information
Assessed non-linear concentration-response	No causal modeling; linear regression assumptions (main results)
Assessed SES via "Medicaid eligible"	Deceptive reporting of effects (as % increase in the RR)
	Age of cohort limits generalizability to broader population

Average ambient concentration: Not given, but 91% of days had concentrations below 60 ppb.
Funders: NIH, EPA, HEI
Transparent to the extent that methods and computer codes for Medicare data extraction and processing are shared with other researchers.

Characterization of the concentration-response curve for ambient ozone and acute respiratory morbidity in 5 US cities

Barry V, Klein M, Winquist A, Chang HH, Mulholland JA, Talbott EO, Rager JR, Tolbert PE, Sarnat SE. *J Expo Sci Environ Epidemiol*. 2018 Jun 19

Although short-term exposure to ambient ozone (O3) can cause poor respiratory health outcomes, the shape of the concentration-response (C-R) between O3 and respiratory morbidity has not been widely investigated. We estimated the effect of daily O3 on emergency department (ED) visits for selected respiratory outcomes in 5 US cities under various model assumptions and assessed model fit. Population-weighted average 8-h maximum O3 concentrations were estimated in each city. Individual-level data on ED visits were obtained from hospitals or hospital associations. Poisson log-linear models were used to estimate city-specific associations between the daily number of respiratory ED visits and 3-day moving average O3 levels controlling for long-term trends and meteorology. Linear, linear-threshold, quadratic, cubic, categorical, and cubic spline O3 C-R models were considered. **Using linear C-R models, O3 was significantly and positively associated with respiratory ED visits in each city with rate ratios of 1.02-1.07 per 25 ppb. Models suggested that O3-ED C-R shapes were linear until O3 concentrations of roughly 60 ppb at which point risk continued to increase linearly in some cities for certain outcomes while risk flattened in others.** Assessing C-R shape is necessary to identify the most appropriate form of the exposure for each given study setting.

Strengths	Limitations
Analytical methods; thorough CRF exploration	Limited statistical power due to single-city (x5) approach
Exposure modeling methods	Unclear if "best" CRF is meaningfully different than other forms
	Even small O3 measurement errors = significant CRF impact

Average ambient concentration range over 5 cities: 38 - 42 ppb

Funders: EPA, EPRI

Transparency undetermined, but likely difficult to achieve without access to investigators' dataset. Morbidity data from hospitals and hospital associations in each of the 5 large cities. If data not available from the investigators, other researchers would need to negotiate separate data use agreements with those medical groups.

The following study is a reanalysis of the previous HEI-funded APHENA study that was featured in the last ozone review [Katsouyanni K, Samet JM, Anderson HR, Atkinson R, Le Tertre A, Medina S, et al. Air pollution and health: a European and North American approach (APHENA). Res Rep Health Eff Inst. 2009; 142:5–90.]. *This reanalysis refined and harmonized the modeling from that original study to address some of the analytical issues that were raised. The results from the study below aren't materially different than those from the original but EPA might consider them as "new".*

Acute effects of ambient ozone on mortality in Europe and North America: results from the APHENA study

Peng RD, Samoli E, Pham L, Dominici F, Touloumi G, Ramsay T, Burnett RT, Krewski D, Le Tertre A, Cohen A, Atkinson RW, Anderson HR, Katsouyanni K, Samet JM. *Air Qual Atmos Health*. 2013 Jun 1;6(2):445-453

The "Air Pollution and Health: A Combined European and North American Approach" (APHENA) project is a collaborative analysis of multi-city time-series data on the association between air pollution and adverse health outcomes. The main objective of APHENA was to examine the coherence of findings of time-series studies relating short-term fluctuations in air pollution levels to mortality and morbidity in 125 cities in Europe, the US, and Canada. Multi-city time-series analysis was conducted using a two-stage approach. We used Poisson regression models controlling for overdispersion with either penalized or natural splines to adjust for seasonality. Hierarchical models were used to obtain an overall estimate of excess mortality associated with ozone and to assess potential effect modification. Potential effect modifiers were city-level characteristics related to exposure to other ambient air pollutants, weather, socioeconomic status, and the vulnerability of the population. Regionally pooled risk estimates from Europe and the US were similar; those from Canada were substantially higher. **The pooled estimated excess relative risk associated with a 10 µg/m3 increase in 1 h daily maximum O3 was 0.26 % (95 % CI, 0.15 %, 0.37 %)**. Across regions, there was little consistent indication of effect modification by age or other effect modifiers considered in the analysis. **The findings from APHENA on the effects of O3 on mortality in the general population were comparable with previously reported results and relatively robust to the method of data analysis**. Overall, there was no indication of strong effect modification by age or ecologic variables considered in the analysis.

Strengths	Limitations
Large number of cities; 3 continents	Administrative data lacking individual confounder information
Common protocol	Still, some non-standard data collection
Common study design protocol	Did not assess non-linear concentration-response
Improved harmonization among reporting locations	No causal modeling; linear regression assumptions
Enhanced regression methods to reduce heterogeneity of RRs	Restricted data on confounders; differing data across locations
	Single pollutant modeling

No ambient exposure information.
Funder: HEI
Transparency is likely nil. Replicating without original investigators' data not practically possible.

Air quality and acute deaths in California, 2000-2012.

Young SS, Smith RL, Lopiano KK. Air quality and acute deaths in California,2000-2012. *Regul Toxicol Pharmacol*. 2017 Aug;88:173-184

Many studies have shown an association between air quality and acute deaths, and such associations are widely interpreted as causal. Several factors call causation and even association into question, for example multiple testing and multiple modeling, publication bias and confirmation bias. Many published studies are difficult or impossible to reproduce because of lack of access to confidential data sources. Here we make publically available a dataset containing daily air quality levels, PM2.5 and ozone, daily temperature levels, minimum and maximum and daily maximum relative humidity levels for the eight most populous California air basins, thirteen years, >2M deaths, over 37,000 exposure days. The data are analyzed using standard time series analysis, and a sensitivity analysis is computed varying model parameters, locations and years. **Our analysis finds little evidence for association between air quality and acute deaths.** These results are consistent with those for the widely cited NMMAPS dataset when the latter are restricted to California. **The daily death variability was mostly explained by time of year or weather variables; neither PM2.5 nor ozone added appreciably to the prediction of daily deaths**. These results call into question the widespread belief that association between air quality and acute deaths is causal/near-universal.

Strengths	Limitations
Number of years in time-series	Limited number of confounders/covariates in model
O3 concentrations closer to annual std than most studies	Standard time-series modeling (not case-crossover)
Robust sensitivity analysis (e.g., lags, "hold out year")	Single-pollutant modeling
Data availability/access (transparent)	Restricted to California
	Tinged with EPA antipathy

Funder: API
Transparent

Respiratory Function

Effects of Policy-Driven Air Quality Improvements on Children's Respiratory Health

Gilliland F, Avol E, McConnell R, Berhane K, Gauderman WJ, Lurmann FW, et al. 2017. The Effects of Policy-Driven Air Quality Improvements on Children's Respiratory Health. Research Report 190. Boston, MA:Health Effects Institute.

This accountability study provides evidence that multiyear improvements in air quality and emissions, primarily driven through a broad array of science-based regulatory policy initiatives, have resulted in improved public health outcomes. Significant improvements in lung-function growth in progressive cohorts were observed as air quality improved over the study period. Improvements in four-year growth of both forced expiratory volume in the first second of exhalation (FEV1) and forced vital capacity (FVC) were associated with declining levels of NO2 (P <0.0001), PM2.5 (P <0.01), and PM10 (P <0.001). These associations persisted after adjustment for important potential confounders. Further, significant improvements in lung function growth were observed in both boys and girls and among asthmatic and non-asthmatic children. **Within-community decreases in O3 exposure were not significantly associated with lung-function growth**. The proportion of children with clinically low FEV1 (defined as <80% predicted) at age 15 declined significantly, from 7.9% to 3.6% across the study periods, respectively, as the air quality improved (P <0.005). We found little evidence to suggest that improvements in lung-function development were attributable to temporal confounding. **Reductions in outdoor levels of** NO2, **O3,** PM10, and PM2.5 **across the cohort years of participation were associated with significant reductions in the prevalence of bronchitic symptoms regardless of asthma status, but observed improvements were larger in children with asthma**. Among asthmatic children, the **reductions in prevalence of bronchitic symptoms at age 10 were** 21% (P <0.01) for NO2, **34% (P <0.01) for O3**, 39% (P <0.01) for PM10, and 32% (P <0.01) for PM2.5 for reductions of 4.9 ppb, 3.6 ppb, 5.8 µg/m3, and 6.8 µg/m3, respectively. Similar reductions in prevalence of bronchitic symptoms were observed at age 15 among these same asthmatic children.

Strengths	Limitations
Study design	No control for secular trends, e.g., demographic shifts, healthcare
Use of multilevel statistical models	Single-pollutant modeling restriction
Models included several confounders & effect modifiers	No within-community and cohort analysis of pollutant variations
Monitoring and health effects data collected over 20 years	Limited consideration of differences btw successive cohorts over time
	Single-site monitor not representative of time-activity patterns
	Could not link any specific action to specific AQ improvements

Funder: HEI
Transparency: Likely, given that this is an HEI-funded study (their policy). Not available on website however.

Cardiovascular function and ozone exposure: The Multicenter Ozone Study in oldEr Subjects (MOSES)
Rich DQ, Balmes JR, Frampton MW, Zareba W, Stark P, Arjomandi M, Hazucha MJ, Costantini MG, Ganz P, Hollenbeck-Pringle D, Dagincourt N, Bromberg PA. *Environ Int*. 2018 Jun 29;119:193-202

BACKGROUND: To date, there have been relatively few studies of acute cardiovascular responses to controlled ozone inhalation, although a number of observational studies have reported significant positive associations between both ambient ozone levels and acute cardiovascular events and long-term ozone exposure and cardiovascular mortality.

OBJECTIVES: We hypothesized that short-term controlled exposure to low levels of ozone in filtered air would induce autonomic imbalance, repolarization abnormalities, arrhythmia, and vascular dysfunction.

METHODS: This randomized crossover study of 87 healthy volunteers 55-70 years of age was conducted at three sites using a common protocol, from June 2012 to April 2015. Subjects were exposed for 3 h in random order to 0 ppb (filtered air), 70 ppb ozone, and 120 ppb ozone, alternating 15 min of moderate exercise with 15 min of rest. A suite of cardiovascular endpoints was measured the day before, the day of, and up to 22 h after each exposure. Mixed effect linear and logit models evaluated the impact of exposure to ozone on pre-specified primary and secondary outcomes. Site and time were included in the models.

RESULTS: We found **no significant effects of ozone exposure on any of the primary or secondary measures of autonomic function, repolarization, ST segment change, arrhythmia, or vascular function (systolic blood pressure and flow-mediated dilation).**

CONCLUSIONS: In this multicenter study of older healthy women and men, **there was no convincing evidence for acute effects of 3-h, relatively low-level ozone exposures on cardiovascular function.** However, we cannot exclude the possibility of effects with higher ozone concentrations, more prolonged exposure, or in subjects with underlying cardiovascular disease. Further, we cannot exclude the possibility that exposure to ambient ozone and other pollutants in the days before the experimental exposures obscured or blunted cardiovascular biomarker response to the controlled ozone exposures. *[Note: This will be assessed in MOSES II in several months]*

Strengths	Limitations
Study design/execution; multiple sites	Low generalizability (very health older adults)
Larger than usual number of participants for this study type	Measured acute exposures to single pollutant (unlike ambient air)
Many mechanistic pathways evaluated	
Common labs and data center	
Technical exposure chamber specs/performance	
Choice of 70 & 120 ppt for analyses	

Funder: HEI
Transparent. Data available at https://dataverse.harvard.edu/dataverse/MOSES

Respiratory Responses to Ozone Exposure. MOSES (The Multicenter Ozone Study in Older Subjects)

Arjomandi M, Balmes JR, Frampton MW, Bromberg P, Rich DQ, Stark P, Alexis NE, Costantini M, Hollenbeck-Pringle D, Dagincourt N, Hazucha M. *J Am J Respir Crit Care Med*. 2018 May 15;197(10):1319-1327.

RATIONALE: Acute respiratory effects of low-level ozone exposure are not well defined in older adults.

OBJECTIVES: MOSES (The Multicenter Ozone Study in Older Subjects), although primarily focused on acute cardiovascular effects, provided an opportunity to assess respiratory responses to low concentrations of ozone in older healthy adults.

METHODS: We performed a randomized crossover, controlled exposure study of 87 healthy adults (59.9 ± 4.5 yr old; 60% female) to 0, 70, and 120 ppb ozone for 3 hours with intermittent exercise. Outcome measures included spirometry, sputum markers of airway inflammation, and plasma club cell protein-16 (CC16), a marker of airway epithelial injury. The effects of ozone exposure on these outcomes were evaluated with mixed-effect linear models. A P value less than 0.01 was chosen a priori to define statistical significance.

MEASUREMENTS AND MAIN RESULTS: The mean (95% confidence interval) FEV1 and FVC increased from preexposure values by 2.7% (2.0-3.4) and 2.1% (1.3-2.9), respectively, 15 minutes after exposure to filtered air (0 ppb). Exposure to ozone reduced these increases in a concentration-dependent manner. After 120-ppb exposure, FEV1 and FVC decreased by 1.7% (1.1-2.3) and 0.8% (0.3-1.3), respectively. A similar concentration-dependent pattern was still discernible 22 hours after exposure. At 4 hours after exposure, plasma CC16 increased from preexposure levels in an ozone concentration-dependent manner. Sputum neutrophils obtained 22 hours after exposure showed a marginally significant increase in a concentration-dependent manner (P = 0.012), but proinflammatory cytokines (IL-6, IL-8, and tumor necrosis factor-α) were not significantly affected.

CONCLUSIONS: **Exposure to ozone at near ambient levels induced lung function effects, airway injury, and airway inflammation in older healthy adults.**

Strengths	Limitations
Study design/execution; multiple sites	Low generalizability (very healthy older adults)
Larger than usual number of participants for this study type	Measured acute exposures to single pollutant (unlike ambient air)
Many mechanistic pathways evaluated	Statistical interpretation of respiratory effects
Common labs and data center	
Technical exposure chamber specs/performance	
Choice of 70 & 120 ppt for analyses	

Funder: HEI

Transparent. Data available at https://dataverse.harvard.edu/dataverse/MOSES

Toxicological literature

The perpetuation of the misconception that rats receive a 3-5 times lower lung tissue dose than humans at the same ozone concentration

McCant D, Lange S, Haney J, Honeycutt M. *Inhal Toxicol.* 2017 Apr;29(5):187-196. doi: 10.1080/08958378.2017.1323982.

This paper highlights the pervasive misconception concerning 1994 findings from Hatch et al. about ozone (O_3) tissue dose in humans versus rats. That study exposed humans to 0.4 ppm and rats to 2 ppm ^{18}O-labeled O_3 and found comparable incorporation of ^{18}O into bronchoalveolar lavage constituents. However, during O_3 exposure humans were exercising, which increased their ventilation rate five-fold, while rats were at rest. This resulted in similar O_3 tissue doses between the two species, and predominantly explained the comparable ^{18}O incorporation at five-fold different concentrations. The five-times higher exercising human inhalation rate offset the five-times lower concentration, producing the same human dose expected at rest at 2 ppm (i.e. 0.4 ppm × 4686 L/2 hour ≈ 2 ppm × 998 L/2 hour). In 2013, Hatch et al. showed that resting humans and resting rats experienced fairly comparable ^{18}O incorporation at the same O_3 exposure concentration and activity state into BALF cells. Despite these findings, we show here that in the peer-reviewed literature a substantial proportion of researchers continue to perpetuate the misunderstanding that human lung tissue doses of O_3 are simply 3-5 times greater than rat doses at the same O_3 concentration, due to interspecies differences, and not considering activity state. It is important to correct this misconception to ensure an appropriate understanding of the implications of O_3 studies by the scientific community and policy experts making regulatory decisions (e.g. the US Environmental Protection Agency's National Ambient Air Quality Standards for O_3).

Funder: TCEQ
Transparency: N/A

Exhibit B

RESPONSE TO EPA REQUEST FOR INFORMATION ON OZONE HEALTH EFFECTS STUDIES & POLICY RELEVANT SCIENCE STUDIES

ORIGINAL RESEARCH

Cox LA Jr, Popken DA. Has reducing fine particulate matter and ozone caused reduced mortality rates in the United States? Ann Epidemiol. 2015 Mar;25(3):162-73

Cox LAT, Liu X, Shi L, Zu K, Goodman J. Applying Nonparametric Methods to Analyses of Short-Term Fine Particulate Matter Exposure and Hospital Admissions for Cardiovascular Diseases among Older Adults. Int J Environ Res Public Health. 2017 Sep 12;14(9).

Cox LAT Jr. Socioeconomic and air pollution correlates of adult asthma, heart attack, and stroke risks in the United States, 2010-2013. Environ Res. 2017 May;155:92-107.

