Chris Jahn Responses to 10/18 Environment Subcommittee Questions for the Record

The Honorable Bill Johnson

Q1. Congress has passed several spending bills over the last few years, including the CHIPS Act, the Infrastructure Investment and Jobs Act, and the Inflation Reduction Act. These laws heavily rely on the presumption that simply throwing federal money at industries and people will make all these things magically appear.

a) The lack of critical manufacturing and supply chains in the United States is a huge concern today. Why doesn't simply throwing money at this problem work?

America depends on the products and innovations made by America's chemical industry. Chemistry is essential to modern life and is at the beginning of countless supply chains. It is the very definition of critical manufacturing.

Building and maintaining resilient supply chains in the U.S. doesn't just rely on government funding and incentives, it requires a policy and regulatory environment that provides certainty for manufacturers.

b) What is the real-world impact of duplicative, overly burdensome, or overlapping regulations?

Sound chemical management policies are critical to American innovation and competitiveness. Regulations must be based on science, promote innovation and support supply chain resiliency. Overly burdensome regulations on the chemical sector have a negative impact on America's ability to lead in the creation of products and technologies needed to accomplish a wide range of societal goals, from energy innovation to national security to vital health care needs.

In particular, new chemistries have faced regulatory barriers under this Administration's implementation of TSCA that impact the timing of reviews and availability of products, creating uncertainty in the supply chain and stifling the ability of companies to bring new products to market.

Such barriers and delays have discouraged new American innovations and resulted in offshoring of both new chemical R&D and manufacturing. In a survey of ACC member companies, respondents representing approximately nearly one-fifth of U.S. chemical sales reported systemic delays, disregarded company-submitted data, and inconsistent reviews. In fact, 70% of respondents reported deciding to introduce new chemicals in jurisdictions outside of the U.S. given the uncertainties and challenges with EPA's New Chemicals Program.

Q2. What is the average time that a new chemical takes to go through EPA review?

Under TSCA, Premanufacture Notice (PMN) review is supposed to take 90 days. However, PMNs are not moving through the review process at a rate that supports innovation and the retention of manufacturing

in the United States. PMNs that have been submitted under the current Administration (2021-current YTD) have taken an average of 396 days to complete.

EPA has only completed 5 of the 130 PMNs that were submitted in 2023. Although these submissions were associated with the photolithography and photoresist categories used in semiconductor manufacturing – a priority for the Administration – the review took an average of 197 days.

Q3. Some think more money and staffing at EPA would solve the issue, have you heard this before? Do you think this is the solution for addressing TSCA implementation challenges?

Providing EPA more resources (e.g., more money and staffing) is not justified unless EPA is delivering value. EPA has a lot to do under amended TSCA, which requires prioritization and coordination with key statutory mandates. This prioritization and coordination is currently missing. Recently, EPA has made choices to broaden and complicate existing risk evaluations. Ultimately, EPA must demonstrate that they can use the resources they have more efficiently to focus on the greatest potential for risk, while also not duplicating the work of other EPA program offices.

The workforce analysis performed by EPA in December 2021 demonstrated that the number of Full Time Equivalents (FTEs) supporting the New Chemicals Division in 2021 was similar to the FTEs assigned to New Chemicals in the prior year, however, the number of PMNs completed decreased by 53%. EPA received additional funding and increased the number of FTEs in the New Chemicals Division but there has not been an associated increase in the number of completed PMNs or the completion of additional PMNs within the 90-day review period.

In addition, EPA made the decision to reopen the first ten risk evaluations rather than moving expeditiously to complete the risk evaluations for the next 20 high priority chemicals. This rework has led to significant delays in the Existing Chemicals Division workflow, increased the costs associated with the TSCA Section 6 program and did not lead to any increase in the protection of human health or the environment. In fact, the delay in the finalization of the risk evaluations and initiation of risk management is in direct conflict with EPA's core mission to protect human health and the environment.

EPA has never provided sufficient information on how the increased funding and FTEs would lead to improvements in the new and existing chemical programs nor have they demonstrated that additional staffing would lead to measurable improvements.

Q4. Is TSCA implementation a problem that simply rearranging guidance and protocols will address or should Congress start considering something statutory to address the problems with implementing TSCA?

Almost eight years after the passage of the 2016 amendments to TSCA, we are seeing significant challenges with implementation, both in the new chemicals program and with existing chemicals in the risk evaluation and risk management process. Some of the problems could be addressed by modifying EPA guidance and policy, while other issues may require statutory changes. We are ready to work with Congress to strengthen and improve the TSCA program.

Q5. Should EPA or should the private sector lead on what innovation looks like in America?

America's private sector is by far the world's most innovative. But overly conservative, unduly restrictive regulations proposed by EPA put America's leadership role at risk. EPA and other federal agencies must focus on smart regulations that embolden, enable and empower the private sector precisely so that it does not fall into the same deindustrialization trap as Europe or lose out to foreign competitors like China. Unless the Biden Administration and Congress take a different approach to how they create and implement regulations, the availability of critical chemistries will dwindle—and the country's climate, infrastructure and supply chain priorities will suffer as well. American success relies on American chemistry.

Q6. Formaldehyde is a "building-block-chemical" that is used to improve fuel efficiency, brake pads, and building materials. The value underpinning an EPA effort to control formaldehyde was reviewed by the National Academies of Sciences, but EPA limited the scope of this evaluation.

a) Does it concern you that EPA is trying to limit criticism of a stringent regulatory proposal?

Yes, ACC objects to the limited scope of the NASEM review, which threatens the independence of the peer review process. NASEM's ability to provide a comprehensive review of the body of scientific literature was constrained by EPA, which imposed a narrow and rigid set of charge questions for NASEM to answer and constrained its ability to exercise independent scientific judgment or consider contrary evidence. This narrow scope precluded any consideration of the best available science. The Federal Advisory Committee Act (FACA) requires that EPA cannot use the advice of NASEM unless the report is "the result of the Academy's independent judgment" and the review process is not under the control and management of the sponsoring agency.

The NASEM Committee acknowledges that they were not tasked with conducting an independent hazard evaluation or dose-response assessment for formaldehyde exposure. Additionally, the Committee acknowledges they were not charged with commenting on other interpretations of scientific information relevant to the draft assessment, nor were they permitted to review alternative opinions on EPA's formaldehyde assessment.

Significantly, NASEM acknowledges that their constrained scope did not address the validity of the toxicity values in EPA's 2022 draft IRIS assessment, stating "the committee did not conduct an independent hazard evaluation or dose-response assessment, and therefore does not recommend alternative hazard identification conclusions or toxicity values." This limitation is a significant failure and disregards the scientific evaluations from global health agencies, regulators, and other international authorities who have used decades of scientific evidence by universities and independent scientists to support a safe threshold for formaldehyde exposure and no causal association with leukemia. These significant constraints ultimately resulted in the failure to appropriately integrate over 40 years of peer-reviewed scientific evidence.

Any assessment of formaldehyde must begin with best available science and the undeniable fact that formaldehyde is an ever-present part of the natural world that, through decades of responsible innovation and regulation, has become essential to goods including sustainable wood products, electric vehicles, and lifesaving vaccines and medical devices.

We need strong, independent, robust science-based assessments as the basis for federal regulations—and the limited scope of the NASEM review resulted in a report that is unfit for use in regulatory decision-making.

ACC has made our concerns clear about EPA's and NASEM's numerous FACA violations, including improper EPA influence, conflicts of interest on the committee, a lack of technical balance, and failure to meet transparency obligations or provide meaningful opportunities for public comment.

More on ACC's filed legal action against EPA and NASEM can be found here: ACC Challenges Lack of Independence, Transparency for Peer Review of EPA's Draft Formaldehyde IRIS Assessment - American Chemistry Council.

b) What would be the impact of EPA being able to cherry-pick the data and criticism it likes to support stringent rules with broad impacts?

Formaldehyde is a core building block of the U.S. chemical industry that is used across a wide variety of sectors, including agriculture, healthcare, construction, automobiles, funeral services, electronics (semiconductors), national security, and aviation. Formaldehyde-based technologies have broad roles in the economy, supporting 961,000 jobs and $506.4 billion in sales in 2021 in the United States.

While EPA's IRIS has never been authorized by Congress, IRIS assessments form the basis for "safe" levels for regulatory and enforcement action at EPA as well as state and federal agencies. This is the case even though they are not designed to look at actual risk or exposure. EPA's IRIS assessment suggests a "safe" level for formaldehyde in a range that defies reality - in the same ballpark as the amount of formaldehyde in exhaled human breath, and well *below* levels that exist in outdoor air, our homes, or background levels in nature. This assessment is also out of step with the rest of the world like the European Union, which recently reviewed the science on formaldehyde and established workplace standards.

