Subcommittee on Environment and Climate Change
Hearing on
"The Fiscal Year 2021 EPA Budget"
February 27, 2020

The Honorable Andrew Wheeler
Administrator
Environmental Protection Agency

The Honorable Frank Pallone, Jr. (D-NJ)

1. Are you planning to finalize the rule EPA wrote to rollback pollution limits for heavy-duty glider freight trucks?

   EPA RESPONSE: In the Spring 2020 Regulatory Agenda, the Revision of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits NPRM is listed under completed actions as "withdrawn." At this time, the Agency does not intend to take further action on this NPRM.

2. Are you planning to work on any regulations pertaining to glider trucks?

   EPA RESPONSE: As noted in the Spring 2020 Regulatory Agenda, the Agency does not currently have plans to work on any glider-related rulemakings.

3. How many glider trucks were sold last year?

   EPA RESPONSE: In 2019, 182 glider trucks were sold.

The Honorable John Sarbanes (D-MD)

1. Despite recent statements by EPA staff to the contrary, the Chesapeake Bay TMDL is, in fact, enforceable. The TMDL itself describes a detailed accountability framework based on authorities in the Clean Water Act and the agreement of the Chesapeake Bay Program Partnership, including EPA, to two-year milestones and interim goals. Therefore, can you clarify how EPA intends to enforce the TMDL and what EPA's threshold is for taking action?

   EPA RESPONSE: As has been done since the Chesapeake Bay Total Maximum Daily Load (TMDL) was issued, EPA will continue to use its existing authorities under the Clean Water Act (CWA) to ensure that all six Chesapeake Bay states and the District of Columbia are accountable for implementing their share of the Chesapeake Bay TMDL's nitrogen, phosphorus, and sediment reductions.

It is EPA's longstanding position that TMDLs themselves are not federally enforceable by the EPA. The question of whether the Chesapeake Bay TMDL itself is enforceable was answered by the previous administration in court filings defending the Chesapeake Bay TMDL. In 2016, the Obama administration told the U.S. Supreme Court that a TMDL is an informational tool that "does not impose any binding implementation requirements on the states," and that "the Bay TMDL does not directly regulate any sources or require any permits."[1] The Trump Administration agrees with these statements from the prior administration.

TMDLs are informational planning tools that are typically implemented through CWA regulatory and nonregulatory programs, including National Pollutant Discharge Elimination System (NPDES) permits and CWA section 319 nonpoint source management program grants, as well as other state and local authorities and actions.

Accountability is ensured by these CWA and other state and local implementing programs, together with the Chesapeake Bay Program partnership's extensive Accountability Framework.[2]

EPA remains steadfast in its commitment to helping our partners meet the goals of the Chesapeake Bay TMDL. We will continue to provide support, track progress, and take appropriate actions within our authorities to ensure the Chesapeake Bay and local waters are protected and restored.

2. As you're aware an additional $12 million was recently appropriated to the Chesapeake Bay Program. This is a critical time as the states begin implementation of their Phase III Watershed Implementation Plans (WIPs), and Congress specifically directed that the money be split between the National Fish and Wildlife Foundation grant programs and the states for implementation in the most effective areas.

    a. Has EPA decided how it will distribute the "most effective basins" money to the states?

    <u>EPA RESPONSE</u>: EPA is committed to working with Congress as well as with our federal and state partners to achieve our shared environmental goals for the Chesapeake Bay.

    The FY 2020 appropriation provided an increase of $12 million to the EPA Chesapeake Bay Program budget compared to the FY 2019 appropriation. EPA added $6 million of the increase to the Innovative Nutrients and Sediment Reduction (INSR) and Small Watershed Grant (SWG) programs managed by the National Fish and Wildlife Foundation.[3]

[1] https://www.justice.gov/sites/default/files/osg/briefs/2016/01/29/15-599_american_farm_bureau_opp.pdf.
[2] https://www.epa.gov/chesapeake-bay-tmdl/sector-specific-epa-oversight-chesapeake-bay-watershed.
[3] https://www.epa.gov/newsreleases/epa-announces-record-18-million-projects-chesapeake-bay-watershed.

EPA allocated the other $6 million of the increase to Chesapeake Bay states to improve water quality by reducing excess nitrogen from agricultural operations.[4] Each state in the Chesapeake Bay watershed submitted Phase III Watershed Implementation Plans (WIP), in which they committed to reduce nitrogen loads from the agriculture sector from 2019 to 2025. The funding allocations were calculated as a percentage of the total of each Bay jurisdictions' WIP agricultural commitments.

b. Does EPA intend to use any existing formulas that are already used to distribute grants under Section 117?

EPA RESPONSE: See above response to Question 2(a).

c. Will this money go toward the state WIPs rather than to the implementation of the Conowingo WIP?

EPA RESPONSE: See above response to Question 2(a).

The Honorable Diana DeGette (D-CO)

1. Why has the EPA not used the new information authorities it was provided under Section 4 of the reformed TSCA?

EPA RESPONSE: In March 2020, EPA issued its first test order under section 4 of the Toxic Substances Control Act (TSCA) to obtain occupational exposure monitoring and solubility data for Pigment Violet 29 (PV29), the first chemical for which EPA issued a draft risk evaluation. This first use of the order authority marks an important step forward for EPA's implementation of its Section 4 authority. In the order, the Agency demonstrated a clear need for the information and requested specific tests to provide EPA with needed information to complete our risk evaluation.

EPA also was guided in developing the test order by the input of the Scientific Advisory Committee on Chemicals (SACC) following their review of the PV29 draft risk evaluation. EPA is in the process of reviewing any potential data needs for the next 20 chemicals that are currently undergoing risk evaluation. EPA is actively assessing how it will use its varied TSCA data gathering authorities, including section 4 test orders, to ensure that we have needed information in hand to conduct risk evaluations, with a particular focus on the 20 high-priority substances currently undergoing risk evaluation.

[4] https://www.epa.gov/newsreleases/epa-provides-6-million-reduce-excess-ag-runoff-chesapeake-bay.

2. Is there a policy used to determine when the EPA should use such information authorities?

   EPA RESPONSE: During the prioritization and risk evaluation processes, the Agency determines if the reasonably available information, including from public comments, is sufficient, identifies data gaps, and determines whether additional information (e.g., hazard or exposure information) is warranted. The EPA's Office of Chemical Safety and Pollution Prevention is working with our Office of Research and Development to conduct comprehensive inventories of reasonably available information regarding exposure, environmental fate, and toxicity, for example, so that we can identify where data gaps exist. Following an assessment of data gaps, EPA will use its information collection authority under TSCA—including sections 4 and 8—to gather existing data or to generate new data on the 20 chemicals for which risk evaluations are underway.

3. If any policies exist that guide the EPA's use of the enhanced information authorities it was given under the reformed TSCA, please provide them.

   EPA RESPONSE: While EPA does not have a document detailing policies associated with the information collection authority under TSCA, our order to the PV29 companies identifies the factors used to determine a section 4 test order was needed (https://beta.regulations.gov/docket/EPA-HQ-OPPT-2020-0070/document). The development of future policy may be necessary depending of trends of data collection efforts.

4. EPA received public comments on the first 10 chemicals it is reviewing under the reformed TSCA that identified serious information gaps. Yet EPA stated publicly that it does not intend to use the information authorities provided to them for almost any of the first 10 chemicals. Please explain this decision.