Young SS, Smith RL, Lopiano KK. Air quality and acute deaths in California, 2000-2012. Regul Toxicol Pharmacol. 2017 Aug;88:173-184

Goodman JE, Zu K, Loftus CT, Tao G, Liu X, Lange S. Ambient ozone and asthma hospital admissions in Texas: a time-series analysis. Asthma Res Pract. 2017 Aug 1;3:6

Zu K, Liu X, Shi L, Tao G, Loftus CT, Lange S, Goodman JE. Concentration-response of short-term ozone exposure and hospital admissions for asthma in Texas. Environ Int. 2017 Jul;104:139-145

Jerrett M, Burnett RT, Beckerman BS, Turner MC, Krewski D, Thurston G, Martin RV, van Donkelaar A, Hughes E, Shi Y, Gapstur SM, Thun MJ, Pope CA 3rd. Spatial analysis of air pollution and mortality in California. Am J Respir Crit Care Med. 2013 Sep 1;188(5):593-9

Carey IM, Atkinson RW, Kent AJ, van Staa T, Cook DG, Anderson HR Mortality associations with long-term exposure to outdoor air pollution in a national English cohort. Am J Respir Crit Care Med. 2013 Jun 1;187(11):1226-33 [not industry-sponsored]

Atkinson RW, Butland BK, Dimitroulopoulou C, Heal MR, Stedman JR, Carslaw N, Jarvis D, Heaviside C, Vardoulakis S, Walton H, Anderson HR. Long-term exposure to ambient ozone and mortality: a quantitative systematic review and meta-analysis of evidence from cohort studies. BMJ Open. 2016 Feb23;6(2) [meta-analysis, not industry-sponsored]

METHODS & RECOMMENDED PRACTICES

Cox LAT Jr. Do causal concentration-response functions exist? A critical review of associational and causal relations between fine particulate matter and mortality. Crit Rev Toxicol. 2017 Aug;47(7):603-631.

Cox LAT. Effects of exposure estimation errors on estimated exposure-response relations for PM2.5. Environ Res. 2018 Jul;164:636-646.

Obenchain RL, Young SS Local Control Strategy: Simple Analyses of Air Pollution Data Can Reveal Heterogeneity in Longevity Outcomes. Risk Anal. 2017 Sep;37(9):1742-1753.

Jaffe DA, Cooper OR, Fiore AM, Henderson BH, Tonneson GS, Russell AG, et al. Scientific assessment of background ozone over the U.S.: Implications for air quality management Elem Sci Anth. 2018;6(1):56

McCant D, Lange S, Haney J, Honeycutt M. The perpetuation of the misconception that rats receive a 3-5 times lower lung tissue dose than humans at the same ozone concentration. Inhal Toxicol. 2017 Apr;29(5):187-196

REVIEWS, CRITIQUES, WEIGHT OF EVIDENCE

Zu K, Shi L, Prueitt RL, Liu X, Goodman JE. Critical review of long-term ozone exposure and asthma development. Inhal Toxicol. 2018 Feb;30(3):99-113.

Goodman JE, Zu K, Loftus CT, Lynch HN, Prueitt RL, Mohar I, Shubin SP, Sax SN. Short-term ozone exposure and asthma severity: Weight-of-evidence analysis. Environ Res. 2018 Jan;160:391-397.

Goodman JE, Prueitt RL, Sax SN, Pizzurro DM, Lynch HN, Zu K, Venditti FJ. Ozone exposure and systemic biomarkers: Evaluation of evidence for adverse cardiovascular health impacts. Crit Rev Toxicol. 2015 May;45(5):412-52.

Prueitt RL, Lynch HN, Zu K, Sax SN, Venditti FJ, Goodman JE. Weight-of-evidence evaluation of long-term ozone exposure and cardiovascular effects. Crit Rev Toxicol. 2014 Oct;44(9):791-822

Goodman JE, Prueitt RL, Sax SN, Lynch HN, Zu K, Lemay JC, King JM, Venditti FJ. Weight-of-evidence evaluation of short-term ozone exposure and cardiovascular effects. Crit Rev Toxicol. 2014 Oct;44(9):725-90.

Goodman JE, Prueitt RL, Chandalia J, Sax SN. Evaluation of adverse human lung function effects in controlled ozone exposure studies. J Appl Toxicol. 2014 May;34(5):516-24.

COMMENTARY

Prueitt RL, Goodman JE. The global burden of ozone on respiratory mortality: no clear evidence for association. Environ Health Perspect. 2011 Apr;119(4):A158;author reply A158-9.

Message

From: Clint Woods [clintwoods@gmail.com]
Sent: 7/29/2018 6:25:22 AM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Ozone Article

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http://www.mdpi.com/1660-4601/15/8/1586

nt. J. Environ. Res. Public Health **2018**, *15*(8), 1586; https://doi.org/10.3390/ijerph15081586

What Are the Net Benefits of Reducing the Ozone Standard to 65 ppb? An Alternative Analysis

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(This article belongs to the Special Issue Economic Evaluation of Environmental Policies and Interventions)

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Message

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To: Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Robbins, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=958b4b78eb42457eacf53514e428efd6-Robbins, Chris]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
CC: Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Ross, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98359cd1f66f46ec91d327e99a3c6909-Ross, Mary]; Jones, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]; Christian, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a0f5e0e9d94271b23cad28db653851-Lizotte, Me]; McPherson, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=useraf3de097]; Kuhn, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be20941b4c1144b8b3635e4df015924a-Kuhn, Kevin]; Fleming, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14b4c2e10bf84f1fa9a3f91f5ca1c4c0-Fleming, Megan]; D'Amico, Louis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78a91f83c4414910be286efe02004dbc-D'Amico, Louis J.]; Sasser, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=477638fe84004800bfdf8e62fe3cafc8-ESASSER]; Dutton, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=795a1526feec425f8be0b3f5c0a671c6-Dutton, Steve]; Greaver, Tara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87aaaee6c3784c4ba57193cdb5ba84f4-Greaver, Tara]; Sacks, Jason [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2099bec11ced4d5c88c07a89aa8ee652-Sacks, Jason]; Wesson, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f3d5329d4ac4b6a9a424c9759c927d1-KWESSON]; Tsirigotis, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d19c179f3ccb4fadb48e3ae85563f132-PTSIRIGO]; Champlin, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59084b342934f42aba4643b326f8611-Osaka, Anna]
Subject: Draft PM ISA
Attachments: PM - FINAL - HEROnet.pdf

Thank you for the opportunity to brief you last week on the draft Integrated Science Assessment for Particulate Matter. I am providing an electronic copy of the draft ISA to you. The file is large, at 34 MB. Please let me know if you have any difficulty accessing the document.

This is a working draft and while the efforts to develop and review the text have been completed, we are still fixing some figures that are not printing correctly and making other minor revisions. We anticipate completing the production of the document by the end of August for transmittal to the CASAC DFO. The CASAC meeting to review this document has been scheduled for December 11-12, 2018.

The hotlinks to publications in the document are for the HERONet version, which is used by the CASAC peer reviewers to access the literature, including copyrighted materials. These links take you to the EPA HERO Login page and may not work for you. Other links in the document, to tables, figures and sections, should work for you. We are checking the links as we prepare the document for release. The "public" version, which does not provide access to copyrighted material, is generated later.

Please let me know if you have any questions.

John

John Vandenberg, PhD
Director, Research Triangle Park Division
National Center for Environmental Assessment/ORD
U.S. Environmental Protection Agency/B243-01
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(919) 541-4527

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
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To: Dickerson, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0440d9f06994021827e0d0119126799-Dickerson,]; Molina, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d19c1d68da1a4587866e1850f22a6ae5-Molina, Mic]
Subject: FW: Clean Air Advisory Committees
Attachments: CASAC Details 10-16-18.docx

FYI - Attached is briefing material. Not sure if our folks have been in touch on timing.

-----Original Message-----
From: adm15.arwheeler.email
Sent: Tuesday, October 16, 2018 2:20 PM
To: Wehrum, Bill <Wehrum.Bill@epa.gov>; Woods, Clint <woods.clint@epa.gov>
Subject: Clean Air Advisory Committees

I would like a briefing on the two committees disbanded last week, sometime tomorrow. Thanks.

- Andrew

Sent from my iPhone

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/16/2018 7:05:00 PM
To: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
Subject: FW: CASAC Talking Points

Suggested briefing material:

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/16/2018 11:45:59 AM
To: Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]
Subject: Re: CASAC Talking Points

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 9/24/2018 3:57:02 PM
To: Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
Subject: Fwd: New IQG Case: RFC 18003 - NATA/Ethylene Oxide
Attachments: RFC 18003 Request.pdf; ATT00001.htm

Begin forwarded message:

From: "Shoaff, John" <Shoaff.John@epa.gov>
To: "Wehrum, Bill" <Wehrum.Bill@epa.gov>, "Woods, Clint" <woods.clint@epa.gov>, "Tsirigotis, Peter" <Tsirigotis.Peter@epa.gov>, "Koerber, Mike" <Koerber.Mike@epa.gov>
Cc: "Lewis, Josh" <Lewis.Josh@epa.gov>
Subject: FW: New IQG Case: RFC 18003 - NATA/Ethylene Oxide

Bill et al,

Thought you might want to be aware of this new IQG case, see attached. Our QA poc, Tom Eagles, just received it from OEI and will likely touch base with Kelly R. in OAQPS for awareness and need for SME with request. Thx.

John

JOHN SHOAFF | DIRECTOR
OFFICE OF AIR POLICY & PROGRAM SUPPORT (OAPPS)
OFFICE OF AIR & RADIATION | U.S. EPA | WJC NORTH 5442-B
1200 PENNSYLVANIA AVE. NW | MC 6103A | WASHINGTON, D.C. | 20460 | USA
Shoaff.john@epa.gov | **1-202-564-0531 DIRECT | 1-202-257-1755 MOBILE**

From: Kirby, Kevin
Sent: Monday, September 24, 2018 10:05 AM
To: Eagles, Tom <Eagles.Tom@epa.gov>
Subject: New IQG Case: RFC 18003 - NATA/Ethylene Oxide

Good Morning Tom,
We just received a new RFC challenge dealing with the NATA framing of EO.
Could you please help me discern the SMEs for this so that I can get a Scoping Team meeting scheduled ASAP.
As you know, we stretch to get the response out within 90 days.
Thanks,
Kevin

Kevin J. Kirby
Enterprise Data Architect
US Environmental Protection Agency

OEI/OEIP/EQMD
202 566-1656 desk

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/10/2018 9:47:48 PM
To: Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
Subject: Fwd: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee

Begin forwarded message:

From: "EPA Press Office" <press@epa.gov>
Date: October 10, 2018 at 5:07:53 PM EDT
To: "woods.Clint@epa.gov" <woods.Clint@epa.gov>
Subject: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee
Reply-To: press@epa.gov

Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee

Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process

WASHINGTON (October 10, 2018) - Today, U.S. Environmental Protection Agency (EPA) Acting Administrator Andrew Wheeler announced the appointment of five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). This seven-member panel, required under Section 109 of the Clean Air Act, provides critical advice related to National Ambient Air Quality Standards (NAAQS), including about how to set standards that protect public health with an adequate margin of safety, the role of background pollution, research needs, and potential adverse effects from strategies to meet these standards. Consistent with the Clean Air Act and CASAC's charter, Acting Administrator Wheeler also tasked this panel with leading the review of science for any necessary changes to the NAAQS for ozone or particulate matter. As outlined in the May 2018 "Back-to-Basics Process for Reviewing NAAQS" memorandum these changes would be finalized by late 2020.

"These experts will provide critical scientific advice to EPA as it evaluates where to set national standards for key pollutants like ozone and particulate matter," said Acting Administrator Wheeler. **"They are highly qualified and have a diverse set of**

backgrounds in fields like toxicology, engineering, medicine, ecology, and atmospheric science. These individuals, including five panelists who work in state, local, or federal environmental agencies, will work hard over the next two years to advise EPA in a manner consistent with the Clean Air Act and the protection of public health."

The seven-member chartered CASAC:

- Dr. Anthony (Tony) Cox, Cox Associates (Chair)
- Dr. James Boylan, Georgia Department of Natural Resources
- Dr. Mark Frampton, University of Rochester Medical Center
- Dr. Sabine Lange, Texas Commission on Environmental Quality
- Dr. Timothy Lewis, U.S. Army Corps of Engineers
- Dr. Corey Masuca, Jefferson County (AL) Department of Health
- Dr. Steven Packham, Utah Department of Environmental Quality

Under the Clean Air Act, CASAC is to provide advice on air quality criteria, recommending any new NAAQS or revisions of existing criteria or standards as may be appropriate as well as advising the Administrator of: areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS; research efforts necessary to provide the required information; the relative contribution to air pollution concentrations of natural as well as anthropogenic activity; and any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.

Following the April 2018 Presidential Memorandum on Job Creation and Domestic Manufacturing, EPA issued a memorandum laying out the following principles to reform the process for setting NAAQS:

- Meet statutory deadlines;
- Address all Clean Air Act provisions for NAAQS reviews;
- Streamline and standardize the process for development and review of key policy-relevant information;
- Differentiate science and policy considerations in the NAAQS review process; and
- Issue timely implementation rules or guidance following the revision of a NAAQS.

CASAC operates pursuant to the Clean Air Act, the Federal Advisory Committee Act, and its charter, which is renewed every two years. Consistent with these authorities, the seven-member chartered CASAC will serve as the body to review key science assessments for the ongoing reviews of the ozone and particulate matter NAAQS (last revised in 2015 and 2012, respectively). In the next two weeks, EPA's Office of Research and Development (ORD) intends to make public the draft Integrated Science Assessment for particulate matter for review and comment by CASAC and the public ahead of an in-person meeting in December. ORD also intends to hold a webinar regarding the Integrated Science Assessment for ozone in late October. EPA will also be releasing a

draft Integrated Review Plan to outline the expected ozone NAAQS review process. These steps will kick off the scientific review process which will result in EPA finalizing any necessary changes to the ozone or particulate matter NAAQS by the end of 2020.

For more information, visit EPA's NAAQS review and CASAC websites.

<!--[if !mso]--> **Visit The EPA's Newsroom** <!--[endif]-->

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Sent: 9/13/2018 2:11:10 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Attachments: Kim-NAAQS_Exceedance_Reports_B.Kim.pdf; ATT00001.txt

https://cleanairact.org/events/documents/Kim-NAAQS_Exceedance_Reports_B.Kim.pdf

GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

NAAQS Exceedance Reports

Byeong-Uk Kim and James Boylan
Planning and Support Program
Georgia EPD - Air Protection Branch

AAPCA 2017 Fall Business Meeting
Raleigh, NC
September 21, 2017

EXCEEDANCE vs. VIOLATION

- **"Exceedance" of the NAAQS**
  - **$PM_{2.5}$** ➔ 24-hour measurement > 35 μg/m^3
  - **Ozone** ➔ 8-hour measurement > 70 ppb
  - **SO_2** ➔ 1-hour measurement > 75 ppb
  - **Pb** ➔ 24-hour measurement > 0.15 μg/m^3
- **"Violation" of the NAAQS**
  - **$PM_{2.5}$** ➔ Annual arithmetic mean, averaged over 3 years > 12.0 μg/m^3
  - **$PM_{2.5}$** ➔ 98th percentile of 24-hour daily average, averaged over 3 years > 35 μg/m^3
  - **Ozone** ➔ Annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years > 70 ppb
  - **SO_2** ➔ 99th percentile of 1-hour daily maximum concentrations, averaged over 3 years > 75 ppb
  - **Pb** ➔ Rolling 3-month average > 0.15 μg/m^3

EXCEEDANCE REPORTS

- **GA EPD writes detailed reports for <u>every</u> exceedance of the NAAQS (O_3, $PM_{2.5}$, SO_2, Pb).**
  - **INITIAL REPORT**
    - Must be completed within 2 business days after the exceedance.
    - In 2016, Ozone (30), $PM_{2.5}$ (9), SO_2 (3), and Lead (4).
    - In 2017, Ozone (10), $PM_{2.5}$ (2), SO_2 (0), and Lead (1).
  - **FINAL REPORT**
    - Submitted after all relevant information has been collected. This could be days, weeks, or months…
- **Reports include discussions on meteorology, emissions, and air quality.**

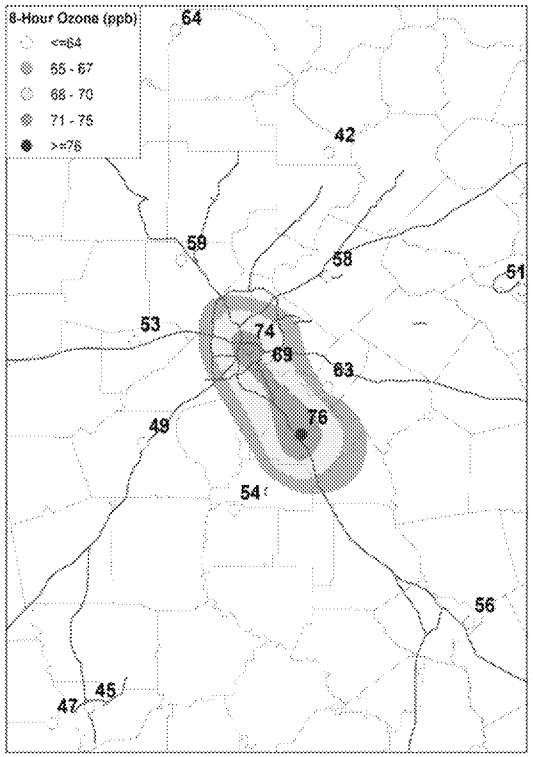
PURPOSE

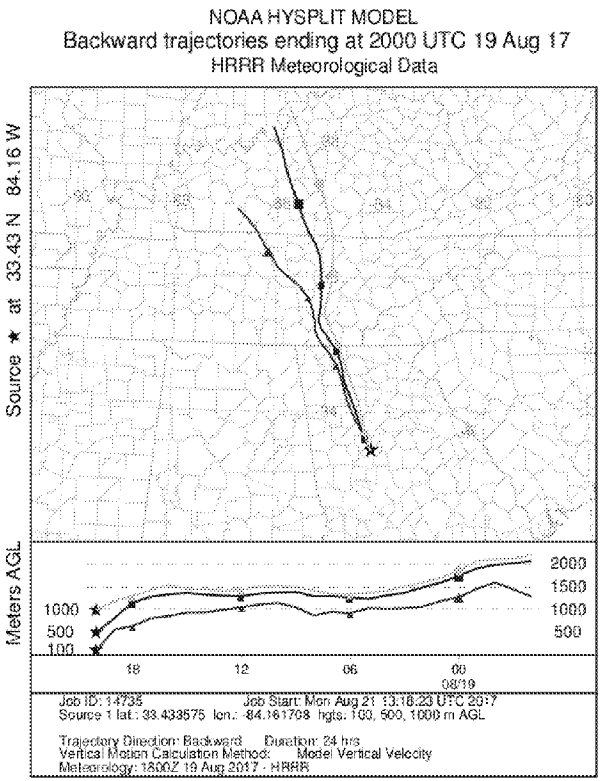
- Previously, there was no set process for investigating the cause of the exceedance, or determining the impact of the exceedance on our design values.
- These exceedance reports are used to better understand the complex conditions leading to exceedances and to help develop effective emission control strategies (if warranted) to prevent future exceedances.
- In the case of wildfire impacts, these reports can be used as the basis of our Exceptional Event demonstrations.