If EPA continues down this path, the impacts will be far-reaching. It could unnecessarily cause unjustified public alarm and lead to inaccurate risk assessment and risk management decisions. EPA regulatory decisions based on a faulty IRIS assessment could result in nationwide bans, unachievable workplace standards, litigation and enforcement actions that result in massive job losses and billions of dollars of cost. Ultimately, this could significantly threaten the availability of formaldehyde and formaldehyde-based products in the U.S.

Q7. Regarding the Integrated Risk Information System (IRIS), we've heard concerns about levels it has issued for some of the chemicals we discussed at the hearing.

a) Is the concern just limited to ethylene oxide and formaldehyde?

b) Are there other concerns with how the IRIS program develops its information and the potential impacts to the availability of important automotive, building and construction and medical devices?

EPA's IRIS Program has been plagued with challenges for decades and continues to be identified by the Government Accountability Office as a high-risk program which needs attention by the executive branch and Congress. IRIS assessments have significant, real-world implications for

industry and the public when they are used to inform regulatory decision-making. Despite some modest reforms, the IRIS Program continues to lack transparency, minimizes or excludes high quality, relevant information, and defaults to selecting the most extreme policy option when faced with scientific choices. The result is overly conservative assessments that are out of step with peer reviewed literature, state agencies and other global assessments.

This is true for ethylene oxide and formaldehyde but also for a myriad of other chemicals that have been reviewed or are currently under review by EPA. For example, ongoing assessments include (but are not limited to), ethylbenzene (used in automotive and aviation fuels as well as to make polymers, and paints), chromium VI (used in the development of pigments, metal finishing and chrome plating, and stainless steel production), chloroform (used in the building and construction, and paper industries), and cobalt/cobalt compounds and vanadium/vanadium compounds (which have uses in medical devices, such as dental and orthopedic implants). If the IRIS Program continues to ignore the best available science and take an extreme, overly conservative approach to developing assessments, we can expect to see unwarranted and non-risk based IRIS levels influence future emissions standards, the availability of key automobile components, the availability and disposal of building materials, and the availability of medical devices.

Q8. The U.S. government considers the chemical sector and its supply chain to be a part of our critical infrastructure.

Q9. Would you describe for me the different parts of this multi-faceted sector, including upstream bulk manufacturers, specialty and batch producers, chemical processors and distributors, and users of these chemicals to make products?

Upstream bulk manufacturers operate with economies of scale using continuous processes, where raw materials are continually fed into a process and finished product is removed. These producers generally make large quantities of homogeneous molecules that are usually building blocks for other chemical or plastics manufacturing.

Downstream specialty chemical producers operate either on a continuous basis or via batch manufacturing, where a product is produced in a separate quantity, often with specific characteristics. Specialty chemicals are generally produced in smaller quantities (compared to upstream bulk chemicals) and are produced for their unique functional properties.

A critical node in the chemical supply chain, chemical distributors purchase inventory from chemical manufacturers to resell to downstream customers. They may repackage chemical products into smaller units.

The universe of chemical users is large and diverse.

- Some purchasers of chemicals use them as raw materials to produce other chemicals and/or plastics.
- Some purchasers use chemicals to produce finished manufactured products (i.e., fire resistant electrical cable) that require the properties or characteristics of that chemical.
- Some purchasers use chemicals in a process (i.e., metal cleaning) and the chemicals do not end up in the final product.

Q10. This Committee is very concerned about the loss of a serious domestic sterilization capacity in this country for medical devices. But that is not the only use of ethylene oxide.

a) Would you please explain the other uses that might be lost if ethylene oxide's use was phased out in this country?

In North America, approximately 69% of ethylene oxide (EO) manufactured is used to produce ethylene glycols. Ethoxylates consume approximately 15% of EO production followed by ethanolamines (9%) and glycol ethers (3%). Sterilization uses consume 1-2% of EO production. The downstream chemicals are used to manufacture countless everyday products – all derived in part from EO. EO plays an important role in the development of batteries for electric vehicles and is used to support agriculture as well as the oil and gas industry. It is used to make household cleaners and personal care items, create fabrics, and manufacture raw materials into more useful forms. Examples include:

- **Electric Batteries**: Ethylene oxide is used to produce ethylene carbonate, which is used in lithium-ion batteries to allow the electricity generated to travel more easily through the battery.
- **Medical Applications**: Ethylene oxide derivatives are utilized for medicinal tableting, medical coatings, medical films, solvents, or aids in the production of pharmaceuticals and vaccines. For example, some EO-based ingredients are used in eye drops, Hepatitis B treatment, or to clean wounds.
- **Oil and Gas**: Ethylene oxide derivatives are used in natural gas purification to reduce corrosion and scale in oil and gas processing, oil well remediation, enhanced oil recovery aids, freeze protection for finished goods, gas dehydration, and carbon capture in gas processing, which ultimately helps enable the energy transition. Using ethylene oxide-based compounds allows for faster drilling and completion of oil and gas wells which helps to lower the overall cost of petroleum products and reduce the frequency of replacing equipment and pipelines.
- **Cleaning**: Ethylene oxide-based surfactants are the workhorse of the cleaning industry. EO-based surfactants are key ingredients in many cleaners used in hospitals, cafeterias, hotels, restaurants, and transportation cleaning. Ethylene oxide derivatives include alcohol ethoxylates, alcohol ether sulfates, and polyethylene glycols. They are key active ingredients in most cleaning products in home care such as all-purpose cleaners, glass/window care cleaners, laundry detergents, hard surface cleaners, dishwashing detergents, degreasers, floor polishes, and stain removers.
- **Agriculture:** Ethylene oxide and its derivatives are utilized to produce a wide variety of active ingredients, used in insecticides, pesticides, and herbicides. Each active ingredient targets specific needs for the agricultural industry – helping to protect crops and boost crop production.
- **Semiconductors:** A major role of ethylene oxide is in the production of a wide variety of solvents, amines, and surfactants used in semiconductor chip manufacturing processes like wafer cutting, chemical mechanical planarization, photoresist, and photoresist residue cleaner. Each product targets specific needs for the semiconductor industry – crucial to the technologies of today and tomorrow, including aerospace, automotive, cloud computing, medical devices, telecommunications, and more.

- **Building and Construction:** Ethylene oxide and its derivatives are used in architectural coatings, asphalt & cement additives, automotive & architectural glass, commercial & residential roofing, drainage aids, epoxy curing agents, metalworking fluids, polyurethanes, solvents, textiles & textile additives, wood & water treatments.
- **Transportation:** Ethylene oxide and its derivatives are used in automotive seating, hydraulic & brake fluids, jet fuel anti-icing additives, motor vehicle antifreezes, noise & vibration reduction products, and electric vehicle batteries.
- **Health & Safety:** Ethylene oxide and its derivatives are used in fungicides, medical sterilants, and safety glass.
- **Manufacturing Applications:** Ethylene oxide and its derivatives are used in cement & glass grinding lubricants, heat transfer materials & fluids, hydrocarbon purification, metal and industrial cleaning, mineral processing, natural gas & oil products, paper additives, rubber & polymer manufacturing, semiconductors, and other lubricants.
- **Downstream Products:** Ethylene oxide and its derivatives are used in adhesives, paints, inks, agrochemicals & oil seed, appliance insulation, bleach activators, carpet backing & furniture cushioning, detergents, cleaners, fabric softeners, dry cleaning products, freeze point lowering solutions, packing films & bottles, personal care products and photographic chemicals.

All these uses and products would be impacted and possibly restricted should ethylene oxide be phased out in the US. The potential for a major market disruption is significant.

Q11. The PFAS class of chemicals gets a great deal of attention. I believe EPA now lists more than 14,000 different substances in this class, but EPA understands the health effects of only a fraction of that number.

a) Is this class of chemicals unique or similar, like on bioaccumulation?
b) Is it appropriate to treat all these chemicals the same in order to streamline their regulation?

No, it is not scientifically accurate or appropriate to group this family of solid, liquid, and gaseous substances into a one-size-fits-all class.

According to EPA, "approximately 600 PFAS are manufactured (including imported) and/or used in the United States." Among these 600 are substances in the solid (e.g., fluoropolymers), liquid (e.g., fluorotelomer alcohols) and gaseous (e.g., hydrofluorocarbon refrigerants) forms. The fundamental physical, chemical, and biological properties of solids, liquids and gases are clearly different from one another, and it is possible to make additional distinctions among the PFAS in each of those groups. PFAS are a highly variable group of chemistries, and an overly simple grouping approach to risk assessment or management would be inadequate.

In a published peer review conducted by a panel of experts, most agreed that all PFAS should not be grouped together for risk assessment purposes. Most experts also agreed that it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS.

