WRITTEN STATEMENT OF AMERICAN FUEL &PETROCHEMICAL MANUFACTURERS

AS SUBMITTED TO THE

SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

House Committee on Energy and Commerce
United States House of Representatives

on

"Testing of Chemicals and Reporting and Retention of Information under TSCA Sections 4 and 8"

Tuesday, February 4, 2014

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About AFPM:

The American Fuel & Petrochemical Manufacturers ("AFPM") is a national trade association of more than 400 companies, including virtually all U.S. refiners and petrochemical manufacturers. AFPM members operate 122 U.S. refineries comprising approximately 98% of U.S. refining capacity. AFPM petrochemical members make the chemical building blocks that go into products ranging from medical devices, cosmetics, furniture, appliances, TVs and radios, computers, parts used in every mode of transportation, solar power panels and wind turbines. AFPM members manufacture and import chemicals and are regulated under TSCA.

Getting TSCA Modernization Right:

AFPM supports rational modernization of TSCA and sees opportunities for improvement. The United States is on the brink of a manufacturing renaissance, which is largely due to abundant and affordable energy and raw materials. Shale development has enabled the U.S. petrochemical industry to be globally competitive for the first time in decades. Over 80 billion dollars in petrochemical infrastructure investment has already been announced.

Since petrochemicals are building blocks that affect many different manufacturing supply chains, it is imperative that health and environmental considerations are balanced with manufacturing and supply chain considerations. Strong federal preemption, therefore, is necessary to prevent a disparate set of state-level regulations that would disrupt the flow of interstate commerce and bring the manufacturing supply chain to a halt.

Equally important for American manufacturing competitiveness is the protection of intellectual property. The ability to claim intellectual property, including the specific identities of newer chemicals, as confidential business information (CBI) affords American manufacturers a competitive advantage in the global marketplace. AFPM acknowledges limitations of the current statute, which prevents the Environmental Protection Agency (EPA) from sharing CBI with state government officials. AFPM believes that TSCA could be modified to allow EPA to share certain confidential information with state governments, as long as those states can ensure the protection of intellectual property shared.

Another general area that could lead to improved chemical regulation is the inclusion of provisions that address scientific quality and transparency at EPA. The Agency should be required to develop criteria that explicitly and transparently evaluate the quality of data so that EPA and other scientists are able to compare the scientific weight (validity) of one study versus others. These criteria should be proposed and finalized as part of a public notice and comment process to ensure timeliness and transparency.

Sections 4 and 8 of TSCA address the ability of EPA to effectively collect appropriate information for risk assessment. Under an improved TSCA it is likely that information collection under these sections will be centered on the Agency's need to prioritize chemicals and conduct full risk assessments for high priority chemicals. AFPM supports Congress authorizing EPA to prioritize all chemicals in commerce to allow the agency to identify those substances that require further work to reduce uncertainty related to chemical safety.

Background:

The Toxic Substances Control Act (TSCA) was enacted in 1976 and is unique in that it is as much a statute about commerce as it is about human health and the environment. TSCA gives the US EPA broad authority to regulate the entire lifecycle of a chemical, from the point of manufacture through the point of use, all the way to disposal. Although TSCA generally works very well, AFPM acknowledges that EPA has experienced challenges during decades of TSCA implementation, some due in part to legal hurdles posed by certain statutory provisions, and some in part to key EPA decisions. AFPM believes that it is time to start a new dialogue on TSCA modernization that seeks to improve a workable statutory framework.

A key area in TSCA, which is one of the focuses of this hearing, is chemical testing under TSCA Section 4. The current statute authorizes EPA to require the testing of certain chemical substances which either presents an unreasonable risk to human health or the environment, or presents significant exposures to people. During the 1980s and 1990s, EPA expressed difficulty in issuing Section 4 test rules, which authorizes EPA to require companies to conduct laboratory testing on certain chemicals. A reason for the difficulties was that the Agency did not use its data gathering authority under Section 8 to collect relevant exposure information prior to issuing the test rules. Recent experience, however, has been profoundly different. To overcome challenges with finding significant exposures, EPA expanded the Inventory Update Rule ("IUR"), which requires companies to report the chemicals they currently make. The expanded information requirements include use and exposure information pertaining to the reported chemicals, allowing the Agency to justify new testing requirements. Since the expanding the IUR, EPA has successfully issued a series of test rules for high production volume chemicals that have gone unchallenged.