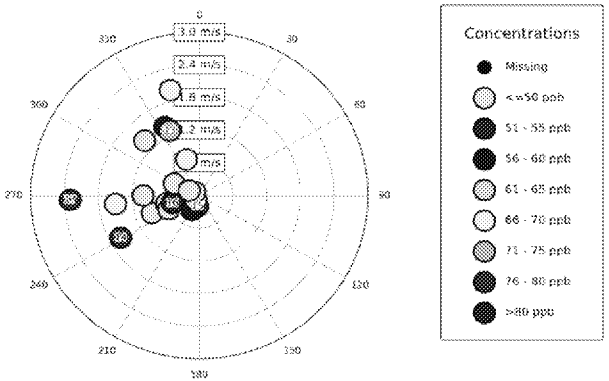
COLLABORATION

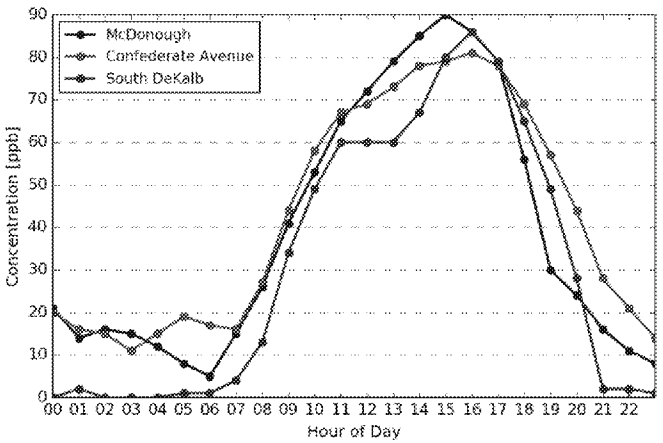
- Planning & Support Program
  - Creates emission maps and graphs, runs HYSPLIT and other models, and puts the reports together
- Ambient Monitoring Program
  - Confirms the exceedance and provides the air monitoring and meteorological information
- Stationary Source Compliance Program and EPD District Offices
  - Provides information on industrial facilities in the area
- Georgia Forestry Commission
  - Provides information on prescribed fires and wildfires

ATLANTA OZONE – AUGUST 19, 2017

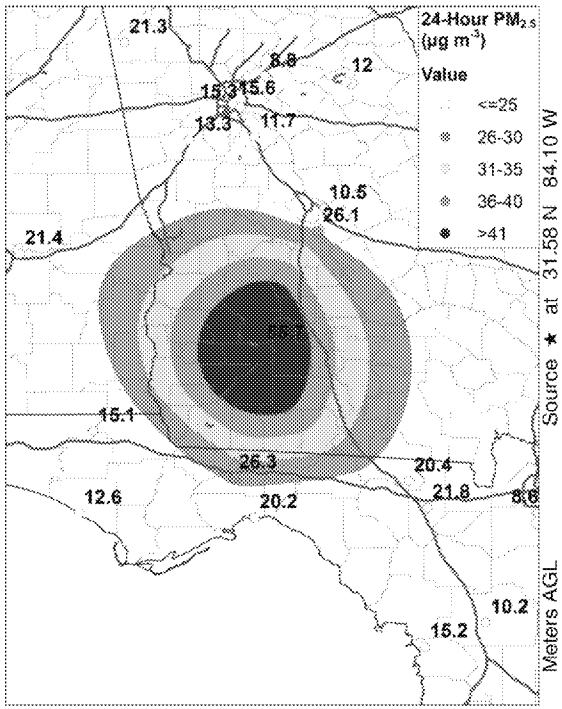


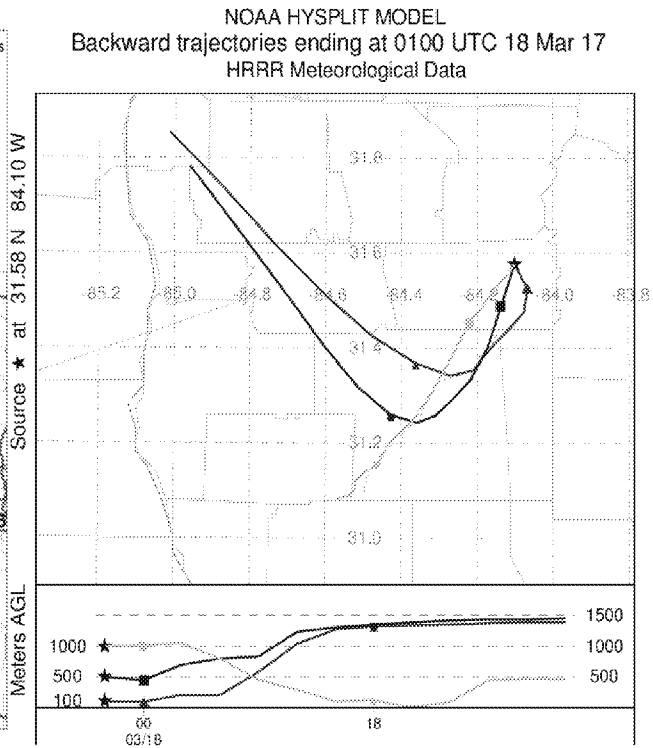


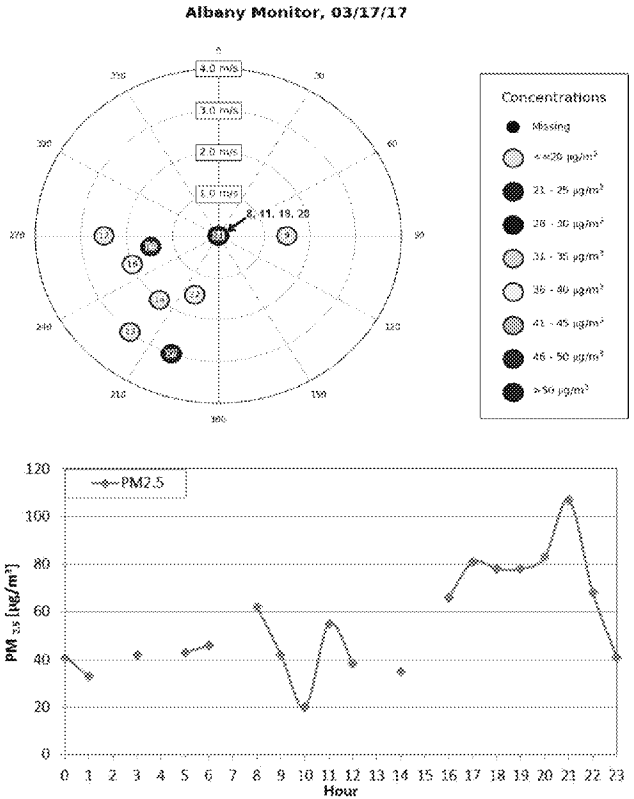




ALBANY $PM_{2.5}$ - MARCH 17, 2017







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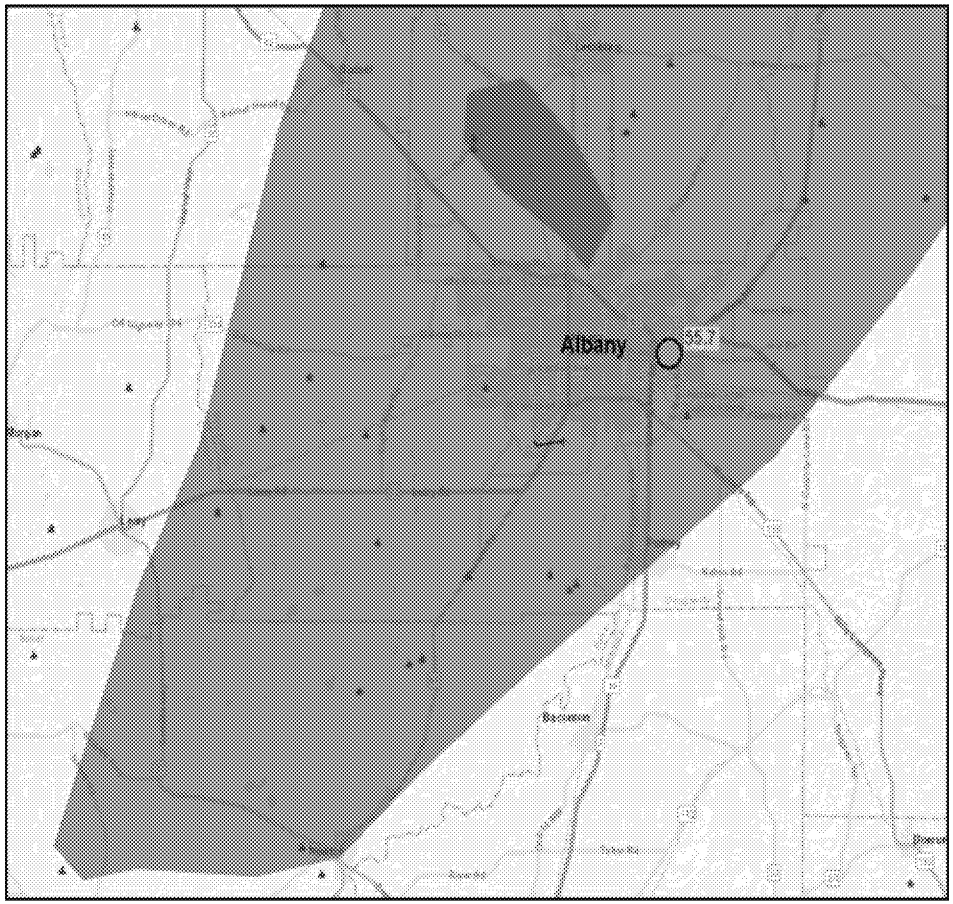
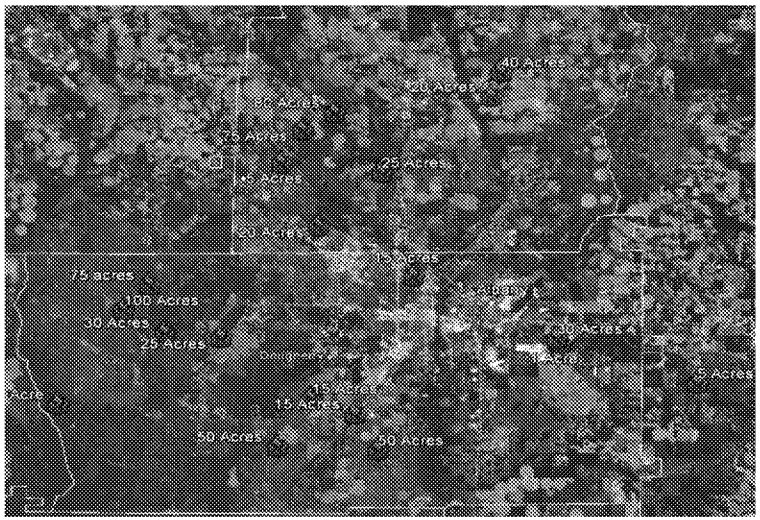
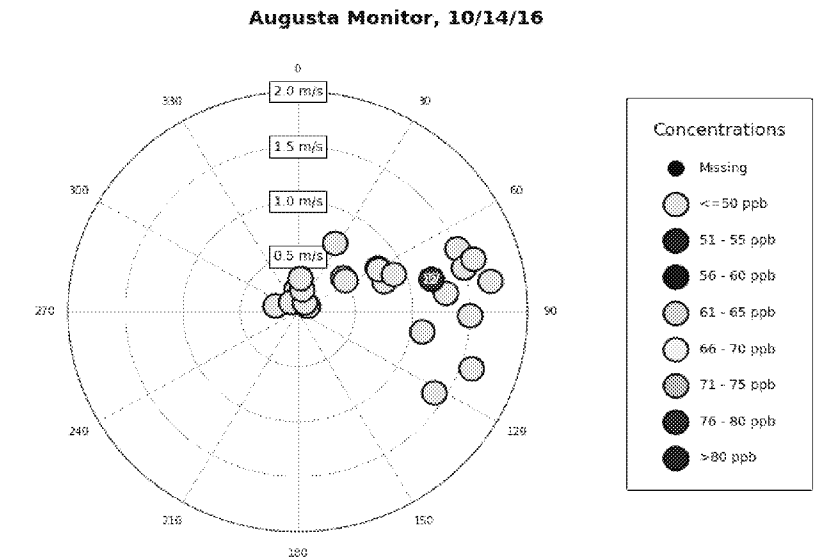
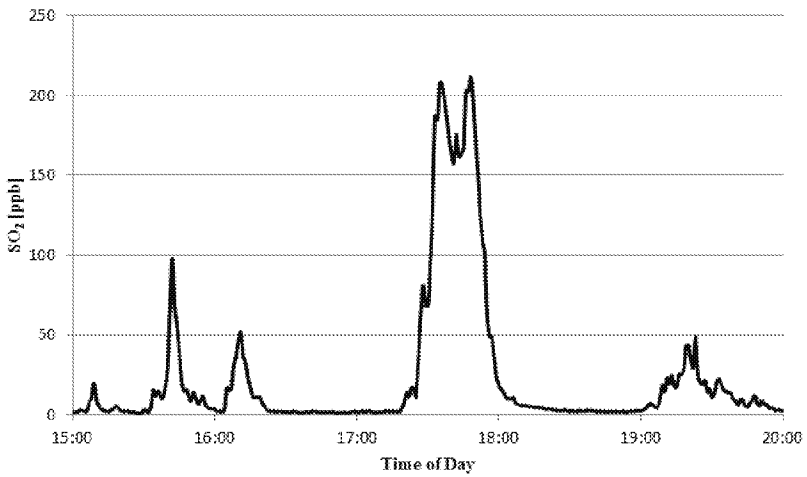
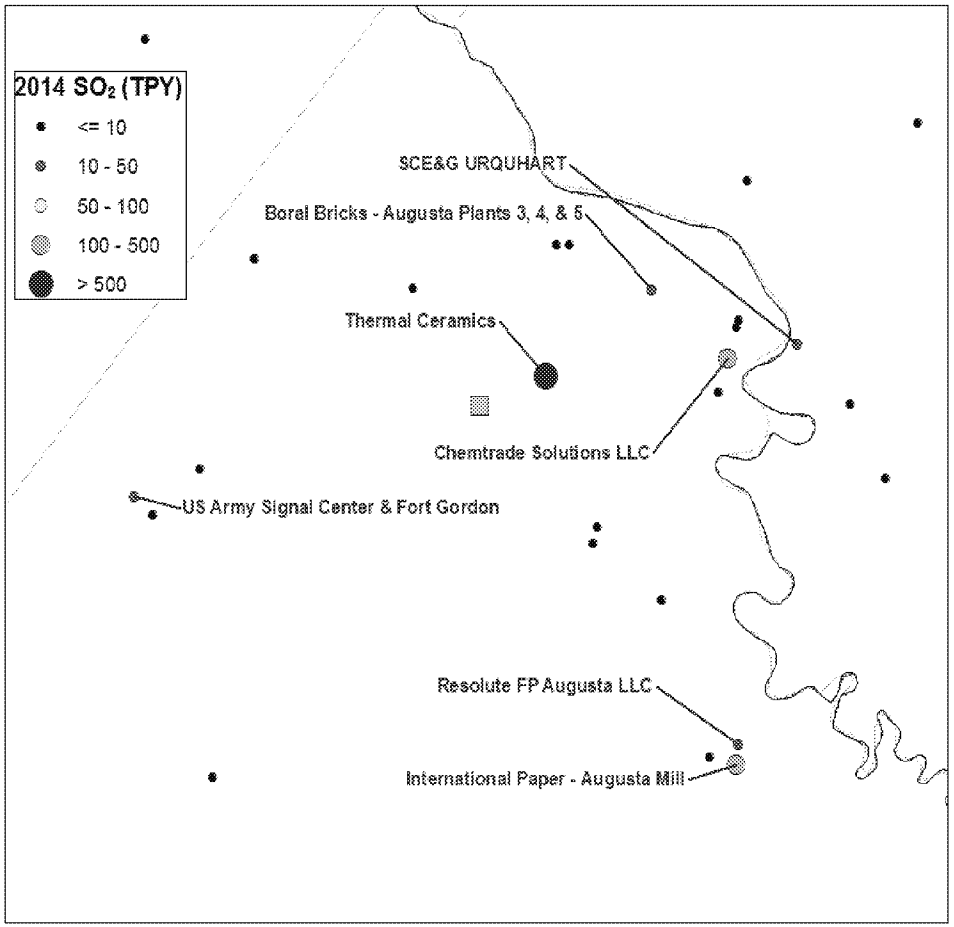