EPA's PFAS Strategic Roadmap and National PFAS Testing Strategy also recognize distinctions within the broad class of PFAS and describe actions the agency will take to gather information on sub-categories within the broader class.

Furthermore, a scientific consensus is emerging that it is not accurate or even possible to group all PFAS chemistries together for the purpose of regulation. Indeed, state, federal and international entities that have explored the possibilities of a class-based approach have recognized significant challenges.

For instance:

- The Organisation for Economic Co-operation and Development (OECD) issued a report saying, "As PFASs are a chemical class with diverse molecular structures and physical, chemical and biological properties, it is highly recommended that such diversity be properly recognized and communicated in a clear, specific and descriptive manner."
- ECOS – the Environmental Council of the States – which represents state and territorial environmental agency leaders, several of whom have implemented regulatory programs in their home states, has said: "Many regulators and subject-matter experts advise against grouping PFAS as an entire class."
- The Vermont Department of Environmental Conservation, which was specifically charged by the legislature to develop a class regulation or to explain why such a regulation wasn't possible said, "The Review Team spent over a year deliberating, researching, and discussing the potential to regulate PFAS as a Class. After reviewing the current peer-reviewed literature, as well as the available toxicology data for PFAS, the Review Team determined that at the current time it is not feasible to regulate PFAS as a Class."
- And federal scientists participating in a workshop convened by the National Academies of Science, Engineering, and Medicine (NASEM) to review the federal PFAS research program acknowledged the broad diversity of properties with this group of substances, concluding that "PFAS substances thus present unique challenges for grouping into classes for risk assessment."

c) Does ACC believe it is a valid scientific practice to regulate 14,000 different chemicals based on what is known about just a few members of this class?

No, as noted above, ACC and others disagree with a single class-based approach to the regulation of chemicals. This approach is neither scientifically accurate, nor appropriate. While we disagree with a single class based approach to PFAS regulation, we have long been on record that a subgrouping approach -- where the grouping of some substances within a class, based on similar physical, chemical, and biological properties -- may be possible.

d) What uses would suffer the most if PFAS as a class was largely removed from commercial use in the United States?

PFAS are a diverse universe of chemistries that are essential to modern life. They provide commercial, industrial, and consumer products with strength, durability, stability, and resilience.

Their properties can be critical to the reliable and safe function of a broad range of products that are important for industry and consumers, including renewable energy, electronics, healthcare technology, pharmaceuticals, and air and ground transportation.

PFAS chemistries are also key to the resiliency of our nation's critical supply chains, including semiconductors, cable coatings, building materials, fuel cell and lithium-ion battery technologies,

and much more. Critically, the Department of Defense's (DoD) recently released "Report on Critical Per- and Polyfluoroalkyl Substance (PFAS) Uses" documents the critical role PFAS chemistries serve in the defense of our nation. According to DoD:

> *Congress and the Federal regulatory agencies should avoid taking a broad, purely 'structural' approach to restricting or banning PFAS. It is critical that future laws and regulations consider and balance the range of environmental and health risks associated with different individual PFAS, their essentiality to the U.S. economy and society, and the availability of viable alternatives… "PFAS are critical to DoD mission success and readiness and to many national sectors of critical infrastructure, including information technology, critical manufacturing, health care, renewable energy, and transportation. DoD relies on an innovative, diverse U.S. industrial economy. Most... PFAS are critical to the national security of the United States.*

Q12. Sometimes EPA regulations place manufacturers in a horrible position when they try to make important items, like chlorine. EPA is trying to ban asbestos under section 6 of the Toxic Substances Control Act.

a) If EPA is successful in removing this use of asbestos, what will be the replacement substance for making chlorine?

Alternative membrane or non-asbestos diaphragms for making chlorine are likely fluoropolymers.

b) If that replacement substance, PFAS, is also eliminated or discouraged by EPA regulations, what is the next best way to make chlorine?

As of now, we are not aware of a widely recognized substitute for the materials used in the chlor-alkali process beyond alternatives like fluoropolymers.

c) Since there really is not a non-asbestos, non-PFAS option to making chlorine, what other chemicals could be used to disinfect drinking water and sterilize hospitals?

While chlorine derived from the chlor-alkali process has been a longstanding and proven solution for disinfecting drinking water and sterilization in hospitals, there is a diverse range of disinfection technologies available. Chlorine-based products, such as sodium hypochlorite, have a strong track record of effectively eliminating pathogens and helping ensure water safety. However, alternative disinfection methods exist, including ultraviolet (UV) irradiation, ozone, hydrogen peroxide, and peracetic acid. Each of these options has its own merits, and their suitability depends on specific application requirements, regulatory considerations, and desired outcomes. Additionally, chlorine-based compounds are preferred for residual disinfection of drinking water, maintaining a low concentration of disinfectant in treated water. This is a crucial aspect of water treatment, creating a sustained barrier against potential pathogens even after the initial treatment process. The choice of disinfection method and the level of residual disinfection are critical factors in achieving and maintaining water quality standards. Finally, other publicly beneficial uses of chlorine-based products, including medicine, pesticides, paper production and more, will also be challenging to replace with equivalent alternatives.

Q13. People like to use the term "science" as justification for policy choices.

a) Can you describe the difference between a science consideration and a policy choice when it comes to regulation?

EPA itself describes the terms "science" and "scientific" as "expansive terms that refer to the full spectrum of scientific endeavors, e.g., basic science, applied science, engineering, technology, economics, social sciences, and statistics."[1] Science provides measurements and methods to assess risk, including consideration of uncertainty and variability.

Policy choices typically weigh pure science along with other considerations, such as risk tolerance, feasibility, availability of information, and national security concerns, among others. Policy addresses what level of risk is reasonable or acceptable. When agencies rely on questionable science, they undermine public confidence in government decision-making. This can lead to unwarranted restrictions or product de-selection, unfounded public alarm and unnecessary costs for consumers and businesses. Government policy must require that regulators' decisions are risk-based, based on the best available science, incorporate a weight of the evidence approach to evaluating data, consider research integrity, and ensure that studies have undergone a balanced peer review.

b) Please give me some examples where science has been exaggerated as a consideration to cover for policy choices.

We understand this question to be asking for examples of where risk has been exaggerated. Both under- and overestimation of risk have consequences. Overestimating risk can lead to policy decisions to overregulate chemicals that are safe for use, which can lead to other negative impacts. Two examples are highlighted below.

Formaldehyde is one of the most studied chemicals in use today and more than 40 years of advanced science and practical experience demonstrate that there is a safe exposure level. Federal agencies, including the Food and Drug Administration, the Occupational Safety and Health Administration, the Department of Housing and Urban Development, the Consumer Product Safety Commission, and agencies across the world have found that it is safe in a variety of applications. However, the 2022 draft IRIS assessment sets an "acceptable exposure limit" significantly lower (up to 4,000 times) than that set by the European Union, which incorporated studies published over the last 30 years in their recent EU assessment. If EPA uses the draft IRIS assessment to set new formaldehyde regulations employing such low exposure limits, the negative impact on vital industry sectors, plus the health and safety of critical food products, could send ripple effects across the U.S. economy.

Ethylene oxide is another versatile and valuable compound that's used to help make countless everyday products, including household cleaners personal care items, fabrics, and it also has a critical use in the sterilization of medical equipment, including the sterilization of personal protective equipment used by doctors and hospitals across the country. Unfortunately, a significantly flawed assessment that was generated by EPA's IRIS program in 2016 is causing unnecessary alarm and grossly misstates ethylene oxide's potential impact on public health. The IRIS program has dramatically overestimated the hazard of ethylene oxide and set "safe" levels far below levels found in our environment, lower than the normal, naturally-created levels of

[1] U.S. EPA Scientific Integrity Policy at 2.

ethylene oxide in the human body and orders of magnitude lower than levels of ethylene oxide from other sources measured in ambient air. This IRIS value is being used to underlie several new EPA proposed air regulations for the chemical sector, commercial sterilization and pesticide uses. ACC and others have detailed the severe science-based flaws with the IRIS value that resulted in an overly conservative value that is below background levels of ethylene oxide. Notably, the Texas Commission on Environmental Quality (TCEQ) identified several flaws underlying EPA's conclusions, and after conducting its own analysis, TCEQ's peer-reviewed assessment concluded that the risk of ethylene oxide is 4,000 times lower than what the IRIS program identified. Unfortunately, to date, EPA has ignored or failed to provide a meaningful response to the core, scientific, and substantive issues that have been raised with the development of the IRIS assessment. The results of using this IRIS value is leading to overly conservative regulations on ethylene oxide that could threaten access to products ranging from electric vehicle batteries to sterilized medical equipment.