   EPA RESPONSE: As noted above, in March 2020, EPA issued its first test order under section 4 of TSCA to obtain occupational exposure monitoring and solubility data for PV29, the first chemical for which EPA issued a draft risk evaluation. In initiating the first 10 chemicals for risk evaluation, EPA believed there was sufficient information to complete the chemical risk evaluation using a weight of scientific evidence approach. The subsequent March 2020 information order was in response to the peer review panel suggestion. EPA selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this risk evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. However, EPA will continue to improve on its method and data collection for the next round of chemicals to be assessed under TSCA.

   EPA follows a transparent process including review by the Science Advisory Committee on Chemicals (SACC) and the public on the draft risk evaluation. This provides

transparency and opportunity for the scientific community and the public to review and provide comment on the risk evaluation, including the information the Agency relied upon, for our risk evaluations of the initial ten chemicals undergoing risk evaluation

a. Has EPA documented the basis for its decision not to rely on these authorities with respect to the first 10 chemicals?

EPA RESPONSE: As noted above, in March 2020, EPA issued its first test order under section 4 of TSCA to obtain occupational exposure monitoring and solubility data for PV29, the first chemical for which EPA issued a draft risk evaluation. In initiating the first 10 chemicals for risk evaluation, EPA believed there was sufficient information to complete the chemical risk evaluation using a weight of scientific evidence approach. The subsequent March 2020 information order was in response to the peer review panel suggestion. EPA selected the first ten chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this risk evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. However, EPA will continue to improve on its method and data collection for the next round of chemicals to be assessed under TSCA.

EPA follows a transparent process including review by the SACC and the public on the draft risk evaluation. This provides transparency and opportunity for the scientific community and the public to review and provide comment on the risk evaluation, including the information the Agency relied upon, for our risk evaluations of the initial ten chemicals undergoing risk evaluation.

b. If so, please provide documents which are related to that decision.

EPA RESPONSE: While EPA does not have a document detailing policies associated with the information collection authority under TSCA, our order to the PV29 companies identifies the factors used to determine a section 4 test order was needed (https://beta.regulations.gov/docket/EPA-HQ-OPPT-2020-0070/document). Any subsequent test orders also will include the factors used to determine order issuance is appropriate. The development of a test order policy could be determined at a future date, depending on data collection needs and trends.

5. Has EPA considered using its information authorities when assessing a new chemical since passage of the Lautenberg Act?

EPA RESPONSE: Yes, EPA has exercised the information-gathering authorities provided in TSCA—both prior to and since the passage of the Frank R. Lautenberg

Chemical Safety for the 21st Century Act. EPA is required under TSCA section 5(a)(3) to review and make one of five determinations on a new chemical substance. Two of those determinations involve circumstances where there is "insufficient information" to perform a reasoned evaluation. In those cases, the statute mandates that EPA issue an order under TSCA section 5(e) with restrictions to protect against unreasonable risks and authorizes the Agency to require the submitter to develop additional information. EPA makes these determinations regularly and issues 5(e) orders as required, which include further testing requirements when appropriate.

a. If so, please provide any documentation related to those decisions.

EPA RESPONSE: A record of the Agency's determinations on new chemical substances, including copies of TSCA section 5(e) orders, is publicly available through our ChemView database (https://chemview.epa.gov/chemview).

b. If not, why EPA has not considered using its information authorities when assessing any of the approximately 2,500 new chemical submissions it has reviewed over this time period?

EPA RESPONSE: EPA has exercised the information-gathering authorities provided in TSCA—both prior to and since the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

c. Has EPA requested or required-and received- any vertebrate animal or non/vertebrate or non-animal toxicity information?

EPA RESPONSE: Yes.

6. Does EPA consider that the law, in any manner, constrains EPA's authority to request or require testing if the needed test is an animal test? If so, please indicate where such a constraint is stated in the law.

EPA RESPONSE: TSCA requires EPA to take into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information to meet the data need before requiring animal testing (see TSCA section 4(h)). EPA does not consider this a constraint; rather, it has been a regular part of the risk assessment process under TSCA to identify and review the available information in order to identify data gaps and to determine whether and what specific testing may be necessary to conduct a risk assessment prior to requiring testing.

In addition, TSCA requires EPA to develop a Strategic Plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures (TSCA section 4(h), Reduction of

Testing on Vertebrates). In addition, I have made reducing animal testing a priority. In September 2019, I signed the *Directive to Prioritize Efforts to Reduce Animal Testing*, which reiterated the EPA's commitment to move away from animal testing across the Agency (https://www.epa.gov/sites/production/files/2019-09/documents/image2019-09-09-231249.pdf). EPA will reduce its requests for, and its funding of, mammal studies by 30 percent by 2025 and any mammal study requested or funded after 2035 will require Administrator approval on a case-by-case basis.

7. Has EPA, requested or required the use of any tests, whether involving vertebrate animals or not, using its section 4 authorities since the passage of the Lautenberg act?

   EPA RESPONSE: In March 2020, EPA issued its first test order under section 4 of TSCA to obtain occupational exposure monitoring and solubility data for PV29. This order did not involve any vertebrate testing.

8. When and how will EPA make publicly available any:

   a. Voluntary exposure and toxicity information it receives for new and existing chemicals;

      EPA RESPONSE: In the existing chemicals program, TSCA section 26(j) and the implementing regulation at 40 CFR 702.51 require EPA to make available both a list of studies and the results of those studies that EPA considered in carrying out each risk evaluation. EPA provides this information in the docket for each chemical undergoing risk evaluation. In addition, EPA has set up a docket for each Work Plan chemical to allow for the submission of information and to make any submissions publicly available.

      In the new chemicals program, EPA publishes a significant amount of information within 45 days of receipt on its publicly available ChemView database (https://chemview.epa.gov/chemview). This includes sanitized copies of all notices (Premanufacture Notices (PMNs), Microbial Commercial Activity Notice (MCANs), Significant New Use Notices (SNUNs)) received, supporting information, attachments, amendments, and copies of the Agency's determinations, including TSCA section 5(e) orders.

   b. Any requests or requirements EPA issues regarding new or existing chemicals; and

      EPA RESPONSE: EPA makes public any test orders issued. If future test orders apply to companies who have claimed their identities as confidential business information (CBI), the public version will be sanitized. For existing chemicals undergoing prioritization or risk evaluation, EPA has solicited information from stakeholders in *Federal Register* notices. EPA places in the docket for the risk evaluation all information it receives, consistent with statutory and regulatory requirements regarding protecting CBI. A record of all the Agency's

determinations on new chemical substances, including public copies of TSCA section 5(e) orders that may contain testing requirements, is available publicly through our ChemView database (https://chemview.epa.gov/chemview).

c. Exposure or toxicity information it receives as a result of such requests or requirements?

EPA RESPONSE: Exposure and toxicity information used in the prioritization process and the risk evaluation will be made publicly available in the HERO **database (https://hero.epa.gov/hero/) as a data source, consistent with statutory and regulatory requirements regarding protecting CBI. Information related to new chemical submissions and reviews is available in our ChemView database as described above in response to Questions 8(a), and 8(b).**

9. EPA has stated that the agency intends to rely principally or entirely on voluntary submissions of information in implementing the reformed TSCA.

a. Please describe any steps that the EPA has taken to ensure that it obtains all reasonably available information through voluntary submissions.