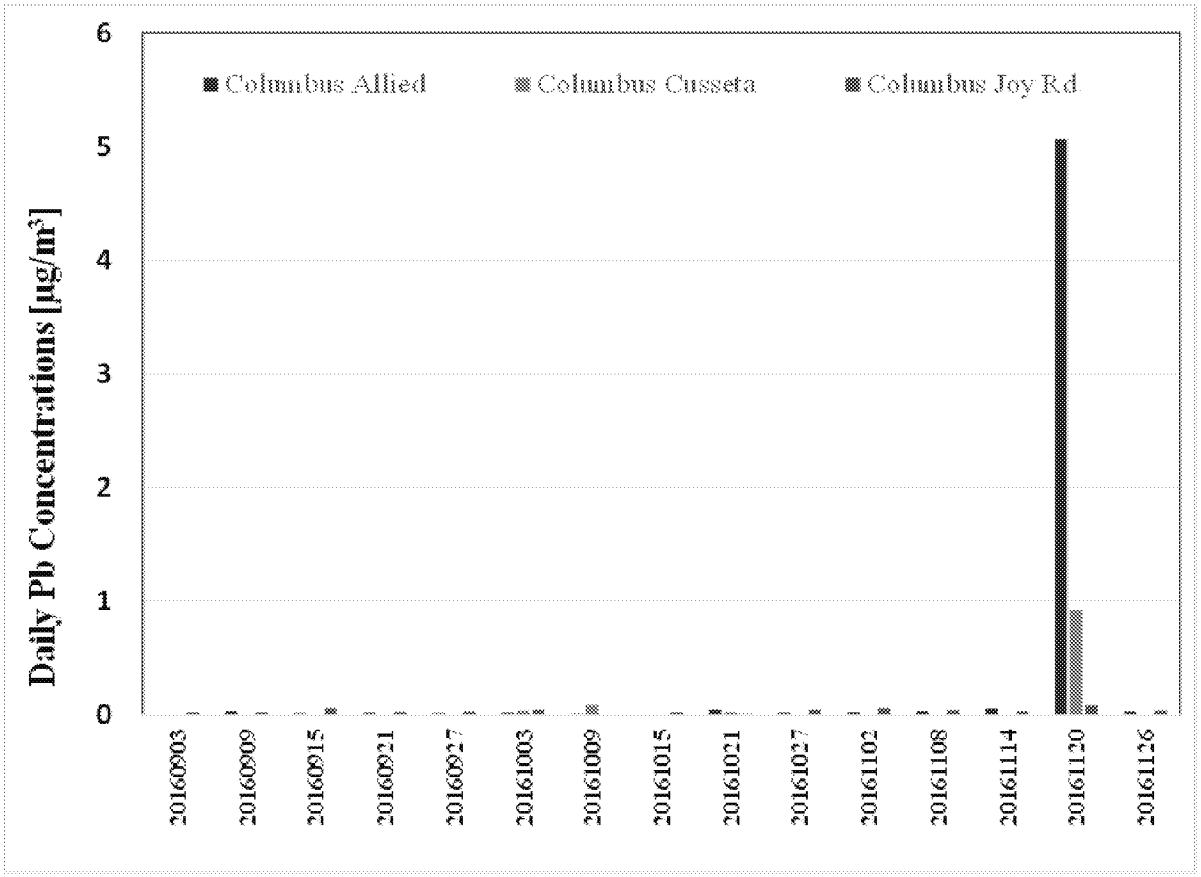
AUGUSTA SO_2 – OCTOBER 14, 2016

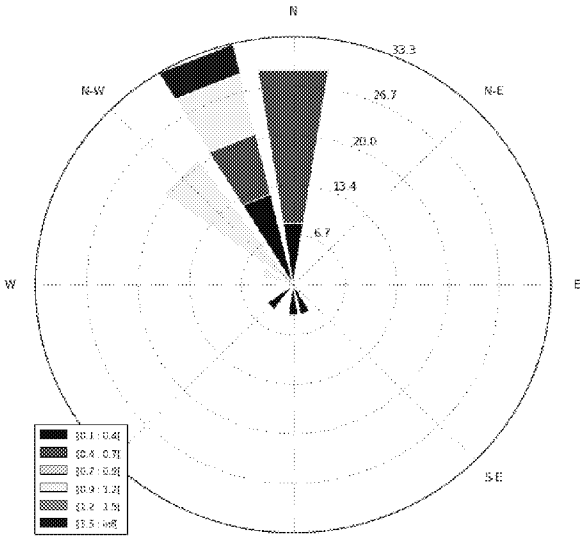


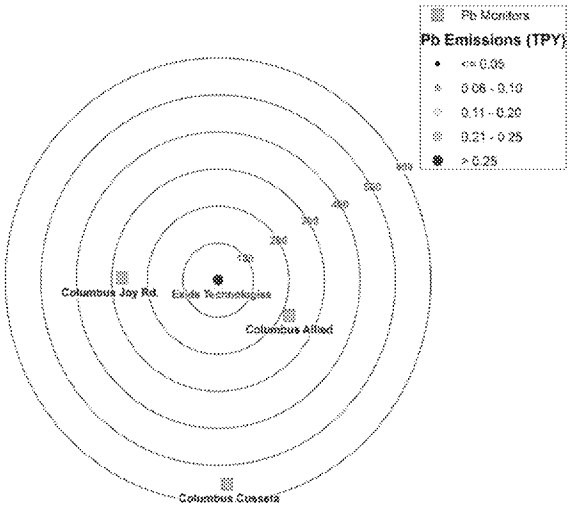




COLUMBUS Pb – NOVEMBER 20, 2016







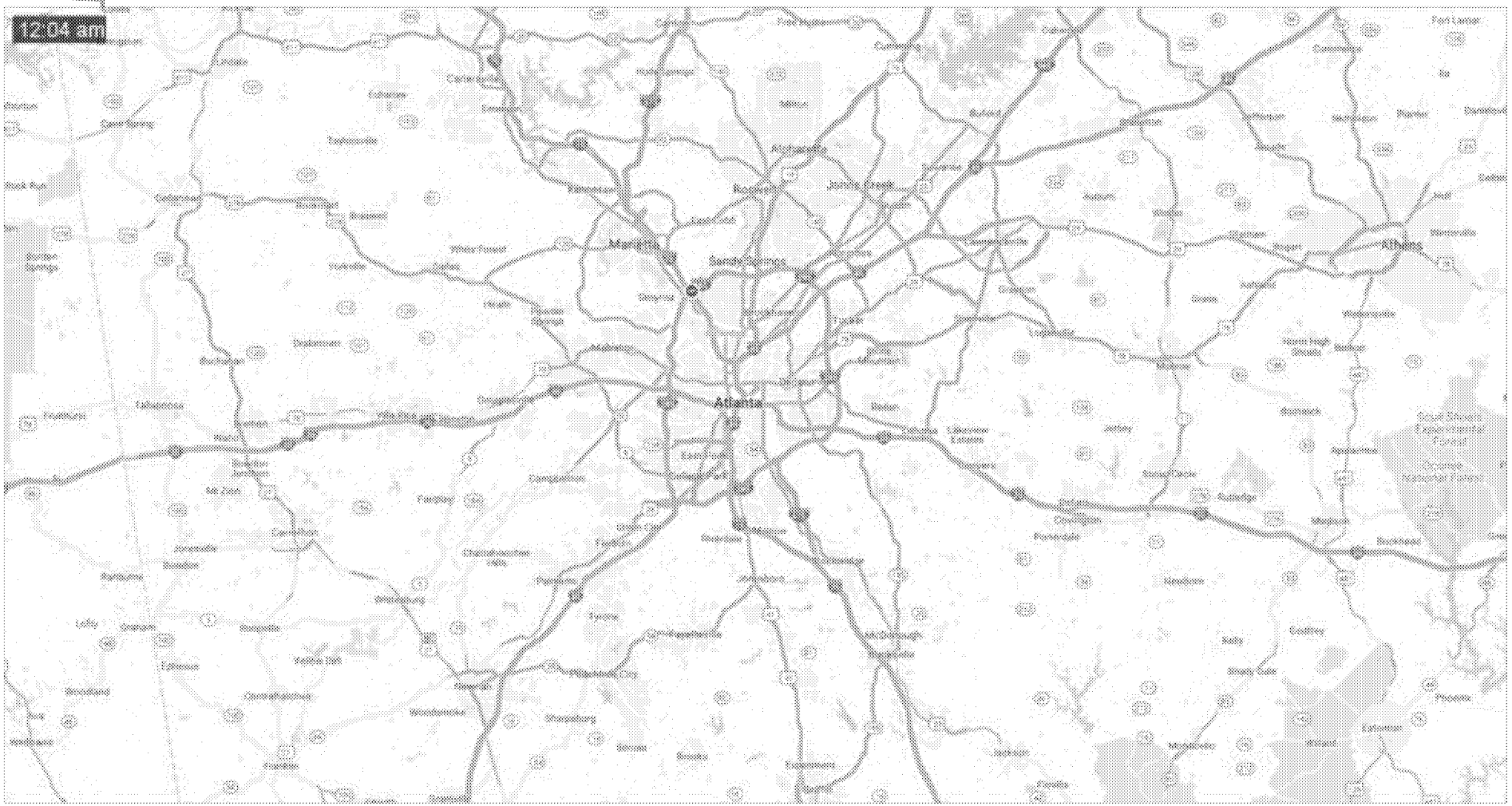
FINAL OZONE EXCEEDANCE REPORT

- Trend analysis of ozone concentrations and meteorological conditions in Atlanta during 1990-2016
- Multiple Linear Regression (MLR) analysis
- Classification and Regression Tree (CART) analysis
- HYSPLIT back trajectory
- Detailed analysis of VOC and NOx precursor measurements

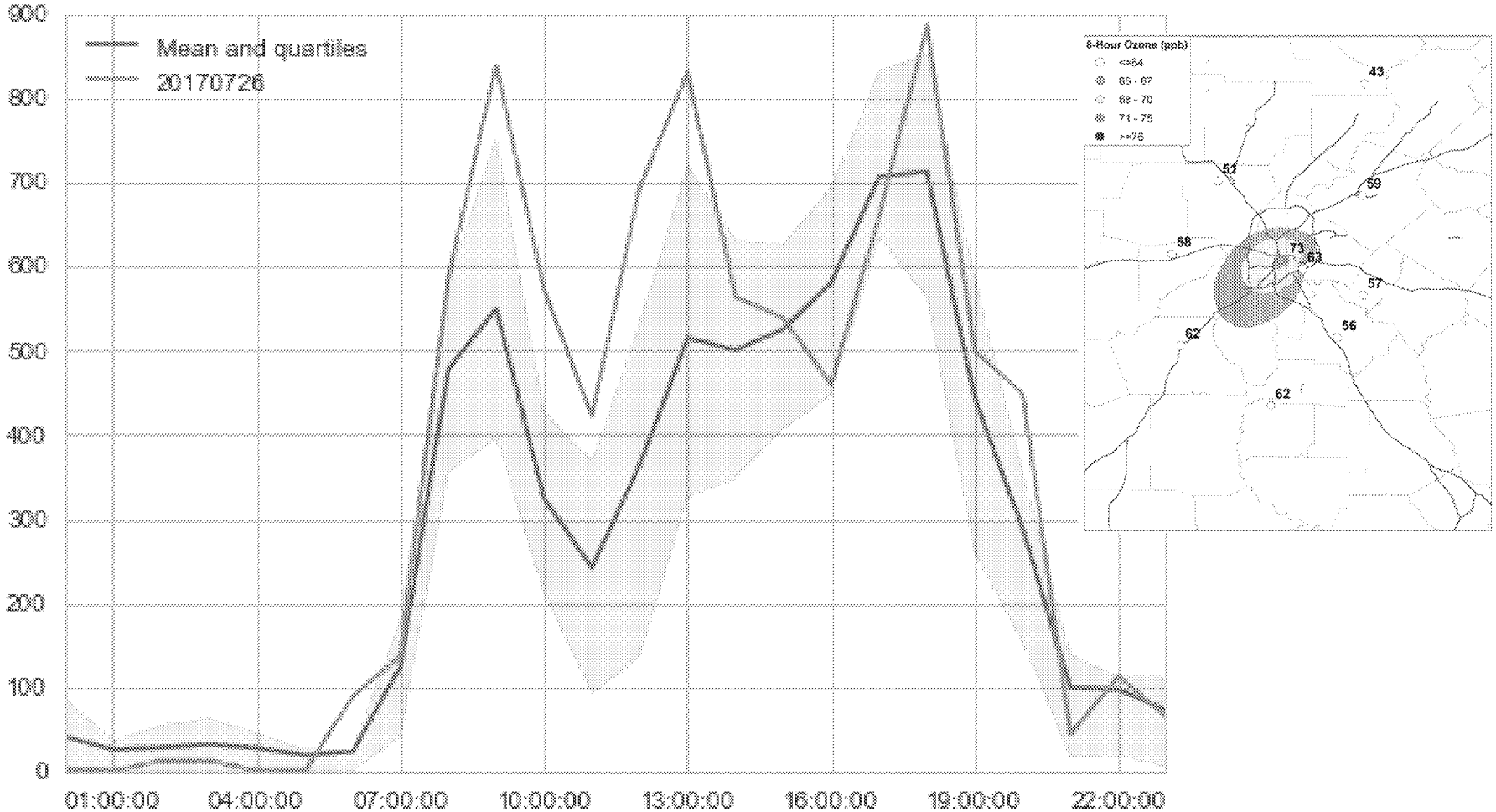
OZONE CONTRIBUTION SUMMARY

- Low relative humidity (PM), high daily maximum air temperature, low cloud coverage, low wind speed
- High ozone on previous days
- NOx emissions, mainly from on-road mobile sources
- VOC emissions, mainly from biogenic sources in the summer months with additional contributions from local on-road mobile sources in the evening and morning hours
- Local transport of ozone and precursor emissions from the Atlanta urban core to monitors outside the urban core.
- Many of the ozone exceedances were local events rather than regional events.