Q14. There has been a huge push, in the name of cleaning up plastic litter, to eliminate plastic production and use here in America. EPA has taken an aggressive posture on plastic production and use through TSCA, RCRA, and even its work with the Federal Trade Commission's Green Guides.

a) Could you please provide feedback on these efforts and the point you made in your testimony about eliminating items we really need as a modern society?

Plastic is an extraordinary innovation that has made modern life possible and plays an essential role in food safety, medicine, renewable energy, transportation and inside your home. Plastic is also critical to reducing carbon emissions and combating climate change.

Today's cars on average are made of about 50 percent plastic by volume but only 10 percent by weight. The increased fuel efficiency from using plastics reduces vehicle emissions and saves drivers money at the pump. Plastic packaging helps to dramatically extend the shelf life of fresh foods and beverages while allowing us to ship more product with less packaging material—reducing both food and packaging waste. Plastic insulation, sealants, and other building products are making our homes significantly more energy efficient, while reducing costs for heating and cooling. And plastics are fundamental to drug delivery devices, needle free injections and longer-lasting medical equipment.

The federal government plays a key role in combating plastic pollution, and ACC views the federal government as a partner in making plastics more sustainable, addressing microplastics and plastic pellets, and confronting other significant environmental challenges. However, we disagree when the federal government's approach to curbing plastic pollution includes tactics designed to limit domestic production and use. Plastic is often chosen for many of the above-referenced applications because it is the sustainable choice: you can do more with less material. For example, plastic packaging has been shown to increase the shelf life of cucumbers from 3 to 14 days, lettuce from 2 – 4 to 14 days, fresh red meat from 2 – 3 to 21 days, fresh pasta from 3 to 60 days, and cheese from 7 to 180 days.[2]

[2] Todd Bukowski and Michael Richmond, "A Holistic View of the Role of Flexible Packaging in a Sustainable World," Industry report (Flexible Packaging Association, April 9, 2018), https://perfectpackaging.org/wp-content/uploads/2018/09/FPA-Holistic-View-of-Sustainable-Packaging.pdf.

Regulations that cause or result in material substitution could raise costs for consumers and have worse environmental impacts than the plastics being deselected.[3] For example:

- As a result of their lightweight properties and lower energy requirements, PET bottles produce lower emissions compared to common alternatives.
- The GHG emissions from metal cans are three times higher than those from multilayer plastic pouches.
- The GHG emissions from reusable plastic bottles of hand soap are reported as 15 percent lower than those from reusable glass bottles.
- The use of plastic packaging for meat preservation reduces GHG emissions by 35 percent compared to butcher paper.

Instead, ACC has called on Congress to take steps to address plastic waste while boosting domestic manufacturing. ACC's "5 Actions for Sustainable Change" is a comprehensive approach towards ending plastic waste, boosting circularity, and creating a stronger domestic recycling infrastructure. The "5 Actions" increases the likelihood of more materials being recycled, getting us all closer to the EPA's goal of increasing the U.S. recycling rate. We would be happy to talk more with you about our legislative proposals and our industry's commitment to ending plastic waste.

Q15. Does it make sense for your members to have a regulator that seems driven to regulate their practices based solely upon stringency?

No, it doesn't make sense for anyone to have overly stringent regulations that exclude important, relevant factors, like the best available and most relevant science. Regulators should regulate to the point of safety, taking other factors into consideration.

a) Is regulating to background or below background level sustainable?

Regulating to below background level is almost always deeply flawed or impossible. What is important is regulation to safe levels, and background levels are not necessarily the only safe level. Regulating to background levels would only be justified in extraordinary cases and the tradeoffs must be considered.

b) What about efforts by regulators to insist companies achieve levels more stringent than what the law and agency regulations require?

A core regulatory principle is to avoid overregulating and the creation of unnecessary regulatory burden. Regulations are designed and informed by notice and comment to help ensure that burden is minimized and the agency has taken an appropriately considered path.

Q16. Should environmental regulations balance societal, environmental, and economic considerations?

[3] David Feber et al., "Climate Impact of Plastics," Industry report (McKinsey & Company, July 2022), https://www.mckinsey.com/industries/chemicals/our-insights/Climate-impact-of-plastics.

Yes, environmental regulations, like any regulations, must take into account a suite of other factors, including consideration of public health and innovation. It is impossible to ensure zero risk, and this must be balanced against tradeoffs. As a matter of fact, TSCA recognizes this in Section 2:

> (3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.[4]

Q17. In recent years we've seen a lot of talk about onshoring supply chains for products like semiconductors, automotive goods, and raw materials.

a) **Why are chemicals important to these efforts?**
b) **How does overregulation impact that?**

From manufacturing of computer chips and electric vehicles (EVs), to producing clean energy, rebuilding the country's infrastructure, power delivery, national security, and healthcare and biotechnology all depend on the innovations produced by America's chemical industry. The U.S. chemical industry manufactures essential innovative inputs that go into building and construction materials to computers, electronics, healthcare, and clean energy solutions including EVs, wind turbines, solar panels, and replacements for ozone-depleting substances. But there's been a recent surge in overregulation. Some of these regulations would unnecessarily ban certain chemistries or regulate them at such low levels that manufacturing becomes virtually impossible. All of this hinders the chemical industry's ability to innovate, grow and create products and it jeopardizes our national priorities, our economy, and America's ability to compete with countries like China. Overregulation can disrupt the supply chain for crucial technologies and everyday products.

Q18. America is largely reliant on China for rare earth materials to make things like EV batteries and solar panels.

a) **Is this also true for chemicals?**

China's market share of the global industry is more than three times that of the U.S. and China has significant capacity coming online. Keep in mind this production is manufactured with far different environmental and worker and consumer safety standards than America has.

Most worrisome should be goods where China exercises considerable market power. For the following chemicals and chemical products traded in international markets, China had a near dominant share of world trade (>75%) in 2021:

Products Where China Has the Highest Global Trade Share, 2021.

HS Code	*Product Name*	*Global Trade Share*
293137	Methyl phosphonate	99.7%

[4] 15 U.S.C. § 2601.

292424	Ethinamate	99.7%
290436	Perfluorooctane sulfonyl fluoride	98.0%
290373	Dichlorofluoroethanes	97.2%
300341	Medicaments containing ephedrine	94.3%
294140	Antibiotics: Chloramphenicol	92.8%
293352	Barbituric acid	89.3%
290372	Dichlorotrifluoroethanes	89.1%
360410	Fireworks	89.0%
382474	Hydrochlorofluorocarbons (HCFCs), excluding CFCs	88.9%
290374	Chlorodifluoroethanes	85.0%
293133	Diethyl ethylphosphonate	84.9%
290715	Naphthols	84.4%
291634	Phenylacetic acid	83.6%
291462	Coenzyme Q10	82.8%
281640	Strontium and Barium oxides, hydroxides, peroxides	82.4%
292024	Triethyl phosphite	81.7%
282710	Ammonium chloride	81.5%
290551	Ethchlorvynol	78.1%
392640	Plastic Statuettes/Ornamental articles	76.2%
292221	Aminohydroxynaphthalenesulfonic acids	76.1%
293625	Vitamin B6	75.4%

Q19. How are the regulatory challenges your industry is facing today different than what you faced in previous Administrations?

We find that the number of major rules in the queue impacting our industry is the highest we have seen this century, based on a review of the Semi-Annual Agenda of Regulatory and De-Regulatory Actions issued at the midpoint of a president's first term. See table:

Chemical Manufacturing Is in the Crosshairs

President	*Date of Regulatory Agenda*	*Number of Rules in the Queue*		
		Economically Significant or 3f1 Significant	*Significant*	*Nonsignificant*
Bush 43	Spring 2003	1	15	40
Obama	Spring 2011	1	27	29
Trump	Spring 2019	0	16	14
Biden	Spring 2023	9	21	21

Source: ACC analysis of the *Unified Regulatory Agenda of Regulatory and De-Regulatory Actions.*

Q20. In your testimony you talked about how EPA's new chemicals program is standing in the way of innovation.

a) Can you elaborate on what you see as the challenges with the EPA's new chemicals program?

Current challenges with EPA's New Chemicals program include the inability to meet statutory deadlines, refusal to use industry-submitted data in favor of default models, lack of consistency in reviews and in decisions, lack of transparency into the Agency processes, lack of sufficient standard operating procedures (SOPs)/Guidance, and high staff turnover.

Additionally, the Existing Chemicals program can also affect innovation by impacting access to critical supply chain chemistries that are necessary to support the innovation of new chemicals. This can have impacts beyond the chemical industry into supply chains regulated under other regulatory authorities.

b) Is merely giving the program more resources and/or making administrative changes the way to fix it?

