MEMORANDUM October 16, 2023

TO: Members, Subcommittee on Environment, Manufacturing, and Critical Materials

FROM: Committee Majority Staff

RE: Hearing entitled "Exposing EPA Efforts to Limit Chemicals Needed for Life-Saving Medical Devices and Other Essential Products."

I. INTRODUCTION

On Wednesday, October 18, 2023, at 10:30 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Environment, Manufacturing, and Critical Materials will hold a hearing titled "Exposing EPA Efforts to Limit Chemicals Needed for Life-Saving Medical Devices and Other Essential Products." Witnesses are by invitation only.

II. WITNESSES

- **Peter Huntsman,** President and CEO, Huntsman Corporation
- **Chris Jahn,** President and CEO, American Chemistry Council (ACC)
- **Scott Whitaker,** President and CEO, Advanced Medical Technology Association (AdvaMed)
- **Tracey Woodruff**, PhD, MPH; UCSF Program on Reproductive Health and the Environment

III. BACKGROUND:

Chemicals are vital for everyday life. They are the building blocks for other chemistries, and they facilitate innovation in many important sectors and improved standard of living for Americans. According to the North American Industry Classification System, the United States' chemical manufacturing sector – which transforms organic and inorganic raw materials via chemical process and the formulation of products – is comprised of the production of basic chemicals in bulk and specialty chemicals in batch form, as well as intermediate and end products [1]

The American Chemistry Council (ACC) reported that the chemical industry generates $639 billion annually, employs 555,000 Americans, and supports more than 25 percent of U.S. GDP.[2] In addition, the chemical industry directly impacts 96 percent of all manufactured goods.[3]

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[1] https://www.bls.gov/iag/tgs/iag325.htm#about
[2] https://www.americanchemistry.com/chemistry-in-america/data-industry-statistics/the-business-of-chemistry-by-the-numbers
[3] The State of The Chemical Industry - EHS Daily Advisor (blr.com)

In addition, ACC reported that the United States is the second largest producer of chemicals in the world – resulting in a $24 billion trade surplus for industrial chemicals. In aggregate, 10 percent of U.S. exported goods come from the chemistry sector.[4] Yet, McKinsey & Company reported "an ongoing decline in the growth rate of the demand for chemical products."[5] McKinsey & Company's analysis attributes the downturn to a growing number of Chinese competitors in the industry (which decreased return on investment capital for U.S. companies and a downward trend in those companies' volume growth), as well as increased regulatory requirements on (A) chemical processes in the United States and elsewhere, (B) feedstocks, and (C) end products throughout the chemical manufacturing supply chain.[6]

The Environmental Protection Agency (EPA) is currently promulgating at least one dozen regulatory or supplemental efforts that impact the chemical manufacturing sector. Some of these actions have been precipitated by litigation, some by executive order, and others are part of EPA initiated efforts through statute or the regulatory review process.

IV. RECENT EPA REGULATORY MATTERS INVOLVING THE CHEMICAL SECTOR:

The Toxic Substances Control Act (TSCA):

TSCA Title I is unique among all Federal laws. For the purpose of addressing identified, "unreasonable risks" posed to health or the environment by chemical substances, TSCA gives the EPA broad authority to regulate the entire chain of commerce. Specifically, TSCA Title I explicitly authorizes the EPA to require testing of chemical substances and to regulate the manufacture (including importation), processing, distribution in commerce, sale, use, and disposal of chemical substances, chemical mixtures, and articles containing chemical substances found to pose an "unreasonable risk." TSCA also requires regular collection of manufacturing information, governs what trade secrets should generally be kept confidential from the public, and permits the EPA to assess user fees to cover 25 percent of its activities.