EPA RESPONSE: EPA is not relying entirely on voluntary submissions of information. EPA is making use of its information gathering authority under TSCA. As noted above, in March 2020, EPA issued its first test order under section 4 of TSCA to obtain occupational exposure monitoring and solubility data for PV29, the first chemical for which EPA issued a draft risk evaluation. In initiating the first 10 chemical for risk evaluation, EPA believed there was sufficient information to complete the chemical risk evaluations using a weight of scientific evidence approach. The subsequent March 2020 information order was in response to the peer review panel suggestion. EPA selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this risk evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. However, EPA will continue to improve on its method and data collection for the next round of chemicals to be assessed under TSCA. It is important to note that, in part, these chemicals were selected because they provided the Agency the best opportunity to meet the timeframe in the statute for completing the evaluations by virtue of the reasonably available hazard and exposure information. Thus, EPA would not need to require development of new information for those chemicals (e.g., hazard and exposure). EPA has also received additional information in the course of issuing and soliciting public comments on the scopes, problem formulations, and draft risk evaluations.

During the prioritization process for existing chemical substances, there are two public comment periods to solicit reasonably available information. After the risk evaluation process begins for chemicals designated as high-priority substances, EPA publishes a draft scope document for each substance with another public comment period to solicit public input and reasonably available information. EPA also publishes a draft risk evaluation for each substance with another request for reasonably available information. During the prioritization and risk evaluation processes, the Agency determines if the reasonably available information, including from public comments, is sufficient, identifies data gaps, and determines whether additional information (e.g., hazard or exposure information) is warranted. EPA anticipates using our information collection authority under TSCA—including sections 4 and 8—to gather existing data or to generate new data on the high-priority substances currently undergoing risk evaluation, as appropriate. In addition, EPA has set up a docket for each Work Plan chemical to allow for the submission of information and to make any submissions publicly available.

b. Please describe any steps that the EPA has taken to ensure that all companies with relevant information choose to provide information.

EPA RESPONSE: As previously stated in the response to Question 9(a) above, EPA is not relying entirely on voluntary submissions of information and is making use of its information gathering authority under TSCA. EPA has also received additional information in the course of issuing and soliciting public comments on the scopes, problem formulations, and draft risk evaluations. During this prioritization and risk evaluation processes, the Agency determines if the reasonably available information, including from public comments, is sufficient, identifies data gaps, and determines whether additional information (e.g., hazard or exposure information) is warranted. EPA anticipates using our information collection authority under TSCA—including sections 4 and 8—to gather existing data or to generate new data on the high-priority substances currently undergoing risk evaluation, as appropriate.

c. Please describe any steps that the EPA has taken to ensure that companies provide information to EPA even when it is unfavorable to their chemicals or that they for some other reason do not wish to provide EPA or have been made public.

EPA RESPONSE: In addition to the responses to Questions 9(a) and (b) above, TSCA section 8(e) states that "Any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has

been adequately informed of such information." 15 U.S.C. 2607(e). TSCA Section 8(e) notices are posted in ChemView on an on-going basis.

10. Does EPA have a written policy or procedure to prevent receiving only incomplete or biased information when relying solely on voluntary submissions. If so, please provide it.

EPA RESPONSE: As previously detailed in the response to Question 9, EPA does not rely solely on voluntary submissions of information. In addition, TSCA section 26 mandates that EPA apply science standards including the best available science and weight of scientific evidence when conducting risk evaluations. In complying with these requirements, EPA conducts a systematic review process on information used to inform the risk evaluation. This review provides transparency and assurance that EPA is using quality data for risk evaluations. The nature of the systematic review process is such that EPA reviews any bias that may be present and must have complete study reports to evaluate the quality of the study and assess the conclusions. Under this process, EPA might give little or no weight to summaries or studies that are not complete (https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf).

For new chemical reviews, EPA regulations at 40 CFR 720.50 require that submitters provide all information related to health and environmental effects that are in the possession or control of the submitter and a description of any environmental and health effects data that is known to or reasonably ascertainable by the submitter.

11. Why has EPA failed to carry out its duty to ensure workers are protected under the reformed TSCA and is instead deferring to the much weaker health standards and regulations of OSHA?

EPA RESPONSE: EPA continues to ensure workers are protected. EPA's determinations for new chemical substances are partially based on the expectation that employers will comply with the Occupational Safety and Health Administration (OSHA) regulations designed to protect workers. EPA assesses risks to workers considering occupational health and environmental controls required by OSHA regulations and site-specific engineering controls described in the premanufacture notice (PMN). If risks are preliminarily identified, EPA then considers whether the risks would be mitigated with the use of personal protective equipment (PPE) such as gloves, respirators, or other protective equipment. Because hazard testing is not required to be conducted on new chemical substances before a company submits a PMN, EPA often identifies hazards using predictive models and read-across methods as part of the TSCA section 5 review process. To increase transparency regarding the potential hazards of untested new chemical substances, EPA may request that submitters include EPA-identified hazards in their Safety Data Sheets (SDS). Where potential risks to workers are identified, EPA may make a determination that a chemical is "not likely to present unreasonable risk" if the Agency has determined that risks to workers would be sufficiently mitigated by the appropriate use of PPE

consistent with the SDSs submitted with the PMN (or as modified to include additional protections based on EPA's review).

For new chemical reviews, unless case-specific facts indicate otherwise, EPA believes that a chemical substance is generally not likely to present unreasonable risks to workers if the use of PPE and/or other exposure controls identified in an SDS submitted with the PMN would sufficiently mitigate potential risk.

For risk evaluations for existing chemicals, EPA expects there is compliance with federal and state laws, such as worker protection standards, unless case-specific facts indicate otherwise. Therefore, EPA expects that existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE consistent with the applicable SDSs that achieves the stated assigned protection factor (APF) or protection factor (PF). OSHA and the National Institute for Occupational Safety and Health (NIOSH) are consulted on chemical risks and appropriate worker protections during the interagency review process of the existing chemical risk evaluations.

12. On what legal basis is EPA allowing, without any conditions or restrictions, new chemicals onto the market that may present risk to workers, when the law clearly requires EPA to regulate such chemicals?

    EPA RESPONSE: EPA is reviewing and applying risk management to new chemicals in accordance with section 5 of TSCA. Where potential risks to workers are identified, EPA may make a determination that a chemical is "not likely to present unreasonable risk" if the Agency has determined that risks to workers would be sufficiently mitigated by the appropriate use of PPE consistent with the SDS submitted with the PMN (or as modified to include additional protections based on EPA's review), as further detailed in the response to Question 11 above.

    a. What actual evidence does the agency have that American workers will be sufficiently protected once those chemicals are on the market?

       EPA RESPONSE: At the time the Agency is conducting review of a new chemical, there often would be no actual evidence of how the chemical is used in the market. Instead, EPA must assess the chemical under its conditions of use—the known, intended or reasonably foreseen circumstances of manufacture, processing, distribution in commerce, use and disposal of the chemical substance—and make a determination. For all the reasons described in response to Question 11, and unless case-specific facts indicate otherwise, EPA believes that a chemical is generally not likely to present unreasonable risks to workers if the use of PPE and/or other exposure controls would sufficiently mitigate potential risk.

13. Please promptly provide us with your new chemicals decision-making policies that set forth the legal basis for your decisions regarding worker safety, along with any evidence that

workers are being sufficiently protected under your approach. If you lack any such written policies or evidence, please explain why EPA has consistently applied this approach to so many of its recent new chemicals decisions.

EPA RESPONSE: EPA's approach to addressing workers is described in the *TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5* (the "*Working Approach*"), which is publicly available on the Agency's website (https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/approach-making-determinations-tsca). This framework document was initially issued for public comment in November 2017, and EPA updated it in December 2019, based on public comments and additional experience implementing the amended provisions of TSCA section 5. EPA also solicited public comment on the December 2019 updated *Working Approach*.

The updated *Working Approach* provides additional clarity on how EPA ensures adequate protection for workers, identifies reasonably foreseen conditions of use, and uses significant new use rules (SNURs) in the new chemicals program. EPA believes that the *Working Approach* and the availability of TSCA section 5 submissions (including attachments) and EPA documents used in its determination decisions demonstrate that new chemical reviews and determinations are being carried out in a manner consistent with the provisions of section 5 of TSCA.

14. What are EPA's plans to publish and take public comment on the legal and scientific justification for its new decision-making framework?

EPA RESPONSE: As detailed in the response to Question 13 above, EPA's approach to addressing workers is described in the *TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5* (the "*Working Approach*"), which is publicly available on the Agency's website (https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/approach-making-determinations-tsca). This framework document was initially issued for public comment in November 2017, and EPA updated it in December 2019, based on public comments and additional experience implementing the amended provisions of TSCA section 5. EPA also solicited public comment on the December 2019 updated *Working Approach*.

15. On what statutory basis does EPA believe it has authority to separate its consideration of potential risks arising from intended versus reasonably foreseen conditions of use of a new chemical, given the reformed TSCA's clear mandate that they be assessed together?

EPA RESPONSE: As discussed in the *Working Approach,* in reviewing new chemical notices, TSCA requires EPA to assess the chemical substance "under the conditions of use," defined in the law as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." The

identification of conditions of use is a key step in making a determination under TSCA section 5(a)(3). EPA's approach is consistent with this requirement and described in the *Working Approach*. Where EPA identifies reasonably foreseen conditions of use associated with a new chemical notice, but lacks sufficient information to perform a reasoned evaluation and/or has identified potential risks associated with those conditions of use, EPA considers whether a SNUR would address those concerns. Specifically, prior to making a determination under TSCA section 5(a)(3), EPA may propose a SNUR designating those reasonably foreseen conditions of use as significant new uses. This allows the Agency to make a determination on the notice under TSCA section 5 while ensuring that any manufacturing or processing activity for those newly designated significant new uses would first be subject to closer scrutiny by EPA through submission of a SNUN and regulation where appropriate in accordance with TSCA section 5(a)(3). For that reason, the reasonably foreseen conditions of use would be unlikely to present unreasonable risk.

16. How does EPA's exclusion of known uses and exposures to chemicals represent use of the "best available science," as required under the reformed TSCA section 26(h)?

EPA RESPONSE: As required in TSCA section 26, EPA makes decisions under TSCA section 5 based on the weight of the scientific evidence and employs scientific standards consistent with best available science. As discussed in Section G of the *Working Approach,* for new chemicals, it is often the case that the manufacture or import of the chemical has not yet commenced, hence, there are no known conditions of use associated with a new chemical substance given that the chemical is typically "new" to the U.S. marketplace. It is the exception, but occasionally there may be chemicals that are already being manufactured in the United States pursuant to an exemption under TSCA section 5(h). In such cases, EPA does identify and include in the review the known conditions of use associated with these chemicals, including to potentially exposed or susceptible subpopulations. Because TSCA jurisdiction extends only to activities in the United States, EPA interprets known uses as limited to uses within the United States. However, evidence of use of a chemical outside the United States could result in EPA identifying such a use as a reasonably foreseen condition of use.

For existing chemicals, as discussed in the preamble to the final risk evaluation rule (82 Fed Reg at 33729-33730), EPA may identify circumstances that may generally not be considered to be "conditions of use." For example, EPA does not generally intend to include intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in a chemical substance's risk evaluation.

EPA also may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. This may include uses that EPA has sufficient basis to conclude would present only "de minimis" exposures, uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. Finally, EPA may

identify exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental programs and statutes and which EPA does not expect to include in the risk evaluation. EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, and also furthers EPA's intent to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations. EPA may therefore tailor the scope of the Risk Evaluations using authorities in TSCA sections 6(b) and 9(b)(1).

EPA described how our risk evaluations will take into account the requirements to consider best available science in section II.A.4 of the preamble to the "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" Final Rule (Risk Evaluation Rule) (https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0108):

> **"TSCA section 26 requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific standards and base those decisions on the best available science and on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). TSCA does not however explicitly define either of these terms. Section 26(h) lists factors for the Agency to consider, as applicable, in employing best available science. These are: (1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models. As statutory requirements, they apply to EPA's decisions under TSCA sections 4, 5, and 6."**

17. How is EPA complying with the reformed TSCA section 26(k)'s requirement that EPA consider all reasonably available information when EPA ignores known uses and exposures to chemicals?

EPA RESPONSE: TSCA section 26(k) requires EPA, when carrying out sections 4, 5, and 6, to take into consideration during the systematic review process and the weight of scientific evidence information relating to a chemical substance, including hazard and exposure information, under the conditions of use, that is reasonably available to the Agency. EPA's approach to reasonably available information is described in preamble to the *Risk Evaluation Rule* as follows:

> **"EPA is defining "reasonably available information" to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. However, there is a preference for reasonably available information that is consistent with the required quality standards. Information that meets the terms of the preceding sentence is reasonably available information whether or not it is claimed as confidential business information."**

For new chemical reviews EPA described information sources that EPA uses to identify conditions of use in the *Working Approach*:

> **"The identification of reasonably foreseen conditions of use is necessarily a case-by-case determination and highly fact-specific, necessitating that EPA apply its professional judgment, experience, and discretion. The sources EPA uses to identify reasonably foreseen conditions of use may include, but are not limited to, searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, patent abstracts in the Chemical Abstract Service STN platform, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), other information in the Chemical Abstract Service STN Platform, REACH Dossiers, and technical encyclopedias (e.g., Kirk-Othmer and Ullmann)."**

18. How will EPA ensure that it meets its obligation under the reformed TSCA to protect against unreasonable risk, including risk to vulnerable subpopulations, if it defers to other agencies or EPA-administered statutes that use health standards that differ significantly from the reformed TSCA's and do not require protection of vulnerable subpopulations?

EPA RESPONSE: As detailed in the response to Question 16 above, for existing chemicals, EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures

and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, and also furthers EPA's intent to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations. As a general matter, EPA believes that certain other federal environmental laws and associated regulatory programs address certain exposure pathways, including to potentially exposed or susceptible subpopulations. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA. EPA is therefore exercising its authority under TSCA to tailor the scope of exposures evaluated in TSCA risk evaluations, rather than focusing on exposure pathways currently addressed under other EPA-administered, media-specific statutes, and regulatory programs.