Providing EPA more resources or making modest administrative changes (e.g., more money and staffing) is not a sustainable or long-term fix to the program. A comprehensive plan to reform

agency processes to ensure the New Chemicals program meets its obligation to complete reviews within 90 days should be developed. This should include how it will enhance communication with manufacturers, update its processes to be transparent and objective, ensure relevant supporting documents from companies are reviewed and adequately considered in a timely manner, and ensure that relevant information from actual use and exposures is considered and incorporated based on the best available scientific practices and approaches.
The plan should also include how the agency is using current resources to address priority areas of concern and how any new resources would be deployed to meet the program's goals and statutory mandates.

Q21. EPA has recently released four risk management proposals under its TSCA program, where it identifies workplace chemical protection programs with levels that are significantly lower than other federal agencies like OSHA or global standards.

a) Why do you believe EPA's numbers are different than other federal agencies that have historically developed workplace exposure levels?

EPA is actively disregarding actual conditions of use in their risk evaluations, this includes a lack of appropriate consideration of industrial hygiene practices and use of personal protective equipment (PPE). This is yielding unreasonable risk determinations that might not otherwise have been reached, resulting in unduly restrictive and exceeding low occupational exposure limits (OELs).

The OELs are different because EPA is not adhering to established methods in the field of industrial hygiene, and stacking uncertainties that overestimate risk and drive overly stringent numbers.

b) How does worker personal protective equipment get factored into the equation?

The statute is clear that EPA must consider actual conditions of use, including for workers. EPA must consider common practices, often mandated by law, but EPA is not doing this for TSCA risk evaluations. Instead of looking at actual workplace conditions and requirements, EPA is assuming that workplace requirements and protocols to use PPE, including PPE required by other federal statutes, are not actually being used in the workplace. Acknowledging conditions of use that incorporate existing industrial hygiene protective measures, such as engineering controls and PPE, must be a key component of the risk evaluation process. EPA cannot and should not ignore, undervalue, or undermine worker protection practices in TSCA risk determinations and risk management actions.

Q22. Good, high quality agency science, peer review by experts and input by the public are key elements in developing sound EPA regulations. Recently the industry has expressed concern over EPA's use of the IRIS value for ethylene oxide for several proposed air regulations.

a) What is ACC's main concern with the ethylene oxide IRIS value and how is it impacting critical product applications and uses?

ACC identified numerous errors and problems with IRIS' analysis of EO, but the primary flaws are based on:

- A technically incorrect model was selected and applied; EPA's selected model predicts higher cancer risk based on low exposures to EO and a lower risk of cancer based on higher exposures.
- There were multiple flaws in the EPA analysis. EPA ignored data on historical worker exposures prior to 1978 and made simple statistical errors. It also ignored basic reality checks. For example, the IRIS value is orders of magnitude below EO levels measured in ambient air and levels produced by the human body.
- Inadequate and misleading information was used and supplied to EPA's SAB review panel on multiple issues, including inaccurate data on the "background" levels of EO in ambient air.

Furthermore, the IRIS value was undercut by the peer reviewed health assessment prepared by the Texas Commission on Environmental Quality, which found numerous flaws in the methodology used by EPA in the EO IRIS assessment and determined the chronic toxicity value to be 4,000 times higher than the IRIS value. The use of the IRIS value as a regulatory exposure level is both a misuse of an IRIS value and a gross overestimation of the actual exposure risk from EO. Ethylene oxide production could be substantially impacted by the imposition of unnecessary stringent control technology requirements that provide little or no reduction in risk. The manufacture of downstream products using EO could be severely disrupted if these stringent requirements are imposed.

Additionally, the use of IRIS values in enforcement actions could have a substantial impact on many businesses in the United States. If the use of IRIS as a basis for enforcement is upheld, companies will understand that they can be found liable for causing imminent and substantial endangerment on the basis of a theoretical hazard assessment that has not undergone judicial review nor formal notice and comment.

Q23. We've heard a lot about PFAS and negative health impacts. How do you respond to those who think PFAS chemicals should be banned or restricted?

All PFAS are not the same, and it is not scientifically accurate or appropriate to consider them all a safety risk. Individual chemistries have their own unique properties and uses, as well as environmental and health profiles. Individual PFAS profiles vary significantly across the broad family of chemistries. Some PFAS are extremely large polymers, while others are small molecules that may move more easily through the environment. Some PFAS are solids (e.g., fluoropolymers), some are liquids (e.g., fluorotelomer alcohols), and some are gases (e.g., hydrofluorocarbon refrigerants). The fundamental physical, chemical, and biological properties of solids, liquids, and gases are clearly different from one another and demonstrate how a simple grouping approach to risk would be inadequate.

Furthermore, there is increased recognition by scientists and policymakers that you cannot group all PFAS chemistries together for the purposes of regulation (Read more here).

Multiple major manufacturers voluntarily joined EPA's PFOA Stewardship Program, committing to cease the manufacture and use of PFOA-related chemicals by 2015. They invested more than $700 million in research and development and also agreed that new PFAS chemistries would undergo enhanced regulatory review before being permitted on the market. PFOS manufacturing was voluntarily ceased in the United States in 2002.

Alternatives to PFOS and PFOA have been thoroughly reviewed by regulators prior to introduction into commerce, are subject to ongoing review, and are supported by a robust body of health and safety data. PFAS chemistries are being regulated at the state and federal levels, including through the actions described in EPA's PFAS Strategic Roadmap.

The industry is dedicated to the responsible production, use, and management of PFAS chemistries in a manner that protects public health and our environment. The manufacturers of PFAS chemistries are employing practices and technologies to minimize environmental emissions every day.

Q24. Established under the Clean Air Act, the Risk Management Plan (RMP) rule is one of many federal programs that regulates chemical safety. For years, EPA has pursued a collaborative and performance-driven approach, which has been fundamental in its success and helped drive down chemical related incidents by more than 80%. Despite this success, EPA is proposing changes that threaten to undermine the program's progress and create problems rather than solving them.

a) What are your major concerns with EPA's proposed changes?

ACC and our members are committed to safe operations, and our Responsible Care program's Process Safety Code sets forth this collective commitment to a culture of process safety throughout chemical facility processing operations, management systems, and leadership organizations. We have several significant concerns with EPA's proposed changes to the RMP regulations, as laid out in the Safer Communities by Chemical Accident Prevention (SCCAP) proposed rule. We believe these provisions either do not improve or are actively detrimental to the agency's goals of improving the safety of fenceline communities.

Information sharing provisions

ACC is concerned that EPA's expanded information sharing requirement could pose a national security threat by creating opportunities for a terrorist or other bad actor to use sensitive information to target a facility or disrupt responses to emergencies.

Upon request by any member of the public residing within six miles of a covered facility, owners and operator would be required to provide a large amount of detailed information. This would include information on the regulated substances (including the name and safety data sheet (SDS) of all covered chemicals), a five-year accident history, and information on the emergency response program for the facility.

First, it is important to understand that the public already has access to risk management plans. Risk management plans can be viewed in Federal Government reading rooms, obtained from state or local government officials with access, or requested from EPA under FOIA.

With regards to the emergency response program, EPA's proposed requirements would be duplicative of other statues, including the Emergency Planning and Community Right-to-Know Act (EPCRA).[5] Under EPCRA, facilities are required to report on the storage, use, and releases of certain chemicals to federal, state, and/or local governments. These reports are then used to prepare for and protect communities from potential risks. EPCRA also establishes Local Emergency Planning Committees (LEPCs), which are responsible for developing an emergency response plan and providing information about chemicals in the community to citizens. Any

[5] 42 U.S.C. § 11001 et seq.

requirements developed for community emergency response should not be duplicative of EPCRA.

Easy access to information on the names and SDSs of regulated substances conflicts with Congressional intent to protect facility-security related information from being widely disseminated. The Chemical Safety, Information, Site Security and Fuels Regulatory Relief Act (CSISSFRRA) was established to address national security concerns for posting databases of Offsite Consequence Analysis (OCA) data.[6] The Department of Justice (DOJ) has acknowledged that certain OCA data "represents information that would provide a would-be perpetrator with refined targeting information, making it possible for him or her to select a facility from which a chemical release would cause the greatest damage, both to humans and the surrounding environment.[7]" In addition, more than 300 RMP-regulated chemical substances are included in the CFATS Appendix A (List of Chemicals of Concern) for posing a terrorism-related risk.

The name of a chemical and its specific hazard information as listed on an SDS may be too security-sensitive to be shared broadly with the public. The SDS, in particular, may highlight chemical properties that could be exploited in the wrong hands. ACC believes that EPA's approach threatens to remove safeguards on highly sensitive chemical and facility security information. EPA should rely on existing programs, such as those under EPCRA, that are designed to curate emergency information for safe public consumption.

Safer Technology Alternatives Assessment (STAA) Provisions

ACC is concerned that that EPA's proposed Safer Technology and Alternative Assessment (STAA) requirement is unwarranted and unduly burdensome.

Under the proposed rule, covered stationary sources would have to consider and document safer technology and alternative risk management measures applicable to eliminating or reducing risk from process hazards. This STAA analysis would need to consider inherently safer technology (IST) or inherently safer design (ISD).

The proposed rule estimates this provision will cost $51.8M annually, using a 3% discount rate – by far the largest annualized cost laid out in the SCCAP. Notably, this is not the cost to *implement* the results of such an analysis – rather, it is the cost only to *conduct* the analysis. EPA does not propose that owners and operators implement the results of a STAA analysis as part of the SCCAP proposal.

Despite the significant cost of such a provision, EPA has not provided adequate justification for why the STAA provision is necessary, or how the STAA provision would improve process safety. Over two decades of regulatory history, EPA has repeatedly evaluated the need for an IST provision in the RMP rule and has repeatedly decided that such a provision is not needed.[8]

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[6] Chemical Safety Information, Site Security and Fuels Regulatory Relief Act, (CSISSFRA), 42 U.S.C. § 7401, note (Pub. L. 106-40, Aug. 5, 1999).

[7] Department of Justice, Assessment of the Increased Risk of Terrorist or Other Criminal Activity Associated with Posting Off-Site Consequence Analysis Information on the Internet (2000) at 33-34 (DOJ Report).

[8] EPA, Risk Management Programs for Chemical Accidental Release Prevention, 58 Fed. Reg. 54190 (Oct. 20, 1993); EPA, Accidental Release Prevention Requirements; Risk Management Programs Under Clean Air Act Section 112(r)(7), 60 Fed. Reg. 13526, 13534-35 (Mar. 13, 1995); EPA, Accidental Release Prevention Requirements: Risk Management Programs Under Clean Air Act Section 112 (r)(7), 61 Fed. Reg. 31688, 31674 (June 20, 1996); EPA, Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, 84 Fed. Reg. 69834, 69852 (Dec. 19, 2019). EPA found that the cost savings from repeal of the STAA provisions would come to $70 million annually. Id. at 69839.

Congress similarly considered and rejected an IST requirement for the CFATS regulation and prohibited DHS from considering it.

Following an analysis of states which have implemented a STAA provision in their state-level regulations, the agency has been unable to determine if the STAA provisions will provide any benefit to preventing RMP-reportable incidents. Furthermore, the agency has not sufficiently considered the regulatory burden on small businesses and the added costs on products throughout the value chain.

Cost increases in the Final Rule

ACC is concerned that EPA intends to vastly increase the scope and cost of new RMP requirements, beyond what was included in the proposed rule.

EPA estimated that the total annualized cost to implement the provisions in the proposed SCCAP to be $75.8M (3% discount rate). However, EPA now estimates the total annualized cost of the final to be $257.2M (3% discount rate).[9] This is more than *three times* the cost estimates in the proposed rule and pushes this rule into "economically significant" territory as defined by the Office of Information and Regulatory Affairs (OIRA).[10] Economically significant rules require a more detailed assessment of the likely benefits and costs of the regulatory action, including a quantification of those effects, as well as a similar analysis of potentially effective and reasonably feasible alternatives.

ACC is concerned that stakeholders have not had the chance to review the additional regulatory requirements that drive this dramatic increase in cost. We strongly urge EPA to repropose the rule to solicit more information from the public.

b) Do you think EPA is heading in the right direction?

We do not believe that EPA's proposed changes to the RMP rule will be effective at improving workplace safety or safety to surrounding communities. ACC emphasizes that the existing RMP regulation is highly effective when correctly implemented and enforced. Based on EPA's own data, the number of incidents at RMP facilities has decreased more than 50% between 2007 and 2018. Of the estimated 1,650 NAICS code 325 chemical manufacturing facilities regulated under the RMP rule, nearly 76% have no accident history.[11] Furthermore, within the chemical manufacturing sector, only 5% of facilities account for more than half of incidents. This data indicates that EPA should take a more targeted approach to address risks at facilities responsible for the majority of incidents, rather than impose broad new requirements across the regulated community.

EPA must clearly demonstrate that the additional regulatory requirements proposed in the SCCAP would substantially reduce accidental risk, which it has not yet done. Instead of proposing complex, unnecessary regulatory mandates that do not improve the safety of workers

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[9] EPA Briefing, "Risk Management Program - Safer Communities by Chemical Accident Prevention - 2023 Final Rule;" September 2023.

[10] https://www.reginfo.gov/public/jsp/Utilities/faq.myjsp

[11] EPA, RMP Accidents 2004-2020 (Appendix A); Technical Background Document for Notice of Proposed Rulemaking: Risk Management Programs Under the Clean Air Act, Section 112(r)(7) Safer Communities by Chemical Accident Prevention, Docket EPA-HQ-OLEM-2022-0174, https://www.regulations.gov/document/EPAHQ-OLEM-2022-0174-0065.

or communities, EPA should focus its efforts on compliance assistance and enforcement, particularly for the 5% of facilities that make up the majority of RMP incidents.

c) Are there any improvements that EPA should make to RMP?

As stated above, EPA should take a more targeted approach, including compliance assistance and enforcement, to address the 5% of facilities that are causing the majority of the RMP-reportable incidents. We believe that is the most cost-effective and impactful way that EPA can improve the safety of workers and fenceline communities.

In addition, there are several provisions in the SCCAP that ACC supports and believes are likely to improve process safety. The first is the proposal to conduct a root cause analysis as part of an incident investigation for both catastrophic releases and those that could have reasonably resulted in a catastrophic release. We also support the proposed requirement for emergency response exercises with local responders and LEPCs to be conducted every ten years.

Q25. You've had some strong words in reacting to the Beyond Petrochemicals campaign launched by Michael Bloomberg last year. Can you elaborate?

American success relies on American chemistry. Attempts to shut down American chemical manufacturing are a losing bet and an insult to our industry's hard-working men and women, sending their essential jobs overseas and threatening America's leadership to innovate and compete with countries like China.

Blocking the development and use of chemicals that are vital to U.S. manufacturing capabilities will drive production offshore to international competitors who don't have the same high environmental and labor safety standards we do. In fact, if this administration and billionaire-backed NGOs really cared about the environment, they should be wanting us to manufacture more in America, not less.

We remain steadfast in our mission to create the products people around the world use and need every day while working to solve complex global sustainability challenges, reduce emissions, and develop climate solutions.

Q26. TSCA is built on the premise that EPA should only regulate "unreasonable risks", not *any* risks. Yet, I increasingly hear that EPA is using overly conservative assumptions that intentionally ignore the very things that make a risk "unreasonable." One possible explanation is that TSCA requires that the "unreasonable risk" EPA determines and regulates to avoid must be one that disregards "costs or other non-risk factors." EPA appears to read this requirement broadly, including preventing the consideration of risk trade-offs that might be incurred from disuse a chemical or the damages that might be incurred from its replacement. Practically speaking, it's a "ban first, exempt later" posture.

a) Has "unreasonable risk" under TSCA become too "unreasonable?

We recognize that the amended TSCA treats unreasonable risks as a health-only exercise in the risk evaluation stage. However, a risk assessment is only a risk assessment if it fully considers exposure. EPA is not entitled to make up its own facts. Where the facts are that there is substantial compliance, such as wearing PPE and ventilation practices, those cannot be

disregarded. Disregarding actual conditions of use across the board artificially inflates what might have been unreasonable risk to reasonable risk.

In the environmental health and safety context, regulable unreasonable risk is understood to mean substantial risk. At a minimum significant, not minimal, negligible or no risk. This is why, for example, determining that well-controlled, closed-loop systems present unreasonable risk is inappropriate. These scenarios under actual conditions of use generally present minimal, negligible, or approaching zero risk. Unreasonable risk must be more than identifiable or negligible. EPA's current approach is turning this on its head.

b) Do you think there are statutory improvements that could be made to TSCA, relating to "unreasonable risk," that would help avoid these misuses of it?

EPA has yet to complete a final risk management phase in a regulation, but we have significant concerns with the outcomes of some risk evaluations and proposed rules. The statute certainly could be amended to clarify that only serious, substantial, severe, ongoing human health or environmental risks are "unreasonable" and subject to risk management regulation. The statute could further clarify that minor, insignificant, or negligible risks cannot constitute unreasonable risk. That said, a thoughtful, science-based application of the statute that appropriately considers real-world exposures could be sufficient to yield more reasoned outcomes.

c) Do you think human health will still be adequately protected with this change?