The biggest intersection between commercial manufacture of a chemical and Federal regulation of that chemical or process comes in TSCA sections 5 and 6. TSCA section 5 requires producers of new chemicals and new uses of existing chemicals to submit review notifications to the EPA before commercially manufacturing those items. No commercial manufacture of a new chemical or a new use of an existing chemical can occur in the United States until the EPA has make a risk determination about the chemical. TSCA section 5 gives the EPA at least 90 days, but no more than 180 days, to make this determination. The Government Accountability Office (GAO) found in 2022 that the EPA completed no new chemical reviews within the statutory deadline of 90 days. Only 10 percent of reviews were completed before the statutorily permitted extension of 180 days, and 90 percent of new chemical applications receiving no decision

[4] The Business of Chemistry by the Numbers - American Chemistry Council
[5] https://www.mckinsey.com/industries/chemicals/our-insights/the-state-of-the-chemical-industry-it-is-getting-more-complex
[6] https://ehsdailyadvisor.blr.com/2022/05/the-state-of-the-chemical-industry/

whatsoever within the statutory time frame.[7] As of October 1, 2023, the EPA listed 348 pending, pre-manufacture applications and 76 exemption requests awaiting EPA action.[8]

The EPA may select chemicals already in the marketplace for risk evaluation and subsequent regulation based upon the findings of that evaluation. Under TSCA section 6, the EPA is periodically required to sort chemicals into both "high priority" and "low priority" risk categories. Selected "high priority" chemicals must receive a determination about whether it presents an unreasonable risk – "without regard to cost or other non-risk factors" – and those posing an unreasonable risk must be regulated to control for that discovered unreasonable risk in the manufacture, processing, distribution in commerce, use, or disposal of that chemical substance.

TSCA Section 6 generally requires the EPA to complete risk evaluations within 3 years, promulgate final rules within 2 years after (though the EPA can extend for another 2 years), and requires that each of these rules becomes effective within 5 years of their promulgation. The EPA is being sued for missing its statutory deadline for 22 chemical risk evaluations.[9] TSCA section 6 provides limited exemptions from regulation for chemicals offering a critical or essential use for the national economy and public health. The EPA currently lists 33 ongoing or completed risk evaluations for "existing chemicals" since 2016[10] – 20 of which were prioritized as high priority chemicals on December 20, 2019. The EPA also informally proposed designating 5 new chemicals from a list of 15 on October 5, 2023.[11]

Integrated Risk Information System (IRIS):

The EPA's IRIS Program – which has never been explicitly authorized by Congress.[12] Each IRIS assessment can cover a chemical, a group of related chemicals, or a complex mixture. IRIS assessments and their toxicity (i.e., hazard) information are used by the EPA in all rulemakings, as well as by state and local health agencies, other federal agencies, and international health organizations.[13]

Because of the importance of each IRIS value to domestic and international regulations, the integrity and validity of IRIS assessments is critical. However, the National Academies of Sciences, Engineering, and Medicine (NASEM) and GAO have been critical of the IRIS program on the scientific validity of some of its findings. For example, a recent NASEM review of EPA's draft work on an IRIS value for formaldehyde (formaldehyde is a building block

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[7] https://www.gao.gov/assets/gao-23-105728.pdf
[8] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review
[9] Community In-Power and Development Association Inc, et. al. vs. U.S. EPA; https://subscriber.politicopro.com/eenews/f/eenews/?id=0000018a-a8eb-dee9-adca-ebffb8bc0000
[10] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under
[11] https://insideepa.com/daily-news/epa-floats-15-chemicals-candidates-next-tsca-prioritization-cycle
[12] https://crsreports.congress.gov/product/pdf/IF/IF11680
[13] https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system

chemical used in the production of "hundreds of items"[14]) – stated that the EPA did "not satisfactorily follow [NASEM's 2014] recommendations for problem formulation and protocol development."[15]

The Clean Air Act (CAA):

- *Hazardous Organic National Emissions Standards for Hazardous Air Pollutants (HON)*: The EPA regulates emissions by individual source categories, which the Agency defines as "a specific industry sector or group of similar emitting sources."[16] The Synthetic Organic Chemical Manufacturing Industry (SOCMI) source category includes chemical manufacturing processes producing commodity chemicals while the polymers[17] and resins[18] source categories include elastomer[19] production processes and resin production processes that use epichlorohydrin feedstocks. On April 25, 2023, the EPA took two distinct actions affecting the SOCMI source category, proposing amendments to the New Source Performance Standards (NSPS) that apply to the SOCMI source category and amendments to the National Emissions Standards for Hazardous Air Pollutants (NESHAP) that apply to the SOCMI (more commonly referred to as the HON) and Group I and II Polymers and Resins Industries. Specifically, the proposed amendments would address volatile organic compound leaks from SOCMI equipment and lower emission standards for ethylene oxide (EtO) and chloroprene. These actions were taken under the statutory authority of CAA sections 111, 112, 301(a)(1), and 307(d)(7)(B).