The other area of focus for this hearing is TSCA Section 8, which authorizes EPA to require the collection, maintenance and reporting of information related to hazard, exposure and risk for chemicals, as well as information that accurately reflects chemicals that are currently in commerce. After EPA expanded the reporting requirements to update the TSCA Inventory, it finalized a new system called the Chemical Data Reporting (CDR) rule to better align with the statutory provisions under Section 8. CDR reporting requires companies to provide the identities and amounts of chemicals they manufacture and import, the uses of those chemicals, and information regarding potential human exposure to those substances.

Toxicity Testing and Hazard Information under TSCA Section 4:

Under the current TSCA statute, before the Agency can issue a test rule requiring companies to conduct laboratory testing on that particular chemical, EPA must find that a chemical either poses an unreasonable risk of harm to human health or the environment, or that a significant number of people could be exposed to the substance. AFPM acknowledges that it is irrational to require a demonstration of unreasonable risk before requiring test data that would help demonstrate that risk. The finding of unreasonable risk should be deleted in Section 4.

The Agency should focus its resources on collecting information that will help prioritize chemicals and reduce scientific uncertainty with respect to risk. Moreover, there should be a basis of significant exposure before EPA can require companies to conduct animal studies. To guide EPA, Congress should require the Agency to promulgate a Section 8(a) Preliminary Assessment Information Rule (PAIR) to collect the necessary exposure information prior to proposing a test rule that involves animals. PAIR

actions under Section 8(a) are not subject to review by the Office of Management and Budget (OMB), so the rules should present a minimal burden to the Agency. The exposure finding in Section 4 should be retained.

One of the criticisms concerning Section 4 under TSCA is the rulemaking burden placed on EPA. AFPM believes that some of that criticism is misplaced because EPA must follow procedural requirements that fall under other statutes, such as the Administrative Procedures Act. Another idea that has been discussed among stakeholders is to provide EPA with order authority, under which EPA could require companies to conduct laboratory testing without having to go through a public notice and comment process. AFPM believes that order authority may be appropriate to a certain degree, as long as there is an exposure basis for the order. For situations where EPA is seeking animal-intensive testing – for example, a multigenerational animal study – EPA should be required to go through rulemaking. For *in vitro* and other non-animal tests, order authority may be more appropriate; again, as long as there is some sort of exposure basis for the order.

Non-animal methods have been developed to measure the potential hazards of particular chemicals. Many *in vitro* methods have been validated over the years to avoid animal testing and still provide a screening-level view of potential toxicity. Currently, there are efforts underway to examine the use of high-throughput screening for evaluating the potential toxicity of substances. High-throughput screening is a non-animal laboratory method that uses cell cultures to test for specific toxicity effects. AFPM strongly supports more research in this area. High-throughput screening methods should be validated using the same scientific scrutiny to which all other methods have been held. While this new area of screening holds great promise, many of the methods are not yet ready for use in a regulatory context. When modernizing TSCA, care should be taken so as not to preclude valid non-animal testing approaches in the future.

Information Collection under TSCA Section 8:

Each subsection under Section 8 of TSCA provides EPA with tools to collect information that can help inform prioritizations and safety assessments. Generally, Section 8 should not undergo significant change. EPA has been able to effectively implement the tools authorized under Section 8, so any changes should be subtle in the following areas.

<u>Sections 8(a) and 8(b)</u>

EPA should be required to develop a reporting method to make the TSCA Inventory more reflective of actual chemicals in commerce. Many people have the false impression that there are 80,000 chemicals in commerce. That has never been the case. According to EPA data, there are less than 10,000 chemicals in commerce that are produced in commercial quantities during any given year, excluding polymers, which EPA has determined to be safe, and substances used in research and development. Fundamentally, there is no process by which chemicals can be removed from the Inventory when they are no longer in commerce. EPA does collect up-to-date information as part of the Chemical Data Reporting (CDR) rule, now under Section 8(a); however, there should be some type of Inventory reset to identify specific substances that are currently in commerce, or active, and those that are not actively in commerce but were placed on the Inventory when it was created. After an Inventory reset, CDR reporting should be sufficient to maintain an accurate view of chemicals in commerce.