The statute requires that EPA regulate uses that present unreasonable risk to the extent necessary that that the chemical no longer presents such risk and, therefore, is protective of human health.

Q27. Are systematic reviews more robust or rigorous than other scientific methods?

Yes, systematic reviews are generally considered more robust and rigorous than non-systematic narrative reviews. A systematic review is a literature review methodology employed specifically to summarize, critically evaluate, and synthesize a large body of evidence, including human, experimental animal, and mechanistic studies. Systematic review methods are highly detailed and developed and communicated *a priori* (i.e., before a review begins), facilitating consistency, transparency, and reproducibility.[12,13] For example, systematic review involves a detailed protocol, which many agencies and authors publish online prior to beginning the review. The protocol details the literature search strategy, the inclusion and exclusion criteria for selecting studies, how the methodological quality of studies will be evaluated and weighed in forming conclusions, and how the evidence will be synthesized (including strategies for considering conflicting and inconsistent findings within and across the lines of evidence). In a narrative review or "classic" weight of evidence analysis, methods tend to be less standardized, and there are no specific requirements for the methodology (e.g., quality evaluation) nor are there requirements for a protocol clearly documenting the methodology.[14] Overall, while scientific judgment is inherent in any

[12] Suter, G., Nichols, J., Lavoie, E., & Cormier, S. (2020). Systematic Review and Weight of Evidence Are Integral to Ecological and Human Health Assessments: They Need an Integrated Framework. *Integrated Environmental Assessment and Management,* 16(5), 718–728. https://doi.org/10.1002/ieam.4271

[13] WHO (World Health Organization). Framework for the use of systematic review in chemical risk assessment. World Health Organization; 2021. https://apps.who.int/iris/handle/10665/347876.

[14] Suter et al. (2020).

review, the systematic review methods provide full transparency of areas in which scientific judgment was exercised. Stakeholders are thus able to identify areas of disagreement in the review that may necessitate further study or discussion.[15]

There are varying frameworks available, but most echo similar key basic principles, particularly with respect to the identification and selection of literature. Differences emerge in certain aspects, however, particularly in how these frameworks assess methodological quality and bias in the scientific literature. Variation in specifics of a systematic review approach among different agencies is expected, fit-for-purpose approaches may be required to meet the needs of different programs and research.

Q28. Are the suggested scientific review methods validated that Dr. Woodruff suggested EPA use?

A bedrock principle for quality science is that it is reproducible, utilizes validated methods, is peer-reviewed, and meets standards for quality. Good science is agnostic to the source of funding. However, it is appropriate to disclose sources of funding and affiliations.

As noted in response to Question 27, systematic review facilitates comprehensive and transparent reviews, including a robust evaluation of the methodological quality and risk of bias in the studies included in the review. Critically, both EPA's IRIS and TSCA frameworks for systematic review do not include the funding source as a metric by which to evaluate a study's quality. While funding and other potential conflicts of interest are considered important to report, these evaluation frameworks do not "downgrade" a study's overall quality rating for having been conducted by industry. ACC supports the current frameworks' handling of perceived or actual conflict of interests in evaluating individual studies.

Dr. Woodruff's concerns about bias from funding sources align with the systematic review framework that she and her colleagues at UCSF developed in 2011, termed the Navigation Guide.[16] This framework has been used by some researchers, but no formal "validation" of this framework has been done by any US health or regulatory agency. The Navigation Guide includes a "conflict of interest" risk of bias domain. Effectively, this domain allows for a study reviewer to downgrade a study for overall quality based solely on perceived COI due to an "industry" funding source. If the study is supported by industry, it is automatically considered "high risk of bias" in that category. Low risk of bias is automatically assigned to studies funded by the government, non-profits, or academic grants funded by government, foundations and/or non-profit organizations. There is no further guidance on how to apply this criterion of assessment. As noted in a letter to the editor in response to a systematic review conducted using Navigation Guide,[17] in the absence of specific guidance for this metric, industry-funded studies can and sometimes are downgraded for "conflict of interest" regardless of any evidence that a conflict affected the study results. For example, in the systematic review Goodman and Lynch were responding to, there was a study which, despite being funded by an unrestricted grant with no apparent participation by the funders, was assigned a "high risk of bias" rating for the conflict-of-interest domain.

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[15] Lynch, H. N., Mundt, K. A., Pallapies, D., & Ricci, P. F. (2022). Lost in the woods: Finding our way back to the scientific method in systematic review. *Global Epidemiology*, *4*, 100093. https://doi.org/10.1016/j.gloepi.2022.100093

[16] Woodruff, T. J., & Sutton, P. (2014). The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. Environmental health perspectives, 122(10), 1007–1014. https://doi.org/10.1289/ehp.1307175

[17] Goodman, J. E., Lynch, H. N., & Beck, N. B. (2017). More clarity needed in the Navigation Guide systematic review framework. *Environment international*, *102*, 74–75. https://doi.org/10.1016/j.envint.2017.01.011

It also is problematic to assume that certain funding sources guarantee a study is "free" of bias. Every author has potential bias, and any funding source could potentially influence study results. Academic researchers are motivated to find and report statistically significant findings, in this case, an increased risk of disease from chemical exposure, due to pressure from grant organizations and journals to seek out and publish "impactful" studies, also a form of funding bias.[18] Criteria for grants favor studies expected to be significant, in some way; for example, NIH research proposals are scored on five criteria, including significance, investigator(s), innovation, approach and environment (where research is to be carried out). Regarding the journals' role, Šimundić succinctly summarized it as follows, "Unfortunately, scientific journals are much more likely to accept for publication a study which reports some positive than a study with negative findings."[19]

This type of funding bias can result in publication bias, which is the failure to publish studies due to the direction or strength of the findings, a common problem in the scientific literature. In environmental health specifically, a survey of systematic reviews indicated that over half of meta-analyses that evaluated publication bias found evidence of it.[20] Typically, publication bias is more common with studies that do not have statistically significant findings because either the author did not submit the article for publication, or a journal or reviewers rejected the article.

Overall, systematic review methods have become standard practice in agency risk assessments. There are varying frameworks available, with most sharing key basic principles, particularly in the identification and selection of literature.[21] However, there is substantial variation among frameworks in the specific approaches for evaluating study quality and risk of bias, even among offices at EPA. The Navigation Guide includes recommendations consistent with systematic review principles similar to those already instituted by EPA for the IRIS program and for TSCA. However, it stands alone among other US frameworks in its unbalanced assessment of biases in studies based on funding source. Based on this issue alone, the Navigation Guide should not be applied and certainly should not be viewed as the solution to any specific perceived inadequacies of existing EPA (TSCA or IRIS) systematic review approaches.

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[18] Marín-Franch I. (2018). Publication bias and the chase for statistical significance. Journal of optometry, 11(2), 67–68. https://doi.org/10.1016/j.optom.2018.03.001

[19] Simundić A. M. (2013). Bias in research. Biochemia medica, 23(1), 12–15. https://doi.org/10.11613/bm.2013.003

[20] Sheehan, M. C., & Lam, J. (2015). Use of Systematic Review and Meta-Analysis in Environmental Health Epidemiology: a Systematic Review and Comparison with Guidelines. *Current environmental health reports*, *2*(3), 272–283. https://doi.org/10.1007/s40572-015-0062-z

[21] Lynch et al. (2022).

The Honorable Larry Bucshon, M.D.

Q1. Some people believe that if we remove most uses of certain chemicals but allow for their critical uses then everything will be fine.

a) **Do you believe that a strong business case exists for a company to continue manufacturing a chemical in bulk if, for instance, 95 percent of its domestic market has been extinguished?**

Bulk chemical manufacturing benefits from economies of scale. As a result, it likely wouldn't make business sense for a plant to run at 5% capacity. In addition, many chemical operations are integrated with other production streams (a byproduct of one process becomes the feedstock for another), so reducing by 95% one piece of a chemical plant's production portfolio could negatively impact the business case for the entire plant.

b) **For those producers that are more willing to produce only batch amounts of critical chemicals, what is the impact on price, reliability, and availability for these necessary substances.**

By removing economies of scale and benefits of integrated processes, it is possible that availability of some critical chemicals may be reduced, and reliable delivery could be negatively impacted by the lower level of supply and/or fewer number of producers.

The Honorable Dan Crenshaw

Q1. The Government Accountability Office (GAO) found that the EPA completed no new chemical reviews within the statutory deadline of 90 days for the pre-manufacturing notices it received in 2022. Of those notices, only 10 percent received a review before the statutorily permitted extension of 180 days elapsed, and 90 percent of pre-manufacturing notices for new chemical applications received no decision whatsoever within the statutory time frame. What effect do these unnecessary and illegal delays have on your members' ability to innovate on critical, sometimes even lifesaving, chemistries?