- *NESHAP for Ethylene Oxide Emissions at Sterilization Facilities:* On April 13, 2023, the EPA proposed amendments to the NESHAP under CAA section 112 for the Commercial Sterilization Facilities source category. Under this proposal, EPA targeted ethylene oxide (EtO) emissions from commercial sterilization facilities, which are facilities that use ethylene oxide to sterilize medical devices and food products like spices and dried vegetables.[20] The amendments address removing

[14] https://www.americanchemistry.com/chemistry-in-america/chemistries/formaldehyde
[15] https://nap.nationalacademies.org/download/27153#
[16] https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors#:~:text=A%20source%20category%20is%20a,balance%20studies%2C%20and%20engineering%20estimates.
[17] A polymer is a substance or material consisting of very large molecules called macromolecules, composed of many repeating subunits. Due to their broad spectrum of properties, both synthetic and natural polymers play essential and ubiquitous roles in everyday life. Examples include nylon and Teflon.
[18] In polymer chemistry and materials science, a resin is a solid or highly viscous substance of plant or synthetic origin that is typically convertible into polymers. Resins are usually mixtures of organic compounds.
[19] Any rubbery material composed of long chainlike molecules, or polymers, that are capable of recovering their original shape after being stretched to great extents.
[20] https://www.federalregister.gov/documents/2023/04/13/2023-06676/national-emission-standards-for-hazardous-air-pollutants-ethylene-oxide-emissions-standards-for

general exemptions for startup, shutdown, and malfunction (SSM) periods; adding work practice standards for periods of SSM; and revising monitoring, reporting, and performance testing requirements.[21]

- *The Miscellaneous Organic Chemical Manufacturing (MON):* Under CAA section 112(d), EPA must promulgate regulations establishing emission standards (NESHAP) for each category or subcategory of major sources and area sources of HAPs pursuant to Section 112(c)].[22] The standards must require the maximum degree of emission reduction that the EPA determines to be achievable by each particular source category.[23] The EPA's NESHAP for the MON manufacturing industry requires all major sources to meet hazardous air pollutants (HAP) emission standards and work practices to incorporate maximum achievable control technology (MACT). On April 27, 2023, the EPA proposed amendments to the petroleum and chemical sectors, including for ethylene and MON products.[24] This proposal eliminated *Force Majeure* requirements from the rule, raised questions about the clarity of initial compliance demonstration and monitoring requirements for temporary storage tank control devices, and presented concerns about practical considerations related to pressure release devices.

- *National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM):* Two sections of the CAA govern the establishment and revision of the NAAQS. CAA Section 108 directs the EPA to identify and list certain air pollutants and then to issue air quality criteria for those pollutants, and CAA Section 109 directs the EPA to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants with air quality criteria.[25] On January 6, 2023, the EPA announced a proposed decision to lower the primary annual $PM_{2.5}$ standard from its current level of 12.0 µg/m3 to within the range of 9.0 to 10.0 µg/m3. EPA is also taking comment on lowering the primary annual PM2.5 standard to 8.0 µg/m3.[26]

- *Risk Management Plan regulations:* The Risk Management Program (RMP) implements CAA Section 112(r). RMP requires facilities that use extremely hazardous substances to develop a Risk Management Plan to outline practices to address accidental releases to the ambient air of these hazardous substances. These plans must be revised and resubmitted to the EPA every five years. On

[21] Id.
[22] https://www3.epa.gov/airtoxics/112dpg.html
[23] Id.
[24] https://www.federalregister.gov/documents/2023/04/27/2023-07627/national-emission-standards-for-hazardous-air-pollutants-ethylene-production-miscellaneous-organic
[25] https://www.regulations.gov/document/EPA-HQ-OAR-2015-0072-1543
[26] National Ambient Air Quality Standards (NAAQS) for PM | US EPA

August 18, 2022, the EPA proposed revisions to RMP, including identifying "safer technologies" and chemical alternatives, more comprehensive incident investigations, greater public access to information about a company's operations, and third-party auditing.