Equally important to an accurate Inventory is the collection of accurate exposure-related information. If EPA is going to continue to collect use and exposure information under the CDR, it should, where appropriate, include processors in reporting. The same holds true for collecting use and exposure information under Section 8(a) PAIR rules. Petrochemicals and other commodities are traded in the open markets as futures, NYMEX being a typical venue. Commodities can also go through extensive and complex distribution markets, where the producers relinquish ownership early in the supply chain and distributors physically sell the chemicals. For these reasons it is improbable that the original producer of a commodity chemical would know where their particular chemical ends up in the supply chain, let alone how it would be used and by whom. The inclusion of processors will be integral to use and exposure information collected and used by the Agency.

Prioritization of Chemicals in Commerce:

AFPM strongly urges Congress, when updating TSCA, to include provisions that require EPA to prioritize all chemicals in commerce. The prioritization process should not necessarily have the objective of regulation. Rather, it should be a prioritization for further work, similar to the approach used in the Canadian Chemicals Management Plan. Under this process, EPA would use existing information and consider potential hazards and exposures to make screening-level risk evaluations. If the Agency found that a particular chemical could pose a risk or if there was insufficient information to make that judgment, then the Agency would place that substance into a high priority for further work. EPA could then use its testing and information collection rules to help reduce any uncertainty pertaining to that chemical's safety.

The Office of Pollution Prevention and Toxics (OPPT) at EPA employs competent scientists with a high degree of technical expertise in risk assessment. OPPT has developed sophisticated methods and models to predict potential hazards and exposures, and has a great deal of experience evaluating substances that do not have an abundance of measured laboratory data. The predictive models used by the Agency are sufficiently protective, which EPA has pointed out through retrospective studies. There is no technical or logistical reason that EPA would not be able to prioritize all chemicals in commerce.

Making Chemical Information Publicly Available:

EPA has made great strides over the past 10 years to make chemical safety information available to the public. The Agency collects data on over 2,000 chemicals from the High Production Volume (HPV) Challenge program available through its HPV Information System. In addition, EPA just launched its new web-based portal, ChemView, which was created to provide one-stop shopping for those seeking health and safety data on chemicals regulated under TSCA. EPA does not release CBI through these internet sites. AFPM supports EPA's efforts to make appropriate information on chemicals publicly available, as long as the information systems continue to protect intellectual property.

Conclusion:

AFPM supports rational modernization of TSCA and believes that Congress should take the opportunity to improve certain parts of the statute and provide more guidance to the Agency. Because chemicals are used throughout the manufacturing supply chain, and supply chains for most products cross many state

lines, strong federal preemption is paramount. Without strong preemption provisions, supply chains and the interstate movement of raw materials and goods will be disrupted.

Sections 4 and 8 are key components of TSCA that allow EPA to collect information related to chemical hazard, exposure and risk, which can assist the Agency in prioritizing chemicals for further work and in its risk assessment activities. AFPM does not see a need for dramatic change in these sections as they provide a strong regulatory framework and tools for the EPA to collect information. The risk finding under Section 4 should be deleted and the exposure finding should be retained. In addition, EPA should be required to collect use and exposure information under Section 8(a) before issuing a test rule. The Agency should have the authority to use test orders; however, any new testing required by EPA should have an exposure basis.

The TSCA Inventory is out of date and should be reset. Congress should guide EPA in how to reset the Inventory with an objective of accurately reflecting which chemicals are actively in commerce and which are not. Furthermore, processors should be included in reporting use and exposure information, as they are more likely than producers to possess this type of information.

To improve TSCA and its implementation, Congress should explicitly require EPA to prioritize all chemicals in commerce for further work within a reasonable amount of time. Further, Congress should require the Agency to develop criteria by which to judge the quality of studies it considers in its hazard characterizations, exposure assessments and risk assessments.

In closing, TSCA is a law that affects commerce as much as it does human health and the environment. The current TSCA statute provides a solid regulatory framework for chemical regulation and does not see a need for dramatic overhaul. AFPM supports the rational modernization of TSCA and sees this as an opportunity for Congress to make improvements.