These delays are resulting in multiple adverse effects. First, manufacturers are closely watching system efficacy and are making decisions to delay initiating new PMNs in the US given program uncertainties, costs and delays. In some cases, companies elect to start manufacturing overseas. Second, delays in PMNs can have severe effects on the entire supply chain, including companies depending on availability of the chemicals to manufacture their products, and federal agencies which may rely on critical uses. For example, downstream companies producing new high-tech products can't begin manufacture until the material is available, and the material cannot be available until the new chemical review is complete. This includes new, sustainable, and innovative chemistries that may replace other chemistries, and further delays phaseouts.

Q2. Does the EPA's mismanagement of the Toxic Substances Control Act make it harder for American companies to invest in domestic manufacturing of these and other key chemicals?

EPA's approach has a direct impact on the U.S. economy, and America's ability to create products and technologies. Delays in chemical reviews or risk management activities and missing Congressionally mandated deadlines can squeeze U.S. supply chains, impede the uptake of innovative new chemical uses, or limit access to important existing chemistries which have crucial uses. U.S. businesses, jobs,

innovation, and competitiveness rely on a high-functioning, effective, reliable, risk-based, and timely TSCA program.

Q3. Does the Administration's disastrous handling of the Toxic Substances Control Act and other regulatory programs risk driving new and existing chemical manufacturing overseas to adversaries like China?

Sound chemical management policies are critical not only to American innovation and competitiveness, but also to meeting supply chain, climate, sustainability, energy efficiency, national security, and infrastructure needs. Ineffective, inefficient implementation of TSCA—implementation that is not risk-based and/or not grounded in the best available science—has a direct impact on the U.S. economy, and America's ability to lead in the creation of products and technologies needed to accomplish a wide range of societal goals. Notably, chemistries the EPA reviews and manages under TSCA—both new chemicals and existing chemicals—are used to make essential products from building and construction materials to computers, electronics, healthcare, and clean energy solutions including EVs, wind turbines, solar panels, and replacements for ozone-depleting substances. In particular, new chemistries have faced regulatory barriers under this Administration's implementation of TSCA that impact the timing of reviews and availability of products, creating uncertainty in the supply chain and stifling the ability of companies to bring new products to market.

Such barriers and delays have discouraged new U.S. innovations and resulted in offshoring of both new chemical R&D and manufacturing. In a survey of ACC member companies, respondents representing approximately $97 billion or nearly one-fifth of U.S. chemical sales reported systemic delays, disregarded company-submitted data, and inconsistent reviews. In fact, 70% of respondents reported deciding to introduce new chemicals in jurisdictions outside of the U.S. given the uncertainties and challenges with EPA's New Chemicals Program.

Q4. What are some of the past and current actions that the industry has taken to drastically reduce both pollution and greenhouse gas emissions?

ACC members are investing in, developing and deploying commercially available solutions to reduce emissions. Chemical companies are among the leaders and participants in exploring the development and use of multiple innovative lower-emissions technologies—including carbon capture, utilization and storage (CCUS); lower-emission hydrogen, steam, and electricity; use of biomaterials and circular feedstocks; cracker electrification; and industrial energy efficiency programs, to name a few. We can use these technologies in our own companies and facilities to help save energy, reduce emissions, and compete globally.

We're also providing chemistries and plastics that help other sectors save energy and reduce their own emissions. Many energy efficient, renewable energy and innovative lower-emissions solutions are enabled by chemistry and plastics. From lithium-ion batteries to solar cells and wind turbines, to high-performance building materials like insulation, to lightweight materials for fuel efficient cars and automobiles, chemistry—and the facilities that produce chemistry—are guiding the way forward.

ACC members are committed to an ethos of continual improvement. For more than 35 years, ACC member companies have implemented Responsible Care®, the chemical industry's leading environmental, safety, sustainability, and security stewardship program.

Environmental, safety, sustainability, and security performance excellence and transparency are essential to being a Responsible Care company. Under Responsible Care, ACC member companies agree to measure, track, and aim to continually improve performance across their operations. Responsible Care companies report and audit their annual performance against specific environmental, health, safety, and security (EHS&S) metrics ACC reports information on the membership on publicly available sites. Some of these metrics include hazardous air pollutants (HAPs), sulfur oxide (SOx) and nitrogen oxide (NOx) emissions, and greenhouse gas (GHG) emissions intensity.

Transparently reporting these metrics demonstrates ACC members' commitment to accountability – to their customers, communities and employees. Through Responsible Care, ACC's members have reduced GHG intensity by more than 12% since 2017; and NOx emissions by 18 percent and SOx emissions by nearly 40 percent in that same time period. Additionally, our members have reduced HAPs emissions by 24 percent over the past decade. (Note performance records are current as of reporting year 2022.)

ACC members also engage actively in the communities where they operate, to address and protect air and water quality. ACC supports its members in advancing community air monitoring initiatives that promote high quality, credible, scientifically robust data sets that are collected and publicly disseminated using rigorous processes that promote principles of data quality and scientific integrity. ACC has also collaborated with nonprofit organizations like The Water Council, to develop a Water Body Risk Assessment framework to help member companies assess and prioritize potential water-related risks at their facilities and identify opportunities to mitigate these risks.

Q5. In addition to using the Risk Management Program to push chemical substitution, the EPA is also considering adding hydrofluoric acid (HF) to the Toxic Substances Control Act's section 6 high priority list. In what ways could these potential regulations impact our nation's ability to produce clean transportation fuel in this country?

Designating HF as a priority substance under TSCA could substantially impact all uses of HF. This could lead to EPA phasing out HF alkylation units in refineries. Approximately 50% of all refineries in the US utilize HF alkylation to boost octane in gasoline and produce cleaner fuels. A prohibition of this HF use could force large refineries to switch to other alkylation alternatives that are less commercially proven or effective.

<u>The Honorable Rick Allen</u>

Q1. Should the EPA or the private sector lead what innovation looks like in America?

America's private sector is by far the world's most innovative. But overly conservative, unduly restrictive regulations proposed by EPA put America's leadership role at risk. EPA and other federal agencies must focus on smart regulations that embolden, enable and empower the private sector precisely so that it does not fall into the same deindustrialization trap as Europe or lose out to foreign competitors like China. Unless the Biden Administration and Congress take a different approach to how they create and implement regulations, the availability of critical chemistries will dwindle—and the country's climate, infrastructure and supply chain priorities will suffer as well. American success relies on American chemistry.

Q2. How does the regulatory burden American manufacturers face impact Americas ability to compete in a global economy?

From manufacturing of computer chips and electric vehicles (EVs), to producing clean energy, rebuilding the country's infrastructure, power delivery, national security, and healthcare and biotechnology all depend on the innovations produced by America's chemical industry. The U.S. chemical industry manufactures essential innovative inputs that go into building and construction materials to computers, electronics, healthcare, and clean energy solutions including EVs, wind turbines, solar panels, and replacements for ozone-depleting substances. But there's been a recent surge in overregulation. Some of these regulations would unnecessarily ban certain chemistries or regulate them at such low levels that manufacturing becomes virtually impossible. All of this hinders the chemical industry's ability to innovate, grow and create products and it jeopardizes our national priorities, our economy, and America's ability to compete with countries like China. Overregulation can disrupt the supply chain for crucial technologies and everyday products.

Q3. How could EPA's approach impact the availability of domestically produced critical products (e.g., like headlights for cars; drinking water disinfection) or does their approach send manufacturing overseas?

Sound chemical management policies are critical not only to American innovation and competitiveness, but also to meeting supply chain, climate, sustainability, energy efficiency, national security, and infrastructure needs. Ineffective, inefficient implementation of TSCA—implementation that is not risk-based and/or not grounded in the best available science—has a direct impact on the U.S. economy, and America's ability to lead in the creation of products and technologies needed to accomplish a wide range of societal goals. Notably, chemistries the EPA reviews and manages under TSCA—both new chemicals and existing chemicals—are used to make essential products from building and construction materials to computers, electronics, healthcare, and clean energy solutions including EVs, wind turbines, solar panels, and replacements for ozone-depleting substances. In particular, new chemistries have faced regulatory barriers under this Administration's implementation of TSCA that impact the timing of reviews and availability of products, creating uncertainty in the supply chain and stifling the ability of companies to bring new products to market. Such barriers and delays have discouraged new U.S. innovations and resulted in offshoring of both new chemical R&D and manufacturing. In a survey of ACC member companies, respondents representing approximately $97 billion or nearly one-fifth of U.S. chemical sales reported systemic delays, disregarded company-submitted data, and inconsistent reviews. In fact, 70% of respondents reported deciding to introduce new chemicals in jurisdictions outside of the U.S. given the uncertainties and challenges with EPA's New Chemicals Program.