19. While EPA announced policies in its final framework rule and risk evaluation scopes and problem formulations, EPA provided relatively little explanation of the legal basis for these approaches. Does EPA have a more robust legal analysis justifying its approach? If so, please provide it/them.

    EPA RESPONSE: EPA engaged in notice and comment rulemaking to develop the framework rules, which included an interagency review process and opportunities for public comment. EPA also provided or is providing opportunities for public comment on the scope, problem formulation, draft risk evaluation documents, and during peer review for each of the first ten chemicals undergoing risk evaluation. These documents, along with the final risk evaluations, describe the body of information used to inform our approaches and the legal bases for the actions proposed or taken.

20. When can we expect to see real progress in the agency meeting its duties under the reformed TSCA section 14? Specifically:

    a. When will EPA provide a fully up-to-date public accounting of how many CBI claims it has received and for what types of information; how many claims it has reviewed and within what timeframe; and the outcomes of (i.e., determinations on) the claim reviews it has conducted, as required?

       EPA RESPONSE: EPA first published statistics providing an accounting of CBI claims received and reviewed on its website in July 2019. These statistics were updated and published along with more detailed information showing the results of completed final CBI determinations in December 2019. Both the statistics and information on completed CBI determinations were updated in June 2020 and

are publicly available on EPA's website (https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program).

b. When will EPA make public a current and complete list of "unique identifiers" for chemical identities for which EPA has been approved CBI claims, which are essential for the public identify other information EPA has on those chemicals?

EPA RESPONSE: A list of unique identifiers was first published in December 2018, and has been updated multiple times since then—most recently in April 2020. An updated list was published in December 2019 (https://www.epa.gov/sites/production/files/2019-12/uid-12-9-19.xlsx). In addition to the stand-alone list, unique identifiers are now included on the publicly available TSCA Chemical Substance Inventory (updated twice per year), and on the CBI determinations table which is publicly available on EPA's website (https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program#reviews).

c. When will government-associated health and environmental professionals, medical personnel and first responders be able to access the confidential information they need to do their jobs through the "request and notification system" for CBI access required under the reformed TSCA?

EPA RESPONSE: As you are aware, guidance for requesting access to CBI under TSCA sections 14(d)(4), (5), and (6) was published in June 2018. No requests for CBI under these provisions have been received by EPA to date.

d. When and how will EPA make public health and safety studies and associated information on chemicals, which are not eligible for protection as CBI under the reformed TSCA?

EPA RESPONSE: As detailed in the response to Question 9(c), regarding the availability of TSCA section 8(e) notices in ChemView, TSCA section 8(e) states that "Any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information." 15 U.S.C. 2607(e). TSCA Section 8(e) notices are posted in ChemView on an on-going basis. Additionally, EPA has regularly published health and safety studies and associated information on chemicals in its ChemView website (https://chemview.epa.gov/chemview/). Some information in health and safety studies may be eligible for confidential treatment under TSCA and its implementing regulations. EPA generally reviews only a subset of confidentiality claims in health and safety studies, per TSCA section 14(g).

As mentioned in response to Question 5(a), a record of the Agency's determinations on new chemical substances, including copies of TSCA section 5(e) orders is available through our ChemView database (https://chemview.epa.gov/chemview).

EPA is addressing its obligations under TSCA section 14(g)(1)(C)(ii) to make confidentiality determinations for a representative subset of information not otherwise exempt from such determinations. Health and safety studies are among the information subject to these determinations.

21. During debate in the House, I successfully amended EPA's appropriations bill to provide $3 million dollars to perform the following two critical measures identified in EPA's EJ 2020 Action Agenda:

    One hundred overburdened communities. In the EJ 2020 Action Agenda, EPA committed itself to working with co-regulators to identify and undertake community-focused compliance reviews and enforcement strategies in at least 100 of the most overburdened communities where data indicate that facilities present a high likelihood of serious non-compliance issues impacting those communities, and addressing serious violations if found.

    Cumulative risk assessments. Also in the Action Agenda, EPA committed itself and EPA-funded grantees to publishing a series of reports and scientific papers that significantly advance the scientific foundation for cumulative risk assessments, supporting the incorporation of information on chemical and nonchemical stressors into selected Agency health assessments. This activity could address a hallmark of many disenfranchised communities – exposure to multiple pollutants from multiple sources.

    What are EPA's plans for implementing these two critical tasks, as provided for in EPA's FY 2020 appropriations?

    EPA RESPONSE: EPA will utilize the appropriated dollars as directed in the report language accompanying the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94).

The Honorable John Shimkus (R-IL)

1. During the hearing you acknowledged in response to a question that States consume considerable staff and resources meeting multiple NAAQS on multiple timelines and that more order could be brought to the process.

    One way to address the burdens on states would be to amend the Clean Air Act to change the review period from five to ten years. This would provide more time for states to meet existing standards, and the Administrator could always issue new standards if he determined it was necessary.

a. What would be the benefit of updating the statute to enable states to have more time to more effectively meet clean air standards?

EPA RESPONSE: One of my jobs as Administrator is to ensure that the Clean Air Act is implemented as written and intended by Congress. Sections 108 and 109 of the Clean Air Act govern the review, and revision, as appropriate, of the National Ambient Air Quality Standards (NAAQS) for each criteria pollutant. Under the statute, "the Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required," but is required to complete review at least every five years. In May 2018, EPA issued the *Back-to-Basics Process fir Reviewing National Ambient Air Quality Standards* memorandum to improve EPA's process for reviewing the NAAQS. The memo laid out goals to get EPA back on track with Clean Air Act requirements, statutory deadlines, and the issuance of timely implementation rules, to ensure continued improvements in air quality across the country. The Agency has received some criticism for the implementation of the *Back-to-Basics* memorandum, but the process the Agency has adopted over time resulted in a seven plus year review process, which could not be completed in the statutorily required five years. EPA is committed to working with communities to provide technical assistance and help them meet the NAAQS upon the promulgation of revised standards, which will ensure adequate protection of public health and the environment. EPA will continue to work with state, local, and tribal agencies as they develop State Implementation Plans to meet the NAAQS while also considering flexibility for economic development.

2. Your work to meet statutory deadlines for review of National Ambient Air Quality Standards, such has for ozone and for particulate matter appears on track.

One obligation of EPA standard setting involves issuance of timely guidance for states, once a standard is issued. The Environmental Council of States (ECOS) issued a resolution in 2013 that urged EPA "to develop guidance and the implementation rule for new or revised [National Ambient Air Quality Standards] and issue a proposed implementation rule concurrent with the final [National Ambient Air Quality Standards] promulgation."

a. Are you considering issuing a proposed implementation rule when you promulgate final standards?

EPA RESPONSE: EPA is aware of states' need for timely guidance after a NAAQS is revised, and we understand the desire for a proposed implementation rule when we promulgate final standards. We also acknowledge and have discussed with ECOS and other state organizations the challenges associated with developing a proposed implementation rule simultaneously with completing the deliberative process of reviewing and revising a NAAQS. To help overcome some of those challenges, EPA promulgated in 2016 an implementation rule

intended to apply to all current and future $PM_{2.5}$ NAAQS. While EPA has not applied this approach for the ozone NAAQS, EPA would consider it in order to provide certainty for states on how EPA interprets the applicable Clean Air Act requirements. That said, NAAQS implementation rules for ozone promulgated over the past five years provide a valuable blueprint for states for ozone NAAQS implementation.

b. What is necessary for you to do so?

EPA RESPONSE: As a general matter, a proposed implementation rule would provide air agencies with key information associated with implementation of a final NAAQS. Given the regulatory process that precedes issuance of a proposed rule, a difficulty in issuing a proposed implementation rule at the same time as a final NAAQS is that the specific standard of the final NAAQS is not known at the time the implementation rule would be under development. EPA appreciates the importance of timely issuance of implementation rules.

c. Would you agree that would assist State compliance planning?

EPA RESPONSE: The implementation rule associated with a new NAAQS supports states in development of state implementation plans (SIPs), particularly nonattainment plans, responsive to the new NAAQS. The SIP deadline associated with a newly promulgated NAAQS can vary depending on area designations, which occur following promulgation of a new NAAQS. EPA appreciates that timely issuance of implementation-related guidance, including an implementation rule, is helpful to states' efforts in air quality planning, and EPA has made significant strides in this area over the past five years, issuing timely technical guidance and implementation rules.

3. Two years ago, on April 12, 2018, the President issued a memo to the EPA directing the Administrator to take specific actions to ensure more efficient and cost-effective implementation of the agency's national air quality standards programs. Last year at the budget hearing you provided an update on your progress. And this is to follow up:

a. The President requested more timely processing of preconstruction permit applications. What have you accomplished in terms of more timely permitting?

EPA RESPONSE: EPA continues to improve how efficiently and effectively it carries out its core responsibilities, including timely processing of preconstruction permit applications under the Clean Air Act. We continue to implement the EPA Lean Management System (ELMS), launched in FY18, which has enhanced the Agency's performance management framework across the board. Speaking specifically to timely preconstruction permit processing, for the period FY19 and through March of this year, we have reduced the number of backlogged permits (*i.e.*, permits that were not issued within 12 months of

submittal of a complete application) by over 80 percent. In addition, the Agency has been and remains keenly focused on providing prompt technical support, reviews, and determinations, as necessary and consistent with applicable law, to assist states in the timely issuance of preconstruction permits. We have also taken steps, through guidance and rulemaking, to streamline and reduce the burden associated with preconstruction permitting under the New Source Review (NSR) program. Those steps have helped facilitate timely issuance of preconstruction permits for EPA and state permitting authorities, and we are continuing our efforts in that regard.

b. The President asked in his memo that you respond more quickly to states' petitions for relief under the exceptional events and international emissions provisions of the Clean Air Act. What have you accomplished on that front?

EPA RESPONSE: By working closely with the states, EPA has eliminated the backlog of exceptional events demonstrations that have regulatory significance. The Exceptional Events Rule identifies the types of regulatory actions to which the rule applies, consistent with the language in Section 319(b) of the Clean Air Act. Since revising the Exceptional Events Rule in 2016, EPA has concurred, in whole or in part, on 109 demonstrations. We have also updated our Frequently Asked Questions document and finalized guidance documents on stratospheric ozone intrusions, high wind dust events, data modification, and prescribed fires (https://www.epa.gov/air-quality-analysis/updated-exceptional-events-rule-faqs). All of these implementation tools help air agencies develop approvable demonstrations and are available on EPA's Exceptional Events website (https://www.epa.gov/air-quality-analysis/treatment-air-quality-data-influenced-exceptional-events-homepage-exceptional). In addition, EPA has developed an electronic tool which will allow air agencies to submit their demonstrations electronically, thus further streamlining the review process.

4. The President's 2018 memo also directed you to fully implement the Clean Air Act provisions that require the Clean Air Scientific Advisory Committee (or CASAC) to advise you on the adverse health or other effects that may result from implementation of revised air quality standards, as required in the Clean Air Act.

   a. In previous Administrations, the legal requirement to look at other adverse impacts, including welfare, social, economic, or energy effects was ignored by EPA.

   b. Have you provided direction or a charge to CASAC to provide you with advice about other adverse impacts that may result from various efforts to meet air quality standards?

   EPA RESPONSE: EPA is committed to improving the NAAQS implementation process, including meeting statutory deadlines, and supporting states better by issuing implementation tools swiftly as the need arises, and we are undertaking

reforms to ensure that the Agency and its independent science advisors follow a transparent, timely, and efficient process in reviewing and revising public health-and welfare-based NAAQS. We have stayed on track and completed the NAAQS reviews for ozone and particulate matter (PM) by the end of 2020. EPA has announced that lead (Pb) will be the next NAAQS review to complete and we issued a call for information to inform the Integrated Science Assessment (ISA) for this review on July 7, 2020.

c. And what is the status of that work? And if not, why not?

EPA RESPONSE: EPA's process aims to ensure that the Agency is addressing, and CASAC is providing, advice on the scientific questions Congress intended to inform the Administrator's NAAQS review, revision, and decision. With the CASAC reviews complete, we finalized the PM policy assessment in January, and proposed action on the PM standard in April of 2020. For ozone, we finalized the policy assessment in May and proposed action on that standard in August of 2020. Both actions were finalized in December 2020.

5. In the FY 2020 budget hearing, you were asked for the record about implementation of Section 321 of the Clean Air Act. You were also asked about the Economic Dislocation Early Warning System, which was conducted by EPA in conjunction with the Department of Labor in the 1970s. EPA's response to the inquiry was that there were analytical and information collection challenges to implementing methods similar to the EDEWS and presumably section 321, but that EPA was "committed to ensuring that its work evaluating employment impacts of regulations is based on the best available science and technical methods in compliance with applicable laws and guidance."

   Section 321 (a) of the Clean Air Act requires that EPA "shall conduct continuing evaluation of potential lass or shifts in employment which may result in administration or enforcement of the provision of this Act and applicable implementation plans, including where appropriate, investigating threatened plant closures or reductions in employment allegedly resulting from administration or enforcement."

   a. What specifically is EPA doing to evaluate employment impacts in the application of its work, beyond Regulatory Impact Analysis?

   EPA RESPONSE: EPA has undertaken several proactive, substantial efforts for evaluating employment impacts, in addition to conducting employment analysis in regulatory impact analyses. First, EPA is revising and updating the discussion of employment impacts in its *Guidelines for Preparing Economic Analyses.*[5] Once

[5] U.S. EPA, *Guidelines for Preparing Economic Analyses*, https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses. "*Chapter 9: Economic Impacts* – Notice of Pending Revisions: EPA is in the process of revising its guidance for assessing the employment impacts of environmental regulation." EPA is working with a special committee of the EPA Science Advisory Board (SAB) to review a revised, draft *Guidelines* document, including a revised chapter on economic impacts, including impacts on employment. The

peer review by our Science Advisory Board (SAB) is complete, EPA will implement the best practices reflected in the revised *Guidelines* for evaluating employment impacts. EPA is also addressing analytic challenges to evaluating employment impacts of regulation. For example, to allow for additional assessments of employment impacts beyond the analysis included in RIAs, EPA constructed a computable general equilibrium (CGE) model of the U.S. economy that underwent peer review by a special committee of the SAB.[6] The model will allow EPA economists to capture employment shifts as a result of Clean Air Act regulations.

b. Specifically explain how EPA is complying with Section 321?

EPA RESPONSE: EPA continues to comply with Clean Air Act section 321 by evaluating employment impacts in the regulatory impact analyses and economic impact assessments that accompany the Agency's Clean Air Act rulemakings.

c. What specific statutory or administrative barriers impede EPA from "continuing evaluation" of employment impacts from (a) administration of the Act, implementation plans, or enforcement?

EPA RESPONSE: As described above, EPA continues to comply with Clean Air Act section 321 by evaluating employment impacts in the regulatory impact analyses and economic impact assessments that accompany the Agency's Clean Air Act rulemakings.

d. What statutory changes would need to be made to ensure effective implementation of Section 321?

EPA RESPONSE: As described above, EPA continues to comply with Clean Air Act section 321 by evaluating employment impacts in the regulatory impact analyses and economic impact assessments that accompany the Agency's Clean Air Act rulemakings.

6. Last year, you told us how important you thought risk communication was and how you wanted to improve that at the Agency. Please update me on actions you've taken over the last year and what do you plan for the coming year?

EPA RESPONSE: Risk communication is of critical importance to the work EPA does across our many Regions, offices, and programs. This is because our mission is to protect public health and the environment, and it is impossible to effectively and efficiently pursue that mission without communicating about risk to the American people.

Agency anticipates having a final revised document by the end of the calendar year.

[6] CGE Modeling for Regulatory Analysis, https://www.epa.gov/environmental-economics/cge-modeling-regulatory-analysis. The EPA received the SAB committee's draft report in January 2020.

Over the past year EPA has continued to build on our risk communication capabilities. In the spring of 2019, EPA launched an Agency-wide Risk Communication Working Group tasked with the goal of improving the consistency and coordination of risk communication processes and practice across the Agency. This group includes high-level representation from every EPA Region and program office. In the fall of 2019 and after an extensive search, EPA hired a new Senior Risk Communication Advisor. The vision for this role is to instill a single point person with the task of centrally coordinating the important risk communication work that goes on across the Agency with a goal of improving the consistency, the quality, the effectiveness, and the timeliness of our risk communication practices.

The Senior Risk Communication Advisor has wasted no time and has worked to build relationships across the Agency as she learns and elevates best practices from our current work.

The Senior Risk Communication Advisor—in coordination with the Agency-wide Risk Communication Working Group—is developing a new Agency-wide *EPA Risk Communication Process Framework*. This *Framework*, when finalized, will guide risk communication efforts through strategic communication and planning, action based on scientifically proven best practices, and processes for EPA to learn from risk communication efforts on a project and Agency level. It will provide EPA staff and partners with practical tools on a wide range of topics.

Efforts are also underway to improve risk communication training for EPA staff; to better leverage EPA, federal, and academic research on the science of risk communication; and to develop content-rich, multi-media risk communication toolkits on contaminants that are emerging or that cut across Agency offices and regions. The toolkits that are currently being developed address the contaminants PFAS, EtO, and lead.

Improving risk communication at EPA will require a long-term focus at the Agency and a gradual culture shift to a place where the Agency is proactively seeking to understand our audience—the American public—to better understand the public's concerns, questions, and knowledge gaps, and then to meet and fill those gaps with risk communication that is meaningful, understandable, and actionable.

Water Infrastructure Finance and Innovation Act (WIFIA):

7. WIFIA is largely still a new program – in that it has only begun making loans in the last couple of years.

    a. How much funding has been loaned and leveraged under this program?

EPA RESPONSE: As of November 16, 2020, EPA has announced 40 WIFIA loans that are providing $7.7 billion in credit assistance to help finance $16.6 billion for water infrastructure while creating more than 38,200 jobs and saving ratepayers $3.6 billion. Since March 2020, WIFIA has announced 24 loans and updated six existing loans with lower interest rates.

b. The program was meant to get a greater than $2 in financing power than $1 of loaned investment. When will we see leveraging at a level that far exceeds this 2:1 split?

EPA RESPONSE: To properly understand the WIFIA program's leveraging power, one should compare the EPA appropriated credit subsidy amount to total infrastructure investment. Over the first three years of the program, the WIFIA program has been able to leverage the funding it receives from Congress in the range of 100:1. Meaning that for every $10 million Congress appropriates, the WIFIA program is able to offer $1 billion in financing.

Drinking Water State Revolving Fund (DWSRF):

8. How has the revolving nature of the DWSRF greatly expanded the scope of federal investment in drinking water projects?

EPA RESPONSE: Since the inception of the Drinking Water State Revolving Fund (DWSRF), Congress has appropriated more than $21 billion to the fund. Together, the 51 DWSRF programs have effectively leveraged these funds to provide $41.1 billion in loans to the nation's water utilities to make capital improvements to infrastructure and nearly $3.5 billion for set-aside programs that enable states and third party providers to help water utilities do the following: develop technical, managerial, and financial capacity, protect source water, and ensure that operators are trained and certified.

For the loan program, leveraging of the federal investment translates into $2 in disbursements for every $1 drawn from the U.S. Department of the Treasury. Because the state loan funds are revolving, the funds grow in capacity to finance infrastructure projects. Loan repayments, interest earnings, bond proceeds, and federal capitalization grants all contribute to the fund's available resources. The lower-than-market rates on DWSRF loans have enabled many communities to move forward in financing their infrastructure needs. Over the lifetime of DWSRF loans made in fiscal year 2019, for instance, the communities that received this assistance will pay $500 million less to finance their infrastructure improvements compared with market rates.

9. In 5 fiscal years, almost all the loans made under the DWSRF will have been required to be paid back to states, creating the best picture yet of whether the program is operating as intended.

a. When do you expect the DWSRFs to be able to revolve on their own without consistent capitalization grants from Congress?

<u>EPA RESPONSE</u>: Projecting future DWSRF revolving levels requires assumptions about the future related to factors such as inflation, interest rates, loan demand, and drinking water regulations. Many of these factors are highly uncertain and subject to significant changes. The longer the projection period, the more likely that projections will vary from actual results, possibly quite significantly. Even in the shorter term, projections may be undermined by events. For example, consider the COVID-19 public health emergency that may result in both immediate and long-term financial stresses on water utilities. Given the ongoing needs of drinking water systems, annual capitalization grants remain essential to the provision of safe drinking water in each state. EPA's most recent drinking water infrastructure needs survey and assessment conducted in 2015 shows that $472.6 billion will be needed to maintain and improve the nation's drinking water infrastructure over a 20-year period, primarily to replace or refurbish aging or deteriorating transmission and distribution pipelines; to construct, expand, or rehabilitate treatment infrastructure to reduce contamination; to construct, rehabilitate, or cover water storage reservoirs; and to construct or rehabilitate intake structures and wells.

Not all drinking water problems can be solved by capital financing of infrastructure improvements. With that in mind, Congress gave states the option to take a portion of their federal capitalization grant as set-asides. States use these DWSRF set-aside funds to support water system capacity development, operator certification, small system technical assistance, wellhead protection, and source water protection activities that complement capital improvements and help utilities succeed in protecting public health. States currently choose to take, on average, about 23 percent of their DWSRF annual grants as set-asides, with a statutorily allowed maximum of up to 31 percent for states individually. New capitalization grants provide a source of funding for these critical, public-health-focused activities.

Capitalization grants assist water systems in other important ways. Many drinking water systems cannot afford a low- or even a zero-percent interest loan and may require further subsidization for needed infrastructure projects. Since the DWSRF's inception, the Safe Drinking Water Act (SDWA) has allowed states to provide a certain portion of the federal capitalization grant as additional subsidy, via the forgiveness of principal or loans with negative interest rates, to state-defined disadvantaged communities. Each state currently must provide at least 6 percent, but no more than 35 percent, of each year's capitalization grant as additional subsidy to disadvantaged communities. Congress has further mandated in appropriations language that states provide an additional, varying portion (*e.g.*, 14 percent in fiscal year 2020) of the federal capitalization grant as additional subsidy that can go to any eligible DWSRF borrower. This appropriations language is a distinct requirement that is additive

to the disadvantaged community subsidy authority in SDWA described above, allowing states both to assist communities most in need and to incentivize communities to move forward with particular projects.

Additional subsidy through the DWSRF is especially critical to small water systems. In the DWSRF's 2019 loan portfolio, 69 percent of water systems serving populations of 500 or fewer received principal forgiveness, with 44 percent of those water systems receiving principal forgiveness for the full loan amount.

The Honorable David B. McKinley, P.E. (R-WV)

1. What are the long-term effects of bathing in or using water that is contaminated with certain contaminants, such as trichloroethylene ("TCE")?

   EPA RESPONSE: The effects of exposure to chemicals such as trichloroethylene (TCE) depend on various factors, including the dose (how much you are exposed to), the duration (how long you are exposed), the frequency (how often you are exposed), and the route of exposure (how you are exposed). Other considerations include other chemical exposures and personal traits and habits.

   EPA established a maximum contaminant level (MCL) of 0.005 milligrams per liter for TCE in drinking water at community water systems, which provides public health protection through the reduction of chronic, or long-term, risks. The MCL is an enforceable standard established under the SDWA for the highest level of a contaminant that is allowed in drinking water and reflects the level that water systems can achieve using the best available technology. Potential health effects from long-term exposure to TCE in drinking water above the MCL may include liver problems and increased risk of cancer. EPA considered multiple exposure pathways (*e.g.*, inhalation, dermal, drinking) in developing the development of this regulation.

   EPA regulates over 90 contaminants in drinking water, including microbial, radiological, and organic and inorganic chemical contaminants. A comprehensive list of these regulated contaminants, including basic information about health effects over the regulatory limits, is publicly available on EPA's website (https://www.epa.gov/dwreginfo/drinking-water-regulations).

2. In your oral testimony, you stated that you don't regulate or collect information regarding the presence of lead or copper pipes in homes.

   a. Does your proposed Lead and Copper Rule do anything to address this issue?

      EPA RESPONSE: Addressing lead and copper in premise plumbing touches on several complex factors, including funding, the jurisdiction of water utilities, and

property issues. EPA's authority under the SDWA for drinking water extends to public water systems (PWS) and certain requirements for lead-free plumbing, but does not extend to property beyond the jurisdiction of regulated water systems and does not regulate private property. For lead service lines, EPA's revisions to the Lead and Copper Rule will require water systems for the first time to prepare and regularly update a comprehensive inventory of lead service lines (LSL) to homes and buildings served to identify the areas with the greatest potential for lead contamination of drinking water. EPA is also ensuring that systems make the LSL inventory publicly available and conduct regular outreach to homeowners with LSLs. Also, EPA's revisions would accelerate the removal of lead service lines by closing loopholes in the current regulation, propelling early action, and strengthening replacement requirements.

To help address lead in premise plumbing, EPA's revisions to the Lead and Copper Rule would improve requirements for corrosion control treatment, which reduces the leaching of lead from lead pipes in homes, based on tap sampling results. The revisions establish a new trigger level, below the existing action level, at which systems that currently treat for corrosion would be required to re-optimize their existing treatment and systems that do not currently treat for corrosion would be required to conduct a corrosion control study so that each such system is prepared to respond quickly when necessary.

b. How might Congress act to appropriately address issues with lead and copper pipes in homes?

EPA RESPONSE: Addressing lead and copper in premise plumbing touches on several complex factors, including funding and the jurisdiction of water utilities. EPA would be happy to work with Congress on this matter. In the meantime, EPA has strengthened the existing Lead and Copper Rule to improve corrosion control throughout the entire public water system distribution network, which will prevent potential leaching from materials located within private residences.

EPA Comment in Response to The Honorable Greg Walden (R-OR)

At the February 27, 2020 hearing, Administrator Wheeler addressed questions from Ranking Member Walden about the disparity in responses by EPA and state regulators to combined sewer overflows in different communities. Following the hearing, they discussed the matter further and Ranking Member Walden asked Administrator Wheeler for details on the sewer overflows in San Francisco. In response, the Agency would like to provide the following supplemental information for the Record:

EPA RESPONSE: Ranking Member Walden, during the February 27, 2020 hearing on EPA's FY 2021 budget request, you and I discussed the disparity in responses by EPA and state regulators to combined sewer overflows in different communities. Following the

hearing, we discussed this matter further and you asked me for more details on the sewer overflows in San Francisco.

San Francisco operates two wastewater treatment plants. One discharges into the Pacific Ocean and the other discharges into San Francisco Bay. The City operates a combined sewer and stormwater system. That means that both stormwater and sewage are collected in the City's pipes and sent to the plants for treatment. However, when it rains, the capacity of the treatment plants can be quickly overwhelmed. When the treatment plants reach capacity, the combined sewage and stormwater does not receive adequate treatment and is diverted away from the plants and sent to combined sewer discharge structures that flow into the Pacific Ocean or into San Francisco Bay. In several locations, these outfalls are located on public beaches. The discharges from the combined sewer discharge structures do not receive secondary treatment or even primary disinfection.

Some of the combined sewer discharge structures are equipped with baffles that are intended to retain "floatables" (including fecal matter) instead of allowing them to flow out the outfall with the rest of the combined sewage and stormwater. However, Region 9 has gathered evidence that shows that when the structures fill with water, the "floatables" flow out along with the rest of the combined sewage and stormwater.

In addition to the problems with the operation of the combined sewage discharge structures, there also have been force main and pump station failures that have diverted substantial volumes of combined sewage and stormwater to flow across beaches and into the San Francisco Bay and the Pacific Ocean. There have even been instances of sewage flowing in the streets and entering people's homes.

On October 2, 2019 EPA Region 9 issued a Notice of Violation (NOV) to the City. As stated in the NOV, the City's data show it is discharging approximately one and a half billion gallons of combined sewage and stormwater annually onto beaches and other sensitive areas, including areas where recreation takes place. Recent data show that the annual combined sewer discharges are closer to 2 billion gallons.

On December 10, 2019 EPA issued a new permit to San Francisco for its plant that discharges to the Pacific Ocean. As we discussed at the hearing, the City is appealing this permit to EPA's Environmental Appeals Board. Among the objections raised by the City are the requirement to update its Long Term Control Plan with information about the current nature of the combined sewer discharges to sensitive areas and their impacts and to evaluate the City's ability to eliminate, relocate, or reduce the magnitude or frequency of discharges to sensitive areas, like beaches. The City is objecting to the requirement in the permit that these discharges meet water-quality-based effluent limitations. The City also is objecting to a requirement to report whenever sewage or sewage mixed with stormwater exits the system, whether in streets, business, residences, or discharges to surface waters.