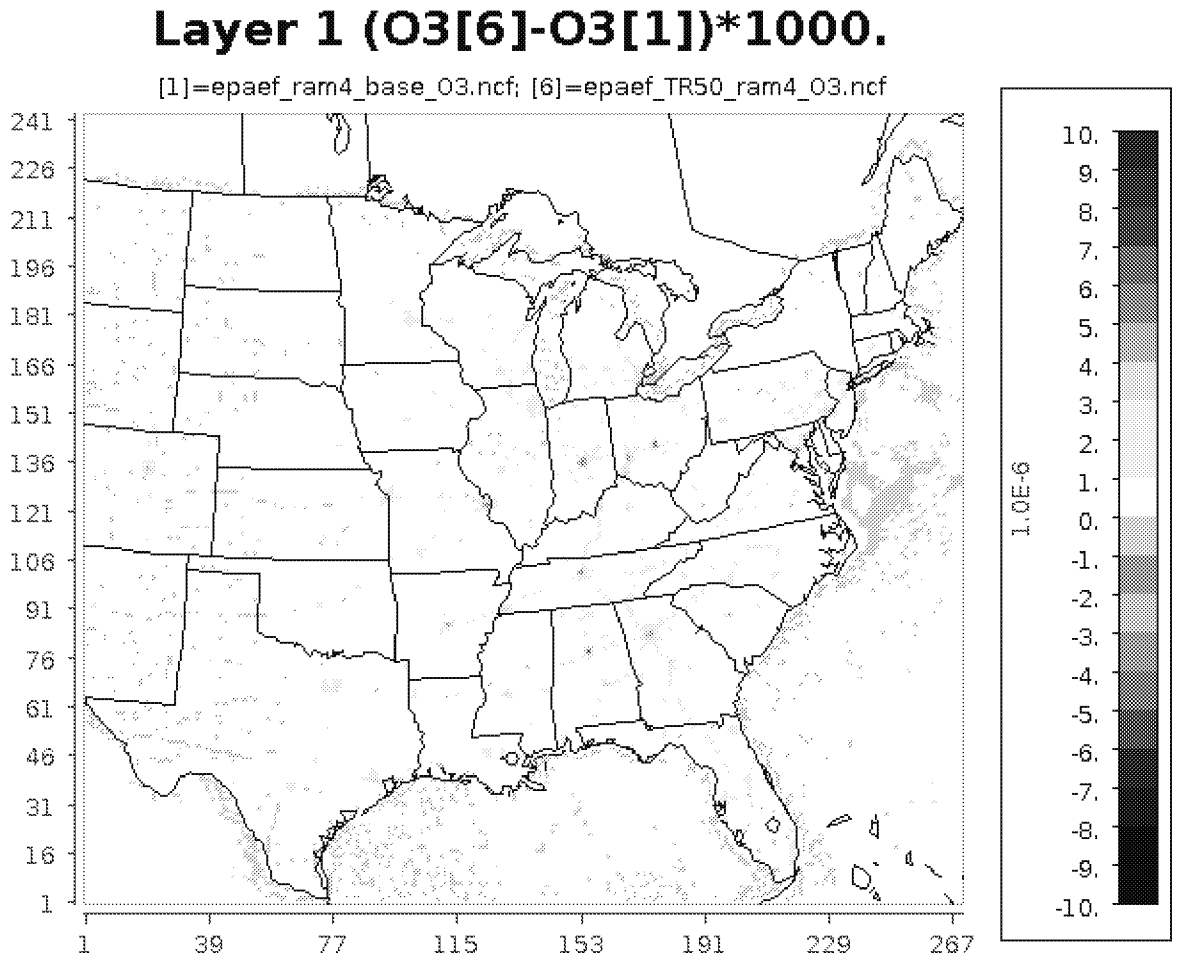
GOOGLE TRAFFIC MAP ON JULY 26



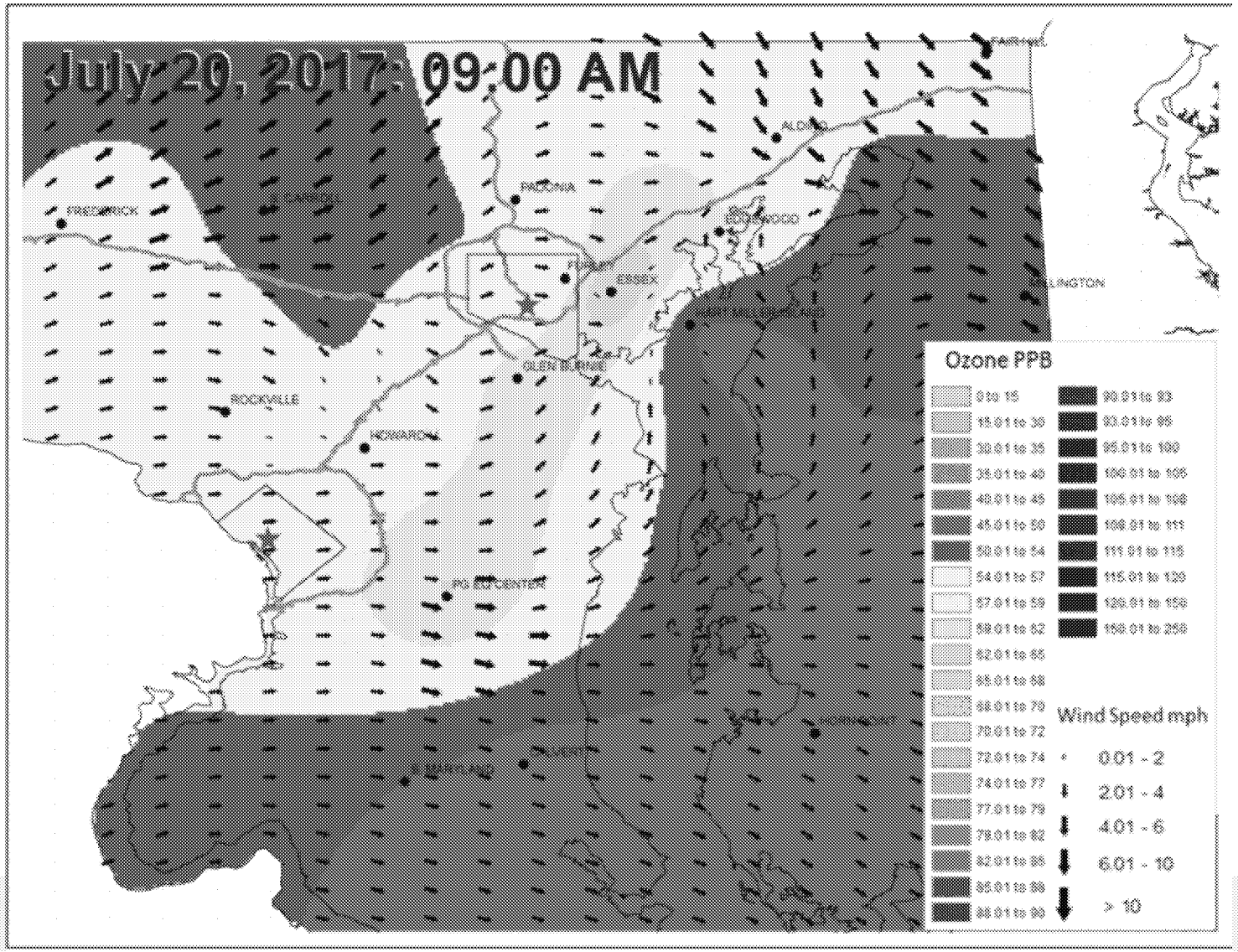
GOOGLE TRAFFIC COUNTS ON JULY 26



50% REDUCTION ON-ROAD NOx



BALTIMORE OZONE EXAMPLE



NOTE: This animation provided by James Boyle (Maryland Department of the Environment)

IMPROVED EFFICIENCY

- When the exceedance reports were initiated in 2015, it took 2-3 days to complete an initial exceedance report.
  - Staff needed time to develop new processes and collaborations, and to learn about the many unique situations that lead to NAAQS exceedances.
- After automating many of the processes and developing SOPs and templates, we became much more efficient and reduced the time down to 2-3 hours per initial exceedance report.

TRANSFERABLE

- EPD's Air Protection Branch uses existing staff, existing monitoring data and data analysis, and existing modeling tools to develop the exceedance reports.
  - We have three staff fully trained to develop the exceedance reports and they rotate responsibility for preparing the reports.
- Other air pollution control agencies could easily adopt this practice without additional funds or staffing.
- Our SOP and example exceedance reports (both initial and final) are available for other air pollution control agencies to use as templates.

CONTACT INFORMATION

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Atlanta, GA 30354

Byeong.Kim@dnr.ga.gov
404-363-7085

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 7/2/2018 7:20:22 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Class II
Attachments: IWAQM3_LRT_Report-07152015.pdf; ATT00001.txt

https://www3.epa.gov/ttn/scram/11thmodconf/IWAQM3_LRT_Report-07152015.pdf

Interagency Workgroup on Air Quality Modeling Phase 3 Summary Report: Long Range Transport and Air Quality Related Values

EPA-454/P-15-003
July 2015

Interagency Workgroup on Air Quality Modeling Phase 3 Summary Report: Long Range Transport and Air Quality Related Values

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Air Quality Analysis Division
Air Quality Modeling Group
Research Triangle Park, NC

Executive Summary

The Interagency Workgroup on Air Quality Modeling (IWAQM) was originally formed in 1991 to provide a focus for development of technically sound regional air quality models for regulatory assessments of pollutant source impacts on Federal Class I areas. The IWAQM process largely concluded in 1998 with the publication of the Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts (EPA-454/R-98-019) (U.S. Environmental Protection Agency, 1998). The IWAQM Phase 2 process provided a series of recommendations concerning the application of the CALPUFF model for use in long range transport (LRT) modeling and informed the promulgation of that model for such regulatory purposes in 2003. The IWAQM process was reinitiated in June 2013 to inform EPA's commitment to update Appendix W to address chemically reactive pollutants in near field and long range transport applications (U.S. Environmental Protection Agency, 2012b). This report provides information and recommendations from the "Phase 3" effort focused on long-range transport of primary and secondary pollutants. The idea of applying photochemical grid models for these purposes is explored in more detail in response to a growing community interest in using these types of models for estimating single source secondary pollutant impacts over long distances.

This document describes chemical and physical processes important to the formation of ground-level O_3, PM2.5, visibility, and deposition in the context of modeled long range transport assessments for permit review programs. Chemical transport models that characterize these processes include both Lagrangian which typically only have a single source included in the model and photochemical grid models which include some representation of all anthropogenic, biogenic, and geogenic sources. Modeling systems appropriate for the purposes of estimating long-range transported single source secondary impacts are described and recommendations are made with respect to the use of certain types of modeling systems for this type of application. Model evaluation is important to ensure that a particular system is fit for the purpose of estimating long-range single source secondary impacts. One aspect of this type of evaluation for long-range transport assessments would be demonstrating model skill in meteorological processes important for long distant transport by replicating appropriate mesoscale tracer release experiments. In addition to establishing whether a modeling system is generally appropriate for this purpose, project specific evaluations that compare model estimated meteorology and chemical estimates with measurements near the project source and key receptors is also an important model evaluation component.

Regulatory context for estimating long-range transport of visibility and deposition is provided to present the range of purposes for single source impact assessments. In the case of visibility, single source impact assessment approaches are compared within the Regional Haze Rule context, Prevention of Significant Deterioration, and National Environmental Policy Act to better illustrate the similarities in these demonstrations and note where differences should be expected.

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1 BACKGROUND: IWAQM Phase 3 process overview

The Interagency Workgroup on Air Quality Modeling (IWAQM) was originally formed in 1991 to provide a focus for development of technically sound regional air quality models for regulatory assessments of pollutant source impacts on Federal Class I areas. Meetings were held with personnel from interested Federal agencies: the Environmental Protection Agency (EPA), the U.S. Forest Service (USFS), the U.S. Fish and Wildlife Service (USFWS), and the National Park Service (NPS). The original purpose was to review respective modeling programs, develop an organizational framework, and formulate reasonable objectives and plans that could be presented to management for support and commitment. The IWAQM process largely concluded in 1998 with the publication of the Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts (EPA-454/R-98-019) (U.S. Environmental Protection Agency, 1998). The IWAQM Phase 2 report provided a series of recommendations concerning the application of the CALPUFF model for use in long range transport (LRT) modeling and informed the promulgation of that model for such regulatory purposes in 2003. Draft updates to the IWAQM Phase 2 report were released in 2009 to better reflect the state-of-the-practice of long range transport modeling techniques based on experience gained since the early 2000s.

The IWAQM process was reinitiated in June 2013 to inform EPA's commitment to update Appendix W to address chemically reactive pollutants in near field and long range transport applications (U.S. Environmental Protection Agency, 2012b). Comments received from the 10th Modeling Conference (March 2012) from stakeholders support this interagency collaborative effort to provide additional guidance for modeling single source impacts on secondarily formed pollutants in the near-field and for long range transport. Stakeholder comments also support the idea of this collaborative effort working in parallel with stakeholders to further model development and evaluation.

This "Phase 3" effort includes the establishment of 2 separate working groups, one focused on long-range transport of primary and secondary pollutants and the other on near-field single source impacts of secondary pollutants. While many of the objectives are similar for each of these groups, the focus and regulatory end-points are different for each.

It is expected the "Phase 3" effort will continue with future efforts related to reviewing and responding to comments given on the 2015 proposed changes to Appendix W related to single source impact assessments for air quality related values. IWAQM3 long-range transport team members include Rick Gilliam (US EPA), Kirk Baker (US EPA), Michael Feldman (US EPA), Gail Tonnesen (US EPA), Chris Owen (US EPA), Bret Anderson (USFS), Tim Allen (US FWS), John Notar (NPS), John Vimont (NPS), and Craig Nicholls (BLM). Additional participation was provided by Erik Snyder (US EPA), Rebecca Matichuk (US EPA), and Robert Elleman (US EPA).

2 REGULATORY MOTIVATION

Sections 165, 169A, and 169B of the Clean Air Act sets visibility goals for Class I areas. The 1999 Regional Haze Rule expands on Section 169 of the Clean Air Act and "Phase I" of the Visibility Protection Program. The Regional Haze Rule (RHR) has multiple provisions that may be supported by air quality modeling. The reasonable progress and BART determination components of the RHR and modeling requirements for the first planning period and future planning periods are shown in Table 1. Additional sections

contain requirements of other programs including Prevention of Significant Deterioration (PSD) and National Environmental Policy Act (NEPA) for visibility modeling.

Table 1. Modeling requirements for multisource and single source assessments to support various regulatory programs.

Program	Multisource Assessment Requirement	Single Source Assessment Requirement
Regional Haze Rule Reasonable Progress	Yes	No
Regional Haze Rule BART	No	Yes (initial planning cycle only)
PSD	No	Yes
NEPA	Yes (method 2)	Yes (method 1)

2.1 Regional Haze Rule Visibility Impairment Modeling: Reasonable Progress Goals (RPG)

Modeling may be used to assess Reasonable Progress by projecting future year visibility impairment at Class I areas due to all emissions sources. Projected visibility is compared to the Uniform Rate of Progress, which is a linear interpolation between recent air quality measurements and the 2064 "natural" visibility goal for each Class I area (U.S. Environmental Protection Agency, 2005b). Single source modeling is not a requirement in setting reasonable progress goals. However, single source modeling can be used to evaluate visibility impacts or benefits from emissions sources or emissions controls to inform decisions on emission reduction measures that may be necessary to meet long-term strategy requirements toward meeting the goal of natural visibility conditions and thus supporting a demonstration of the reasonableness of the reasonable progress goal.

A modeling system that treats emissions from all known anthropogenic and biogenic emissions sources with realistic chemical and physical transformations should be utilized to estimate future visibility conditions at a Class I area. The most appropriate tool that contains these qualities is a photochemical grid model. Commonly applied photochemical grid models for estimating visibility include the Comprehensive Air-Quality Model with Extensions (CAMx) and the Community Multiscale Air Quality Model (CMAQ). EPA has issued SIP modeling guidance for Regional Haze (U.S. Environmental Protection Agency, 2014b) in which an approach for assessing future year visibility impacts with photochemical grid models has been established and applied by States for their initial RH SIP demonstrations for 2018. This same type of photochemical model based assessment will need to be done for upcoming SIP demonstrations for subsequent planning periods (e.g. 2028, 2038, etc.) to determine if Class I areas will be on the glidepath to "natural" conditions.

The estimates of "natural" conditions are critically important for the estimation of the uniform rate of progress. However, any future updates to the calculation of "natural" conditions will not substantively change the nature of the air quality model based assessments of projected visibility impairment. However, changes to the metrics (e.g. 20% worst days) used for demonstrating progress will provide for more influential changes to projected visibility improvements.

2.2 Regional Haze Rule Visibility Impairment Modeling: BART program

Dispersion modeling was recommended by US EPA to support decisions about which BART eligible sources "cause or contribute" to visibility impairment and may need enforceable emissions limits and/or emissions controls (U.S. Environmental Protection Agency, 2005b). If a BART eligible source "contributes" to visibility impairment then additional modeling was done to assess the improvement in visibility due to source control measures. BART-eligible sources meet specific criteria for source category, date of operation or existence, and potential to emit (see 70 FR 39158–39161; July 6, 2005). BART is a program that only applies to the 1st regional haze planning period (the planning period ending 2018).

Single-source air quality modeling for BART assessments was typically done using the CALPUFF modeling system and daily maximum emission rates. However, it is important to note that other Lagrangian models or photochemical grid modeling systems can be used to isolate the primary and secondary impacts of single sources and thus be used for single source visibility assessments (Baker and Foley, 2011; Baker and Kelly, 2014; ENVIRON, 2012a, c; Zhou et al., 2012). Photochemical grid models have been used to support regulatory single source visibility impact assessments (U.S. Environmental Protection Agency, 2014a).

The daily visibility metric for each Class I area is expressed as the change in deciviews compared to natural visibility conditions (U.S. Environmental Protection Agency, 1998). Natural visibility conditions are found in Appendix B of EPA's Guidance for Estimating Natural Visibility Conditions under the Regional Haze Rule (U.S. Environmental Protection Agency, 2003). The daily average visibility degradation beyond natural conditions expressed in deciviews is kept for each Class I area and ranked over the length of the modeling simulation. A threshold expressed in deciviews was commonly employed to determine whether a BART-eligible source "contributes" or "causes" visibility impairment as suggested in U.S. EPA guidance (U.S. Environmental Protection Agency, 2005b). BART assessments consider an estimate of maximum impacts over all modeled days, not the 20% best or 20% worst days which are considered for the reasonable progress assessment.

The air quality impacts of BART controls are sometimes estimated in aggregate rather than on a source-by-source basis. A cumulative "BART alternative" or "Better than BART" analysis can also be completed to examine the visibility benefits of alternative state and/or Federal controls programs that may provide more reasonable progress benefits compared to BART (U.S. Environmental Protection Agency, 2012a). Most "Better than BART" analyses to date have used photochemical modeling to examine the regional visibility benefits of NO_X, SO_2, and primary PM2.5 emissions reductions from BART controls and BART alternatives. These "Better than BART" analyses have focused on changes in visibility due to emissions changes on the 20% best and 20% worst visibility days.

2.3 Differences between single source assessments for BART and RPG

Fundamental differences in required approaches for evaluating source impacts for the purposes of BART determinations and RPG along with inherent differences in the models used for these purposes make directly comparing results for specific sources impossible. Single-source air quality modeling for BART assessments was typically done using the CALPUFF modeling system (69 FR 25,193-194), using maximum

emission rates (24-hr maximum emission rates during the baseline period) and consideration of the maximum visibility impact from the source. On the other hand, due to the need to quantify the future year visibility impairment from all types of emissions sources on the 20% best and 20% worst days, reasonable progress assessments require the use of photochemical grid models. Photochemical grid models include all emissions sources and have realistic representation of formation, transport, and removal processes of particulate matter less than 2.5 microns that causes visibility degradation. Similarly, single source modeling for the purpose of evaluating visibility impacts or benefits from emissions sources or emissions controls for reasonable progress and long-term strategy development may utilize photochemical grid models to estimate potential visibility benefits from controls on future year visibility conditions.

Modeling for the purpose of establishing a reasonable progress goal (RPG) differs from the single source BART determination modeling for a variety of reasons. BART determinations are intended to provide information about current year impacts from a single facility at Class I areas to supplement other relevant emissions control information. Since BART controls need to be assessed against "worst case" emissions from specific sources, these model assessments are done using maximum 24-hr average emissions rates. The 8th highest model estimate of facility impacts at Class I areas from each year modeled are averaged and compared to that Class I area's natural conditions to provide an estimate of a "worst case" scenario (70 FR 39124). The highest modeled impacts are not typically compared directly to visibility thresholds, recognizing some uncertainty exists in the modeling system and abnormal meteorology may result in an unusually high source contribution. In contrast, RPG assessments and single-source assessments for the purposes of reasonable progress and long-term strategy development use actual emission rates to provide a realistic estimate of current and future year visibility impacts on the 20% best and 20% worst days at a Class I area.

Given differences in emissions and modeled impacts for these different assessment approaches, visibility impacts will be lower using the RPG approach compared to a BART assessment. BART determinations are current year "worst case" single source impact scenarios and RPG assessments are intended to provide realistic projections of future visibility. RPG necessitates using actual emissions rather than maximum 24-hour average emissions. In addition, RPG assessments average impacts over the 20% worst days rather that selecting the 8th highest facility impact in a given year. RPG impacts are examined relative to the projected future year 20% worst days visibility estimate, while BART impacts are maximum source impacts compared to background natural conditions irrespective of the relationship to the 20% worst days.

Finally, single source impacts estimated for RPG and BART will be different due to fundamental differences between photochemical grid models and puff dispersion models such as CALPUFF. Photochemical grid models include all emissions sources and provide a dynamic and realistic chemical and physical environment to estimate source emission impacts. The CALPUFF model uses fixed uniform concentrations of important oxidants such as ozone and neutralizing agents such as ammonia and does not perform key thermodynamic transformations that strongly influence atmospheric residence time and thus transport (Karamchandani et al., 2009; Karamchandani et al., 2008). CALPUFF's representation of these important chemical species and PM2.5 chemistry will result in different estimated source impacts than a photochemical grid model even if the exact same source emissions and release characteristics are used in both modeling systems. Additionally, Lagrangian puff models such as CALPUFF allow the project source full access to oxidants (e.g. ozone) and neutralizing agents (e.g. ammonia) while the same source in a photochemical model competes for oxidants and neutralizing agents which may result in different and possibly lower impacts.

In sum, the differences in the types of models, the inputs to the models, and how the models and model results are used means that the results from a BART determination or similar modeling using CALPUFF cannot be directly compared to estimated impacts of emissions controls from a single source on a reasonable progress goal. If recommended procedures change for either BART determination impact assessments or reasonable progress goal impact assessments the comparability between approaches would also change. Photochemical grid models could be applied to estimate single source impacts and post-processed in a manner consistent with requirements for a BART-like assessment but Lagrangian puff models are not ideal for reasonable progress demonstrations since they typically characterize one or a small group of sources.

2.4 Prevention of Significant Deterioration

Pursuant to 40 CFR part 51.166 and 52.21, subsections (k)(1)(i) and (k)(1)(ii), new or modified sources emitting in significant amounts (see 40 CFR part 51.166 and 52.21, subsection (b)(23)(i)) are required to demonstrate that the source under review does not cause or contribute to a violation of any applicable national ambient air quality standards ((k)(1)(i)) or maximum allowable increases over a baseline concentration ((k)(1)(ii)). Additionally, 40 CFR parts 52.27, subsection (d)(1), requires that the permit reviewing authority must provide to all affected FLM's written notification for any permit application which may affect visibility in any Federal Class I area. Notification must include a proposed source's anticipated impact on visibility on any Federal Class I area. The requirements of PSD potentially require the use of LRT models for both the maximum allowable increases (increments) and for air quality related values (AQRV's) including visibility. Unique to this is the authorities under which each of these elements of air quality analyses is administered. The relevant permitting authority administers the NAAQS and increments component of the air quality analysis, while the Federal Land Manager is responsible for recommending models and analytical procedures for the air quality related values analysis (see 40 CFR part 51, Appendix W, subsection 6.1(b)).

Single source impacts are typically compared to significant impact levels (SILs) and increments. For the purposes of long range transport it is expected based on an analysis of multiple hypothetical plants that O_3 and secondary PM2.5 impacts would typically be below any significance threshold beyond 50 km (U.S. Environmental Protection Agency, 2015a). Analysis for primarily emitted pollutants indicates that in most situations significance thresholds are not exceeded beyond 50 km (U.S. Environmental Protection Agency, 2015b). Long-range transport assessments may be necessary in certain limited situations for PSD increment. In these situations, a screening approach could be used that relies upon the near-field application of the appropriate screening and/or preferred model to determine the significance of ambient impact at or about 50 km from the new of modifying source. If this initial screening indicates there may be significant ambient impacts at that distance, then further screening is necessary.

Where a long range transport assessment is still needed for primary pollutant impacts a Lagrangian (e.g. CALPUFF without chemistry) or photochemical grid modeling system (e.g. CAMx, CMAQ) could be used to estimate those impacts. Typically, a Lagrangian model is the type of model appropriate to use for these screening assessments; however, applicants should reach agreed upon approaches (models and modeling parameters) on a case-by-case basis in consultation with the appropriate reviewing authority, Regional Office, and the affected Federal Land Manager(s) (FLM(s)). If a cumulative increment analysis is necessary, for these limited situations, the selection and use of an alternative model shall occur in

agreement with the appropriate reviewing authority (paragraph 3.0(b)) and approval by the EPA Regional Office based on the requirements of section 3.2.2(e).

PSD analyses are also completed for NEPA air quality assessments using dispersion models or photochemical grid models. The typical PSD assessment description includes the following:

> The PSD demonstrations are for information and comparison purposes only and do not constitute a regulatory PSD increment consumption analysis. This PSD comparison analysis is used as an indicator of the relative change of air quality, which is a useful metric for analyzing and comparing air quality impacts. The comparison is made to allowable PSD increments for Class I and Class II areas for project-specific and cumulative impacts.

2.4.1 Visibility

Visibility impairment due to single sources may be assessed for the purposes of satisfying requirements for other programs such as PSD. PSD ensures the preservation of certain levels of air quality related values (AQRVs), including visibility, at designated Class I areas. Model assessments for AQRVs follow the Federal Land Managers' Air Quality Related Values Work Group (FLAG) Phase I Report (revised 2010) (U.S. Department of the Interior, 2010). Visibility in important natural areas (e.g., Federal Class I areas) is protected under a number of provisions of the Clean Air Act, including Sections 169A and 169B (addressing impacts primarily from existing sources) and Section 165 (new source review).

Visibility regulations (40 CFR 51.300–309) require States to mitigate current and prevent future visibility impairment in any of the 156 mandatory Federal Class I areas where visibility is considered an important attribute. In 1999, EPA issued revisions to the regulations to address visibility impairment in the form of regional haze, which is caused by numerous, diverse sources (e.g., stationary, mobile, and area sources) located across a broad region (40CFR 51.308–309). Section 169A of the Act requires states to develop SIPs containing long-term strategies for remedying existing and preventing future visibility impairment in the 156 mandatory Class I Federal areas, where visibility is considered an important attribute. In order to develop long-term strategies to address regional haze, many States will need to conduct regional-scale modeling of fine particulate concentrations and associated visibility impairment.

The FLAG visibility modeling recommendations are divided into two distinct sections to address different requirements for 1) near field modeling where plumes or layers are compared against a viewing background and 2) distant/multi-source modeling for plumes and aggregations of plumes that affect the general appearance of a scene. The recommendations separately address visibility assessments for sources proposing to locate relatively near and at farther distances from these areas (U.S. Department of the Interior, 2010).

2.4.2 Deposition

FLAG (2010) recommends that applicable sources assess impacts of nitrogen and sulfur deposition at Class I areas. This guidance recognizes the importance of establishing critical deposition loading values ("critical loads") for each specific Class I area, as these critical loads are completely dependent on local atmospheric, aquatic and terrestrial conditions and chemistry. Critical load thresholds are essentially a level of atmospheric pollutant deposition below which negative ecosystem effects are not likely to occur. FLAG (2010) does not include any critical load levels for specific Class I areas and refers to site-

specific critical load information on FLM websites for each area of concern. However, this guidance does recommend the use of deposition analysis thresholds (DATs) developed by the National Park Service and the Fish and Wildlife Service. The DATs represent screening level values for nitrogen and sulfur deposition. If the DAT is exceeded then the modeling results are considered significant and further AQRV analysis is required. If a source exceeds the DAT level then a comparison to Class I specific critical load values is necessary (U.S. Department of the Interior, 2011). Project source annual total sulfur deposition and annual total nitrogen deposition are added to Class I area specific measured or estimated total sulfur and total nitrogen deposition to determine whether the Class I area specific screening level or critical load value would be exceeded.

2.5 National Environmental Policy Act – Visibility Assessments

NEPA air quality impact analyses assess potential air quality impacts that could occur from development within the project area and from other documented regional emissions sources within a defined study area. Visibility impairment due to project-specific sources and groups of sources are quantified and compared to applicable state and federal standards and thresholds for AQRV impacts (e.g., visibility) (U.S. Department of Agriculture et al., 2011). Two methodologies are typically used to process model results and evaluate visibility impacts.

The first methodology follows recommendations in the Federal Land Managers' Air Quality Related Values Work Group (FLAG) Phase I Report – Revised 2010 (U.S. Department of the Interior, 2010). This method assesses project-specific visibility impacts at Class I and sensitive Class II areas by determining the incremental changes in light extinction relative to estimated natural background conditions and comparing the incremental changes to visibility thresholds. The visibility evaluation metric used in this analysis is the Haze Index, which is measured in deciview (dv) and used in EPA's Regional Haze Rule. The change in visibility impacts of the proposed development is obtained by calculating the differences between the Haze Index with added project concentrations and the Haze Index based solely on background concentrations. Estimated visibility degradation at the Class I and sensitive Class II areas is presented in terms of the number of days that exceed a threshold percent change in extinction, or deciview (dv), relative to natural background conditions. The maximum and 98th percentile incremental changes in Haze Index (Δdv) at any receptor that intersects with the area of interest are compared to 0.5 dv and 1.0 dv thresholds. A source whose 98th percentile value of the haze index is greater than 0.5 deciview (dv) (approximately a 5% change in light extinction) is considered to contribute to regional haze visibility impairment. Similarly, a source that exceeds 1.0 dv (approximately a 10% change in light extinction) causes visibility impairment and corresponds to a change in visibility impairment that is just perceptible to the human eye.

The second methodology examines the cumulative (all sources) visibility impacts at Class I and sensitive Class II areas (Silva and McCoy, 2012). The cumulative visibility assessments use the estimates of actual emissions that could occur from the proposed development and all sources within a defined study area. This approach consists of five steps, as follows:

Step 1: Calculate the average baseline visibility for each Class I and sensitive Class II area based on five years of monitoring data for the 20 percent best and 20 percent worst days.

Step 2: Estimate site-specific relative response factors (RRFs) for each visibility component (as specified in the new IMPROVE equation) based on the future-year and base-year modeling results. Note that the RRF is defined as the ratio of the future-year to base-year simulated

concentration in the vicinity of a monitoring site. The "future year" may simply be a scenario including the new project source(s).

Step 3: Apply the RRFs to the monitoring data to estimate future-year concentrations corresponding to the 20 percent best and 20 percent worst visibility days.

Step 4: Use the concentration estimates from Step 3 to calculate future-year visibility for the best and worst days.

Step 5: Using the information from Step 4, calculate the future-year mean visibility for the 20 percent best and worst days.

Steps 2 through 5 are applied for model scenarios with and without the proposed project emissions, and then differences in visibility between the model scenarios are calculated and used to quantify the change in cumulative visibility resulting from project-specific emissions. The cumulative multisource (method 2) visibility assessments (Silva and McCoy, 2012) are similar to the multi-source RPG assessments for Regional Haze except that the future year is typically the maximum emission year projected for the proposed project, which in most cases is much closer to the baseline period than a projected future year for reasonable progress goals or 2064 natural conditions.

2.6 National Environmental Policy Act – Sulfur and Nitrogen Deposition Assessments

Wet and dry fluxes of sulfur- and nitrogen-containing species are processed to estimate total annual sulfur and nitrogen deposition values at each Class I and sensitive Class II area. The maximum annual sulfur and nitrogen deposition values from any grid cell that intersects the area of interest are used to represent deposition for that area, in addition to the average annual deposition values of all grid cells that intersect a Class I area and identified grid cells for a sensitive Class II receptor area. Maximum and average predicted sulfur and nitrogen deposition impacts are estimated separately for each area and together across all areas. Nitrogen deposition impacts are calculated by taking the sum of the nitrogen contained in the fluxes of all nitrogen species modeled by the air quality model. If a photochemical grid model is used this includes reactive gaseous nitrate species, organic nitrates, particulate nitrate formed from primary emissions plus secondarily formed particulate nitrate, gaseous nitric acid, gaseous ammonia, and particulate ammonium. Sulfur deposition calculations are sulfur dioxide and particulate sulfate ion from primary emissions plus secondarily formed sulfate.

2.7 National Environmental Policy Act – Acid Neutralizing Capacity

Total annual sulfur and nitrogen deposition impacts from the project source is also used to assess the change in water chemistry associated with atmospheric deposition from project activities and cumulative sources for each of the sensitive lakes. This analysis assesses the change in the acid neutralizing capacity (ANC) for sensitive water bodies, or a threshold for a soil or lichen indicator. Estimates of potential changes in ANC follow the procedure developed by the USFS Rocky Mountain Region (USFS, 2000). Region 2 of the U.S. Forest Service identifies water bodies with background ANC values less than 25 uel/l as being extremely sensitive to additional deposition. However, impacts to sensitive biota can occur below 100 ueq/L. The predicted changes in ANC are compared to threshold specified by the USFS, which include a 10 percent change in ANC for lakes with background ANC values greater than 25 micro equivalents per liter [µeq/L], and no more than a 1 µeq/L change in ANC for lakes with background ANC values equal to or less than 25 µeq/L (U.S. Department of Agriculture, 1985).

3 MODEL SELECTION

This section describes the types of air quality impacts that need to be assessed and the tools that are best suited for this purpose. For a variety of regulatory programs secondary pollutant impacts such as O_3 and PM2.5 need to be assessed at various spatial scales (near-source and long-range transport). It is important that modeling systems used for these assessments be fit for this purpose and be evaluated for skill in replicating meteorology and atmospheric chemical and physical processes that result in secondary pollutants, visibility degradation, and deposition.

3.1 Secondary Pollutant Formation: O_3 and PM2.5

PM and O_3 are closely related to each other in that they share common sources of emissions and are formed in the atmosphere from chemical reactions with similar precursors (U.S. Environmental Protection Agency, 2005a). Air pollutants formed through chemical reactions in the atmosphere are referenced as secondary pollutants. For example, ground-level ozone (O_3) is predominantly a secondary pollutant formed through photochemical reactions driven by emissions of nitrogen oxides (NO_x) and volatile organic compounds (VOCs). Ozone formation is a complicated nonlinear process that typically requires favorable meteorological conditions in addition to VOC and NO_x emissions (Seinfeld and Pandis, 2012). Warm temperatures, clear skies (abundant levels of solar radiation), and stagnant air masses (low wind speeds) increase ozone formation potential (Seinfeld and Pandis, 2012).

In the case of particulate matter with aerodynamic diameter less than 2.5 µm ($PM_{2.5}$ or fine PM), $PM_{2.5}$ can be either primary (i.e. emitted directly from sources) or secondary in nature. The fraction of $PM_{2.5}$ which is primary versus secondary varies by location and season. In the United States, $PM_{2.5}$ is dominated by a variety of chemical species: ammonium sulfate, ammonium nitrate, organic carbon (OC) mass, elemental carbon (EC), and other soil compounds and oxidized metals. $PM_{2.5}$ elemental (black) carbon and soil dust are both directly emitted into the atmosphere from primary sources. Organic carbon particulate is directly emitted from primary sources but also has a secondary component formed by atmospheric reactions of VOC emissions. $PM_{2.5}$ sulfate, nitrate, and ammonium ions are predominantly the result of chemical reactions of the oxidized products of sulfur dioxide (SO_2) and NO_x emissions and direct ammonia (NH_3) emissions (Seinfeld and Pandis, 2012).

3.2 Visibility and Deposition

In most areas of the country, light scattering by PM2.5 is the most significant component of visibility impairment (U.S. Department of the Interior, 2010). The key components of PM2.5 contributing to visibility impairment include sulfates, nitrates, organic carbon, elemental carbon, and crustal material (U.S. Department of the Interior, 2010). Stream acidification is accompanied by decreasing pH levels, increasing aluminum concentrations, and decreasing acid-neutralizing capacity (ANC). As ANC decreases, macroinvertebrate communities begin to decline, followed by fish species richness reductions, and eventually lethal and sub-lethal effects on brook trout populations and marked declines in aquatic insect families. At the same time, as sulfuric acid is deposited from the atmosphere onto the landscape, molecules separate into positively charged hydrogen ions and a negatively charged sulfate molecule. In order to maintain an ionic balance, an equivalent amount of positively charged base cations adhere to the negatively charged sulfates and move into the soil water solution, acidifying the remaining soil and

fundamentally altering soil processes. The reduced availability of these base cations in the soils (specifically, calcium, magnesium and potassium) hinders the capacity for sensitive soils to recover from acidic deposition and compromises the health and continued growth of the plants dependent on these nutrients. Additionally, when soils become sufficiently acidic, aluminum may become mobile, eventually entering plant roots more easily than other bases and displacing other nutrients during uptake, resulting in a nutrient deficiency. This deficiency is compounded by the toxic effect of aluminum on fine roots, further reducing the potential uptake of nutrients and water by plants. More information about acidification effects associated with deposition are available elsewhere (U.S. Department of the Interior, 2010).

3.3 Air Quality Models for Secondary Pollutants

Chemical transformations can play an important role in defining the concentrations and properties of certain air pollutants. Models that take into account chemical reactions and physical processes of various pollutants are needed for determining the current state of air quality, as well as predicting and projecting the future evolution of these issues (U.S. Environmental Protection Agency, 2005a). The chemical and physical processes discussed above are interrelated in a complex system. It is often not possible to predict the response of a certain pollutant to emissions reductions without the aid of models. Models can simultaneously account for these various chemical reactions and physical processes or the chemical coupling of multiple pollutants. A regulatory need exists to model secondary pollutants such as O_3 and PM and appropriately estimating secondary PM necessitates realistic estimates of O_3 and O_3 precursors.

Chemical transport models treat atmospheric chemical and physical processes such as deposition and motion. There are two types of chemical transport models which are differentiated based on a fixed frame of reference (Eulerian grid based) or a frame of reference that moves with parcels of air between the source and receptor point (Lagrangian) (McMurry et al., 2004). Photochemical grid models are three-dimensional grid-based models that treat chemical and physical processes in each grid cell and use Eulerian diffusion and transport processes move chemical species to other grid cells (McMurry et al., 2004). These types of models are appropriate for assessment of near-field and regional scale impacts from specific sources (Baker and Foley, 2011; Baker and Kelly, 2014; Bergin et al., 2008; Zhou et al., 2012) or all sources (Chen et al., 2014; Russell, 2008; Tesche et al., 2006). Photochemical transport models have been used extensively to support State Implementation Plans and to explore relationships between inputs and air quality impacts in the United States and beyond (Cai et al., 2011; Civerolo et al., 2010; Hogrefe et al., 2011).

3.3.1 Lagrangian models

Quantifying secondary pollutant formation requires simulating chemical reactions and thermodynamic partitioning in a realistic chemical and physical environment. Some Lagrangian models treat in-plume gas and particulate chemistry. These models require as input background fields of time and space varying oxidant concentrations, and in the case of PM2.5 also neutralizing agents such as ammonia, because important secondary impacts happen when plume edges start to interact with the surrounding chemical environment (Baker and Kelly, 2014; ENVIRON, 2012c). These oxidant and neutralizing agents are not routinely measured, but can be generated with a three dimensional photochemical transport model. Photochemical models simulate a more realistic chemical and physical environment for plume

growth and chemical transformation (Baker and Kelly, 2014; Zhou et al., 2012), but simulations may sometimes be more resource intensive than Lagrangian or dispersion models.

3.3.2 Photochemical grid models

Publically available and documented Eulerian photochemical grid models such as the Comprehensive Air Quality Model with Extensions (CAMx) (ENVIRON, 2014) and the Community Multiscale Air Quality (CMAQ) (Byun and Schere, 2006) model treat emissions, chemical transformation, transport, and deposition using time and space variant meteorology. These modeling systems include primarily emitted species and secondarily formed pollutants such as ozone and PM2.5 (Chen et al., 2014; Civerolo et al., 2010; Russell, 2008; Tesche et al., 2006). Even though single source emissions are injected into a grid volume, photochemical transport models have been shown to adequately capture single source impacts when compared with downwind in-plume measurements (Baker and Kelly, 2014; Zhou et al., 2012). Where set up appropriately for the purposes of assessing the contribution of single sources to primary and secondarily formed pollutants, photochemical grid models could be used with a variety of approaches to estimate these impacts. These approaches generally fall into the category of source sensitivity (how air quality changes due to changes in emissions) and source apportionment (how emissions contribute to air quality levels under modeled atmospheric conditions).

The simplest source sensitivity approach (brute-force change to emissions) would be to simulate 2 sets of conditions, one with all emissions and one with the source of interest removed from the simulation (Cohan and Napelenok, 2011). The difference between these simulations provides an estimate of the air quality change related to the change in emissions from the project source. Another source sensitivity approach to identify the impacts of single sources on changes in model predicted air quality is the decoupled direct method (DDM), which tracks the sensitivity of an emissions source through all chemical and physical processes in the modeling system (Dunker et al., 2002). Sensitivity coefficients relating source emissions to air quality are estimated during the model simulation and output at the resolution of the host model.

Some photochemical models have been instrumented with source apportionment, which tracks emissions from specific sources through chemical transformation, transport, and deposition processes to estimate a contribution to predicted air quality at downwind receptors (Kwok et al., 2015; Kwok et al., 2013). Source apportionment has been used to differentiate the contribution from single sources on model predicted ozone and PM2.5 (Baker and Foley, 2011; Baker and Kelly, 2014). DDM has also been used to estimate O_3 and PM2.5 impacts from specific sources (Baker and Kelly, 2014; Bergin et al., 2008; Kelly et al., 2015) as well as the simpler brute-force sensitivity approach (Baker and Kelly, 2014; Bergin et al., 2008; Kelly et al., 2015; Zhou et al., 2012). Limited comparison of single source impacts between models (Baker et al., 2013) and approaches to identify single source impacts (Baker and Kelly, 2014; Baker et al., 2013) show generally similar downwind spatial gradients and impacts.

3.4 Recommendations

Photochemical transport models are suitable for estimating visibility and deposition since important physical and chemical processes related to the formation and transport of PM are realistically treated. Source sensitivity and apportionment techniques implemented in photochemical grid models have evolved sufficiently and provide the opportunity for estimating potential visibility and deposition impacts from one or a small group of emission sources. Photochemical grid models using meteorology

output from prognostic meteorological models have demonstrated skill in estimating source-receptor relationships in the near-field (Baker and Kelly, 2014; ENVIRON, 2012c) and over long distances (ENVIRON, 2012b). In order to provide the user community flexibility in estimating single source secondary pollutant impacts and given the emphasis on the use of photochemical transport models for these purposes, Appendix W should no longer contain language that requires the use of a Lagrangian puff model (CALPUFF). A candidate model for use in estimating single source impacts on secondarily formed pollutants such as ozone and PM2.5 for the purposes of PSD and NSR programs should meet the general criteria for an "alternative model" outlined in 40 CFR 51.112 and 40 CFR part 51 (U.S. Environmental Protection Agency, 2005a). The acceptability of a particular model and approach for that model application is an EPA Regional Office responsibility that could include consultation with EPA Headquarters if appropriate. The use of models incorporating complex chemical mechanisms should be considered on a case-by-case basis with proper demonstration of applicability (U.S. Environmental Protection Agency, 2005a). It is important that the application of the wide range of modeling systems be appropriately applied for the purposes of assessing the impacts of sources on secondarily formed pollutants, such as ozone and $PM_{2.5}$. Use of photochemical grid models for AQRV analysis requirements, while not subject to specific EPA model approval requirements outlined in 40 CFR 51.166(l)(2) and 40 CFR 52.21(l)(2), should be justified for each application and concurrence sought with the affected FLM(s).

4 MODEL EVALUATION

There are multiple components to model evaluation for the purposes of assessing long range transport of secondary pollutants for AQRVs. First, an alternative modeling system as defined in Appendix W must meet certain criteria for this purpose (Appendix W Section 3.2.2.e). One type of evaluation for this type of modeling system for this purpose is to show that the modeling system is theoretically fit for purpose. A second evaluation component involves comparison to ambient measurements to assess whether the modeling system and generated inputs are appropriate for a specific project application.

Visibility and deposition are estimated at receptors placed inside Class I areas. This means it is important that a long range transport modeling system be able to capture these types of source-receptor relationships. In addition, since visibility is largely PM2.5 and deposition a combination of primary emitted and secondarily formed pollutants, it is important that a modeling system be able to capture single source primary and secondary impacts. Both of these components are important for generating confidence that a modeling system is theoretically fit for this purpose. Comparing model estimates against regional tracer experiments is one way to generate confidence that a modeling system can replicate long-range transport between a source and downwind receptors. Near-source in-plume measurements are useful to develop confidence that a modeling system captures secondarily formed pollutants from specific sources. These types of assessments are typically only done occasionally when a modeling system has notably changed from previous testing or has never been evaluated for this purpose. This type of assessment is discussed in more detail in section 4.1.

A second type of evaluation fulfills the need to determine whether inputs to the modeling system for a specific scenario are adequate for the specific conditions of the project impact assessment (Appendix W Section 3.2.2.e). This type of evaluation usually consists of comparing model predictions with observation data that coincides with the episode being modeling for a permit review assessment. One of the most important questions in an evaluation concerns whether the prognostic or diagnostic meteorological fields are adequate for their intended use in supporting the project model application

demonstration. Sections 4.2 and 4.3 cover project specific evaluation approaches that develop confidence that a particular model application is appropriate for the project source and key downwind receptors. It is important to emphasize that a broad evaluation of a model platform's skill in estimating meteorology or chemical measurements may not sufficiently illustrate the appropriateness of that platform for specific projects that will be focused on a narrow subset of the larger set of model inputs and outputs. Therefore, broad model platform evaluations should be supplemented with focused evaluation and discussion of the appropriateness of model inputs for specific project assessments.

4.1 Long Range Transport Models – Fit for Purpose Evaluations

The typical regulatory application of an LRT modeling system is for Prevention of Significant Deterioration of Air Quality (PSD) Class I air quality related values (AQRVs) (visibility, deposition, etc.). When employed for these purposes, it is customary to only model discrete receptors defined within the boundaries of national parks and wilderness areas (federal mandatory Class I areas with specially protected air quality related values) and compare modeled concentrations against short-term averaging periods with few exceedance periods. Given the need to capture impacts at specific locations and times, some emphasis is needed on the evaluation of the spatial and temporal metrics. This implies a fundamentally different evaluation philosophy than typically used for dispersion models such as AERMOD that are applied within 50 kilometers, which is noted in the Guideline on Air Quality Models (EPA, 2005) with the statement "the models are reasonably reliable in estimating the magnitude of the highest concentrations occurring sometime, somewhere within an area." Based on this principle, the evaluation of near-source primary pollutant dispersion models focus on a model's ability to replicate the highest end of the concentration distribution, regardless of temporal or spatial pairing. Since model skill in replicating transport in time and space is important for ARQV analysis, model evaluation should place a similar level of emphasis upon a model's ability to simulate spatial and temporal pairing.

It is important that modeling tools used for single source long-range transport impacts assessments demonstrate skill in adequately replicating source-receptor relationships that are not in close proximity. For source-receptor distances greater than 50 km, regional scale models may be applied for the assessment of visibility impacts due to one or a small group of sources. Skill in estimating source-receptor relationships on this scale can be illustrated by evaluating modeling systems against regional scale inert tracer release experiments. These field study releases of inert tracers with downwind receptors typically arranged in arcs or distributed over a given area are designed for assessing model skill in long-range transport (Hegarty et al., 2013). The regional tracer release experiments with designs most relevant for evaluating long range transport modeling systems include the 1980 Great Plains Mesoscale Tracer Field Experiment, the 1983 Cross-Appalachian Tracer Experiment (CAPTEX), the 1987 Across North American Tracer Experiment (ANATEX), and 1994 European Tracer Experiment (ETEX) (ENVIRON, 2012b; Hegarty et al., 2013). Photochemical grid models have been shown to demonstrate similar skill to Lagrangian models for pollutant transport when compared to measurements made from multiple mesoscale field experiments (ENVIRON, 2012b).

Near-source in-plume aircraft based measurement field studies are useful for evaluating model estimates of (near-source) downwind transport and chemical impacts from single stationary point sources (ENVIRON, 2012c). Photochemical grid model source apportionment and source sensitivity simulation of a single source downwind impacts compare well against field study primary and secondary ambient measurements made in Tennessee and Texas (Baker and Kelly, 2014; ENVIRON, 2012c). This work indicates photochemical grid models and source apportionment and source sensitivity approaches

provide meaningful estimates of single source impacts. However, additional evaluations are needed for longer time periods and more diverse environments to generate broader confidence in these approaches for this purpose.

4.2 Long Range Transport Models – Meteorology Evaluation

It is important to determine whether and to what extent confidence may be placed in a prognostic meteorological model's output fields (e.g., wind, temperature, mixing ratio, diffusivity, clouds/precipitation, and radiation) that will be used as input to models. Currently there is no bright line for meteorological model performance and acceptability. There is valid concern that establishment of such criteria, unless accompanied with a careful evaluation process might lead to the misuse of such goals as is occasionally the case with the accuracy, bias, and error statistics recommended for judging model performance. In spite of this concern, there remains nonetheless the need for some benchmarks against which to compare new prognostic and diagnostic model simulations. A significant amount of information (e.g. model performance metrics) can be developed by following typical evaluation procedures that will enable quantitative comparison of the meteorological modeling to other contemporary applications and to judge its suitability for use in modeling studies.

Development of the requisite meteorological databases necessary for use of photochemical transport models should conform to recommendations outlined in Guidance on the Use of Models and Other Analyses for Demonstrating Attainment of Air Quality Goals for Ozone, PM2.5, and Regional Haze (EPA-454/B-07-002) (U.S. Environmental Protection Agency, 2007). Demonstration of the adequacy of prognostic or diagnostic meteorological fields can be established through appropriate diagnostic and statistical performance evaluations consistent with recommendations provided in the appropriate model guidance (U.S. Environmental Protection Agency, 2007).

4.3 Long Range Transport Models – Chemistry Evaluation

An operational evaluation is used to assess how accurately the model predicts observed concentrations. Therefore, an operational evaluation can provide a benchmark for model performance and identify model limitations and uncertainties that require diagnostic evaluation for further model development/improvement. An operational evaluation for PM2.5 is similar to that for ozone. Some important differences are that PM2.5 consists of many components and is typically measured with a 24-hour averaging time. The individual components of PM2.5 should be evaluated individually. In fact, it is more important to evaluate the components of PM2.5 than to evaluate total PM2.5 itself. Apparent "good performance" for total PM2.5 does not indicate whether modeled PM2.5 is predicted for "the right reasons" (the proper mix of components). If performance of the major components is good, then performance for total PM2.5 should also be good. Databases that contain ambient O_3, PM2.5, and key precursors are noted in section 4.4. Section 4.4 is not intended to provide an exhaustive review of all ambient databases but provide an initial set of data that could be used for this purpose.

Regardless of the modeling system (e.g. photochemical transport or Lagrangian puff model) used to estimate secondary impacts of ozone and/or PM2.5, model estimates should be compared to observation data to generate confidence that the modeling system is representative of the local and regional air quality. For ozone related projects, model estimates of ozone should be compared with observations in both time and space. For PM2.5, model estimates of speciated PM2.5 components (such

as sulfate ion, nitrate ion, etc) should be matched in time and space with observation data in the model domain. Model performance metrics comparing observations and predictions are often used to summarize model performance. These metrics include mean bias, mean error, fractional bias, fractional error, and correlation coefficient (Simon et al., 2012). There are no specific levels of any model performance metric that indicate "acceptable" model performance. Model performance metrics should be compared with similar contemporary applications to assess how well the model performs (Simon et al., 2012).

Accepted performance standards for speciated and total PM2.5 and ozone for photochemical models used in attainment demonstrations may not be applicable for single source assessments. Since the emissions and release parameters for the project source are well known, a direct connection between general photochemical model performance and the ability of the modeling system to characterize the impacts of the project source would be difficult to make. It is important that any potential approaches for photochemical model performance for the purposes of single source assessments for PSD and NSR use an approach that would be universally applicable to any single source modeling system, which includes the Lagrangian models described above.

4.4 Model performance evaluation data sources

Provided below is an overview of some of the various ambient air monitoring networks currently available that provide relevant data for model evaluation purposes. Network methods and procedures are subject to change annually due systematic review and/or updates to the current monitoring network/program. Please note, there are other available monitoring networks which are not mentioned here and more details on the networks and measurements should be obtained from other sources.

AQS: The Air Quality System (AQS) is not an air quality monitoring network. However it is a repository of ambient air pollution data and related meteorological data collected by EPA, state, local and tribal air pollution control agencies from tens of thousands of monitors. AQS contains all the routine hourly gaseous pollutant data collected from State and Local Air Monitoring Stations (SLAMS) and National Air Monitoring Stations (NAMS) sites. SLAMS is a dynamic network of monitors for state and local directed monitoring objectives (e.g., control strategy development). A subset of the SLAMS network, the NAMS has an emphasis on urban and multi-source areas (i.e, areas of maximum concentrations and high population density). The AQS database includes criteria pollutant data (SO2, NO2, O3, and PM2.5) and speciation data of particulate matter (SO4, NO3, NH4, EC, and OC), and meteorological data. The data are measured and reported on an hourly or daily average basis. An overview of the AQS can be found at http://www.epa.gov/ttn/airs/airsaqs/index.htm.

IMPROVE: The Interagency Monitoring of PROtected Visual Environments (IMPROVE) network began in 1985 as a cooperative visibility monitoring effort between EPA, federal land management agencies, and state air agencies (IMPROVE, 2000). Data are collected at Class I areas across the United States mostly at National Parks, National Wilderness Areas, and other protected pristine areas. Currently, there are approximately 160 IMPROVE rural/remote sites that have complete annual PM2.5 mass and/or PM2.5 species data. The website to obtain IMPROVE documentation and/or data is http://vista.cira.colostate.edu/improve/.

STN: The Speciation Trends Network (STN) began operation in 1999 to provide nationally consistent speciated PM2.5 data for the assessment of trends at representative sites in urban areas in the U.S. The

STN was established by regulation and is a companion network to the mass-based Federal Reference Method (FRM) network implemented in support of the PM2.5 NAAQS. As part of a routine monitoring program, the STN quantifies mass concentrations and PM2.5 constituents, including numerous trace elements, ions (sulfate, nitrate, sodium, potassium, ammonium), elemental carbon, and organic carbon. In addition, there are approximately 181 supplemental speciation sites which are part of the STN network and are SLAMS sites. The STN data at trends sites are collected 1 in every 3 days, whereas supplemental sites collect data either 1 in every 3 days or 1 in every 6 days. Comprehensive information on the STN and related speciation monitoring can be found at http://www.epa.gov/ttn/amtic/specgen.html and http://www.epa.gov/aqspubl1/select.html.

CASTNet: Established in 1987, the Clean Air Status and Trends Network (CASTNet) is a dry deposition monitoring network where data are collected and reported as weekly average data (U.S. EPA, 2002b). Relevant CASTNet data includes weekly samples of inorganic PM2.5 species and ground-level ozone. More information can be obtained through the CASTNet website at http://www.epa.gov/castnet/.

SEARCH: The South Eastern Aerosol Research and CHaracterization (SEARCH) monitoring network was established in 1998 and is a coordinated effort between the public and private sector to characterize the chemical and physical composition as well as the geographical distribution and long-term trends of PM2.5 in the Southeastern U.S. SEARCH data are collected and reported on an hourly/daily basis. Background information regarding standard measurement techniques/protocols and data retrieval can be found at http://www.atmospheric-research.com/studies/SEARCH/index.html.

NADP: Initiated in the late 1970s, the National Acid Deposition Program (NADP) monitoring network began as a cooperative program between federal and state agencies, universities, electric utilities, and other industries to determine geographical patterns and trends in precipitation chemistry in the U.S. NADP collects and reports wet deposition measurements as weekly average data (NADP, 2002). The network is now known as NADP/NTN (National Trends Network) and measures sulfate, nitrate, hydrogen ion (measure of acidity), ammonia, chloride, and base cations (calcium, magnesium, potassium). Detailed information regarding the NADP/NTN monitoring network can be found at http://nadp.sws.uiuc.edu/.

5 ACKNOWLEDGEMENTS

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6 REFERENCES

Baker, K.R., Foley, K.M., 2011. A nonlinear regression model estimating single source concentrations of primary and secondarily formed PM2.5. Atmospheric Environment 45, 3758-3767.

Baker, K.R., Kelly, J.T., 2014. Single source impacts estimated with photochemical model source sensitivity and apportionment approaches. Atmospheric Environment 96, 266-274.

Baker, K.R., Kelly, J.T., Fox, T., 2013. Estimating second pollutant impacts from single sources (control #27). http://aqmodels.awma.org/conference-proceedings/.

Bergin, M.S., Russell, A.G., Odman, M.T., Cohan, D.S., Chameldes, W.L., 2008. Single-Source Impact Analysis Using Three-Dimensional Air Quality Models. Journal of the Air & Waste Management Association 58, 1351-1359.

Byun, D., Schere, K.L., 2006. Review of the governing equations, computational algorithms, and other components of the models-3 Community Multiscale Air Quality (CMAQ) modeling system. Applied Mechanics Reviews 59, 51-77.

Cai, C., Kelly, J.T., Avise, J.C., Kaduwela, A.P., Stockwell, W.R., 2011. Photochemical modeling in California with two chemical mechanisms: model intercomparison and response to emission reductions. Journal of the Air & Waste Management Association 61, 559-572.

Chen, J., Lu, J., Avise, J.C., DaMassa, J.A., Kleeman, M.J., Kaduwela, A.P., 2014. Seasonal modeling of PM 2.5 in California's San Joaquin Valley. Atmospheric Environment 92, 182-190.

Civerolo, K., Hogrefe, C., Zalewsky, E., Hao, W., Sistla, G., Lynn, B., Rosenzweig, C., Kinney, P.L., 2010. Evaluation of an 18-year CMAQ simulation: Seasonal variations and long-term temporal changes in sulfate and nitrate. Atmospheric environment 44, 3745-3752.

Cohan, D.S., Napelenok, S.L., 2011. Air quality response modeling for decision support. Atmosphere 2, 407-425.

Dunker, A.M., Yarwood, G., Ortmann, J.P., Wilson, G.M., 2002. The decoupled direct method for sensitivity analysis in a three-dimensional air quality model - Implementation, accuracy, and efficiency. Environmental Science & Technology 36, 2965-2976.

ENVIRON, 2012a. Comparison of Single-Source Air Quality Assessment Techniques for Ozone, PM2.5, other Criteria Pollutants and AQRVs, EPA Contract No: EP-D-07-102. September 2012. 06-20443M6.

ENVIRON, 2012b. Documentation of the Evaluation of CALPUFF and Other Long Range Transport Models using Tracer Field Experiment Data, EPA Contract No: EP-D-07-102. February 2012. 06-20443M4.

ENVIRON, 2012c. Evaluation of chemical dispersion models using atmospheric plume measurements from field experiments, EPA Contract No: EP-D-07-102. September 2012. 06-20443M6.

ENVIRON, 2014. User's Guide Comprehensive Air Quality Model with Extensions version 6, www.camx.com. ENVIRON International Corporation, Novato.

Hegarty, J., Draxler, R.R., Stein, A.F., Brioude, J., Mountain, M., Eluszkiewicz, J., Nehrkorn, T., Ngan, F., Andrews, A., 2013. Evaluation of Lagrangian particle dispersion models with measurements from controlled tracer releases. Journal of Applied Meteorology and Climatology 52, 2623-2637.

Hogrefe, C., Hao, W., Zalewsky, E., Ku, J.-Y., Lynn, B., Rosenzweig, C., Schultz, M., Rast, S., Newchurch, M., Wang, L., 2011. An analysis of long-term regional-scale ozone simulations over the Northeastern United States: variability and trends. Atmospheric Chemistry and Physics 11, 567-582.

Karamchandani, P., Chen, S.-Y., Balmori., R., 2009. Evaluatoin of original and improved versions of CALPUFF using the 1995 SWWYTAF data base. Prepared for American Petroleum Institute, 1220 L Street NW, Washington, DC, 20005. Document CP281-09-1.

Karamchandani, P., Chen, S.-Y., Seigneur, C., 2008. CALPUFF Chemistry Upgade. Prepared for American Petroleum Institute, 1220 L Street NW, Washington, DC 20005. Document CP277-07-01.

Kelly, J.T., Baker, K.R., Napelenok, S.L., Roselle, S.J., 2015. Examining single-source secondary impacts estimated from brute-force, decoupled direct method, and advanced plume treatment approaches. Atmospheric Environment 111, 10-19.

Kwok, R., Baker, K., Napelenok, S., Tonnesen, G., 2015. Photochemical grid model implementation of VOC, NO x, and O 3 source apportionment. Geoscientific Model Development 8, 99-114.

Kwok, R., Napelenok, S., Baker, K., 2013. Implementation and evaluation of PM2.5 source contribution analysis in a photochemical model. Atmospheric Environment 80, 398-407.

McMurry, P.H., Shepherd, M.F., Vickery, J.S., 2004. Particulate matter science for policy makers: A NARSTO assessment. Cambridge University Press.

Russell, A.G., 2008. EPA Supersites program-related emissions-based particulate matter modeling: initial applications and advances. Journal of the Air & Waste Management Association 58, 289-302.

Seinfeld, J.H., Pandis, S.N., 2012. Atmospheric chemistry and physics: from air pollution to climate change. John Wiley & Sons.

Silva, S.V., McCoy, C., 2012. Memorandum to Kelly Bott, Wyoming Air Quality Division. February 10, 2012.

Simon, H., Baker, K.R., Phillips, S., 2012. Compilation and interpretation of photochemical model performance statistics published between 2006 and 2012. Atmospheric Environment 61, 124-139.

Tesche, T., Morris, R., Tonnesen, G., McNally, D., Boylan, J., Brewer, P., 2006. CMAQ/CAMx annual 2002 performance evaluation over the eastern US. Atmospheric Environment 40, 4906-4919.

U.S. Department of Agriculture, 1985. The Limits of Acceptable Change (LAC) System for Wilderness Planning. General Technical Report INT-176. http://www.fs.fed.us/cdt/carrying_capacity/lac_system_for_wilderness_planning_1985_GTR_INT_176.pdf.

U.S. Department of Agriculture, U.S. Department of the Interior, Agency, U.S.E.P., 2011. Regarding air quality analyses and mitigation for Federal oil and gas decisions through the National Envionmental Policy Act process. http://www.epa.gov/compliance/resources/policies/nepa/air-quality-analyses-mou-2011.pdf.

U.S. Department of the Interior, 2010. Federal Land Managers' Air Quality Related Values Work Group (FLAG) Phase I Report - Revised 2010. http://www.nature.nps.gov/air/pubs/pdf/flag/FLAG_2010.pdf, Natural Resource Report NPS/NPRC/NRR-2010/232.

U.S. Department of the Interior, 2011. Technical Guidance on Assessing Impacts to Air Quality in NEPA and Planning Documents. http://www.nature.nps.gov/air/Pubs/pdf/AQGuidance_2011-01-14.pdf, Natural Resource Report NPS/NRPC/ARD/NRR-2011/289.

U.S. Environmental Protection Agency, 1998. Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts. EPA-452/R-498-019.

U.S. Environmental Protection Agency, 2003. Guidance for Estimating Natural Visibility Conditions Under the Regional Haze Program. http://www.epa.gov/ttn/caaa/t1/memoranda/rh_envcurhr_gd.pdf, EPA-454/B-03-005.

U.S. Environmental Protection Agency, 2005a. 40 CFR, Part 51, Appendix W. Revision to the Guideline on Air Quality Models, 68 FR 68235-68236, November 9, 2005.

U.S. Environmental Protection Agency, 2005b. 40 CFR, Part 51, Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations, Vol. 70, No. 128, FR 39104-39172, July 6, 2005.

U.S. Environmental Protection Agency, 2007. Guidance on the Use of Models and Other Analyses for Demonstrating Attainment of Air Quality Goals for Ozone, PM2.5, and Regional Haze, EPA-454/B-07-002.

U.S. Environmental Protection Agency, 2012a. 40 CFR, Parts 51 and 52, Regional Haze: Revisions to Provisions Governing Alternatives to Source-Specific Best Available Retrofit Technology (BART) Determinations, Limited SIP Disapprovals, and Federal Implementation Plans , EPA-HQ-OAR-2011-0729; FRL – 9672-9, May 30, 2012.

U.S. Environmental Protection Agency, 2012b. http://www.epa.gov/scram001/10thmodconf/review_material/Sierra_Club_Petition_OAR-11-002-1093.pdf.

U.S. Environmental Protection Agency, 2014a. 40 CFR, Part 52, Approval and Promulgation of Implementation Plans; Texas and Oklahoma; Regional Haze State Implementation Plans; Interstate Transport State Implementation Plan To Address Pollution Affecting Visibility and Regional Haze; Federal Implementation Plan for Regional Haze and Interstate Transport of Pollution Affecting Visibility; Proposed Rule, Vol. 79, No. 241 FR 74818-74892, December 16, 2014.

U.S. Environmental Protection Agency, 2014b. Modeling Guidance for Demonstrating Attainment of Air Quality Goals for Ozone, PM2.5, and Regional Haze. http://www.epa.gov/ttn/scram/guidance/guide/Draft_O3-PM-RH_Modeling_Guidance-2014.pdf.

U.S. Environmental Protection Agency, 2015a. Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 3 Summary Report: Near-Field Single Source Secondary Impacts. EPA-454/P-15-002.

U.S. Environmental Protection Agency, 2015b. Technical Support Document (TSD) for AERMOD-Based Assessments of Long-Range Transport Impacts for Primary Pollutants, Document Number: EPA-454/B-15-003.

Zhou, W., Cohan, D.S., Pinder, R.W., Neuman, J.A., Holloway, J.S., Peischl, J., Ryerson, T.B., Nowak, J.B., Flocke, F., Zheng, W.G., 2012. Observation and modeling of the evolution of Texas power plant plumes. Atmospheric Chemistry and Physics 12, 455-468.

United States Environmental Protection Agency	Office of Air Quality Planning and Standards Air Quality Analysis Division Research Triangle Park, NC	Publication No. EPA-454/P-15-003 July 2015

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 7/31/2018 4:32:08 PM
To: Sabine Lange [Sabine.Lange@tceq.texas.gov]
Subject: RE: New paper

Sabine,

Thanks so much – This is very helpful. I will be at the Superconference for the bulk of the day on Thursday, and look forward to seeing you there.

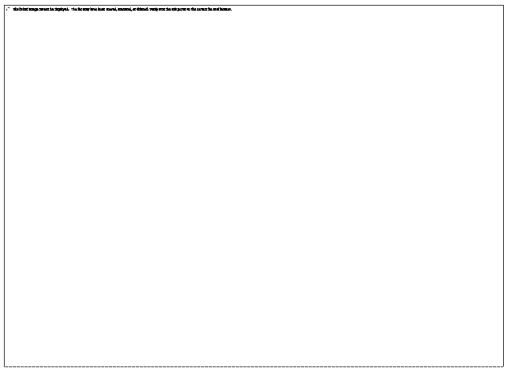
Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

From: Sabine Lange [mailto:Sabine.Lange@tceq.texas.gov]
Sent: Tuesday, July 31, 2018 11:07 AM
To: Woods, Clint <woods.clint@epa.gov>
Subject: New paper

Clint,

I just wanted to send you the link to a new paper I just published in the journal *Science of the Total Environment* that you might be interested in. It addresses comparisons between the ozone standard and ozone concentrations measured in epidemiology studies.

https://www.sciencedirect.com/science/article/pii/S0048969718324483?_rdoc=1&_fmt=high&_origin=gateway&_docanchor=&md5=b8429449ccfc9c30159a5f9aeaa92ffb



Comparing apples to oranges: Interpreting ozone concentrations from observational studies in the context of the United States ozone regulatory standard

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In 2015, the United States Environmental Protection Agency (US EPA) set the ozone National Ambient Air Quality Standards (NAAQS) at 0.070 parts per mi...

I understand that you will be attending the Texas Environmental Superconference this week - I will be there as well, and I hope to see you.

Best,

Sabine

Sabine Lange, PhD, DABT
Section Manager, Toxicology Division
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Sent: 7/31/2018 3:59:21 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: FW: New paper

Two useful articles from the TCEQ folks (along with an economist from North Carolina):
http://www.mdpi.com/1660-4601/15/8/1586

Int. J. Environ. Res. Public Health **2018**, *15*(8), 1586; https://doi.org/10.3390/ijerph15081586

What Are the Net Benefits of Reducing the Ozone Standard to 65 ppb? An Alternative Analysis

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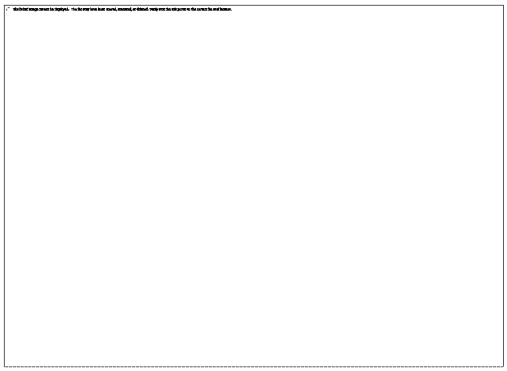
Begin forwarded message:

From: Sabine Lange <Sabine.Lange@tceq.texas.gov>
Date: July 31, 2018 at 11:07:12 AM EDT
To: "Woods.clint@epa.gov" <Woods.clint@epa.gov>
Subject: New paper

Clint,

I just wanted to send you the link to a new paper I just published in the journal *Science of the Total Environment* that you might be interested in. It addresses comparisons between the ozone standard and ozone concentrations measured in epidemiology studies.

https://www.sciencedirect.com/science/article/pii/S0048969718324483?_rdoc=1&_fmt=high&_origin=gateway&_docanchor=&md5=b8429449ccfc9c30159a5f9aeaa92ffb



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Best,

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Sent: 10/7/2018 5:03:23 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Casac list
Attachments: document_pm_01.pdf; ATT00001.txt

https://www.eenews.net/assets/2018/06/13/document_pm_01.pdf

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 7/31/2018 3:11:03 PM
To: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
Subject: Fwd: New paper

FYI

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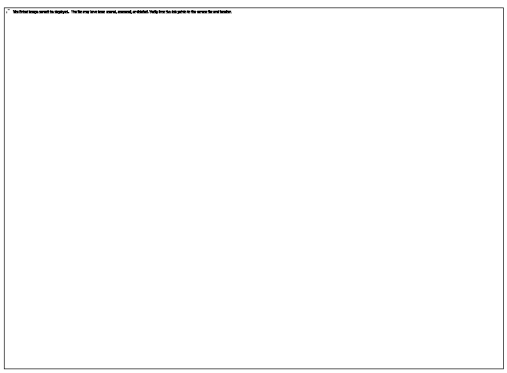
Clint,

I just wanted to send you the link to a new paper I just published in the journal *Science of the Total Environment* that you might be interested in. It addresses comparisons between the ozone standard and ozone concentrations measured in epidemiology studies.

https://www.sciencedirect.com/science/article/pii/S0048969718324483?_rdoc=1&_fmt=high&_origin=gateway&_docanchor=&md5=b8429449ccfc9c30159a5f9aeaa92ffb



Comparing apples to oranges: Interpreting ozone concentrations from observational studies in the context of the United States ozone regulatory standard

www.sciencedirect.com

In 2015, the United States Environmental Protection Agency (US EPA) set the ozone National Ambient Air Quality Standards (NAAQS) at 0.070 parts per mi...

I understand that you will be attending the Texas Environmental Superconference this week - I will be there as well, and I hope to see you.

Best,

Sabine

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