The Federal Insecticide Fungicide and Rodenticide Act (FIFRA):

Under section 3(g) of FIFRA and the Procedural Regulations for Registration Review (40 CFR part 155, subpart C), the EPA conducts registration reviews.[27] A registration review is a [review of new chemical or new chemical use?}. Moreover, FIFRA section 3(g) requires the review of pesticide registrations every 15 years.[28] On April 27, 2023, the EPA announced its registration review of EtO. A final registration review decision for EtO will not be made until the EPA completes (1) an endangered species determination and any necessary consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service, and (2) an Endocrine Disruptor Screening Program determination.[29]

The PFAS Strategic Road Map:

Perfluoroalkyl substances (PFAS) are a class of chemicals with widespread use. To date, the EPA has identified 14,735 chemicals with a PFAS "structure."[30] On October 18, 2021, the EPA announced a PFAS Strategic Roadmap—laying out a whole-of-agency approach to addressing PFAS.[31] The Roadmap sets timelines for the EPA to act and commits to new policies regarding public health and pollution remediation efforts.[32] The following EPA actions are notable parts of the Roadmap:

- On October 26, 2021, the EPA proposed adding four PFAS chemicals as Resource Conservation and Recovery Act (RCRA) Hazardous Constituents.[33] Adding these chemicals as RCRA Hazardous Constituents would ensure they are subject to corrective action requirements and will also make them hazardous substances under the Comprehensive Environmental, Response, Compensation, and Liability Act of 1980 (CERCLA).

- On August 26, 2022, the EPA proposed its first ever designation of a hazardous substance under section 102 of CERCLA — in this case it proposed designating two: PFOA and PFOS. CERCLA liability is strict, joint and several, and

[27] https://www.regulations.gov/document/EPA-HQ-OPP-2013-0244-0044
[28] Id.
[29] https://www.epa.gov/system/files/documents/2023-04/eto-pid.pdf
[30] https://comptox.epa.gov/dashboard/chemical-lists/PFASSTRUCT
[31] https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024
[32] Id.
[33]https://www.epa.gov/newsreleases/epa-responds-new-mexico-governor-and-acts-address-pfas-under-hazardous-waste-law

retroactive, allowing for holding a broad range of parties responsible for Superfund cleanup.[34]

- On April 13, 2023, The EPA issued an Advance Notice of Proposed Rulemaking (ANPRM) to solicit public input regarding potential future hazardous substance designations of PFAS under CERCLA.[35]

- On March 14, 2023, The EPA announced proposed National Primary Drinking Water Regulations (NPDWR), including maximum contaminant level (MCL) goals of 0.0 for PFOA and PFOS; MCLs of 4 parts per trillion for each of PFOA and PFOS; and hazard indexes for four other PFAS. EPA anticipates finalizing the regulation by the end of 2023.[36]

V. ISSUES

The following issues may be examined at the hearing:

- What is the impact of the current regulatory trajectory on America's ability to sustain global manufacturing leadership and re-shore our supply chains?

- Are current regulatory requirements reasonable or achievable and what signal do they send to American businesses trying to innovate?

- What are the applications for the chemicals impacted by these EPA regulatory actions?

VI. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Mary Martin or Jerry Couri of the Committee Staff at (202) 225-3641.

[34] https://www.govinfo.gov/content/pkg/FR-2022-09-06/pdf/2022-18657.pdf
[35] https://www.epa.gov/superfund/advanced-notice-proposed-rulemaking-potential-future-designations-and-polyfluoroalkyl
[36] https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas