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TESTIMONY FOR THE PUBLIC MEETING OF THE SCIENCE ADVISORY COMMITTEE ON CHEMICALS (SACC)
COMMENTS BY GARY E. TIMM ON BEHALF OF THE ENVIRONMENTAL PROTECTION NETWORK

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Good morning. It is a pleasure to be here. I think that my perspective is unique and hope that it is helpful to the Committee. My name is Gary Timm. I worked at EPA for 38 years and retired in 2011. I was chief of the Chemical Testing Branch in the Office of Pollution Prevention and Toxics for 10 of those years. The Chemical Testing Branch is responsible for implementing the testing provisions of Section 4 of the Toxic Substances Control Act (TSCA). I am also a member of the Environmental Protection Network (EPN), a non-profit organization comprised of over 450 former EPA employees volunteering their time to protect the integrity of EPA and provide an informed and rigorous defense against the current Administration's efforts to undermine the protection of public health and the environment.

Today, I want to share my experience with the old TSCA to underscore how EPA today is failing to use the authority Congress has recently given it in the new TSCA to require robust test data to inform its risk evaluation of existing chemicals, including PV29.

In 2016 the Congress amended TSCA to give EPA more authority and correct many of the features of the Act that gave us so much difficulty in doing our job. When I started out as branch chief, the only avenue we had to require industry to test the chemicals they manufactured or processed was to make three legal findings, analyze the cost impact of requiring testing, issue a proposed rule, take public comment, and then issue a final rule to require testing. The three findings, which are still in the Act, are

1. Either find that the chemical may present an unreasonable risk to human health or the environment, or that it is produced in substantial quantities and would result in significant or substantial human exposure or substantial environmental release,

2. That data were insufficient to reasonably assess or predict the effects of the chemical, and

3. That testing was necessary to generate the needed data.

These findings were difficult, and time and resource consuming to make. We could not find that a chemical "may present an unreasonable risk" without locating an existing significant toxicity study and demonstrating the potential for human exposure or environmental release. Alternatively, for high production volume chemicals, we could demonstrate substantial or significant human exposure or substantial environmental release to make the first finding.

Making the second finding meant that we had to conduct a wide search for all available studies as well as collect unpublished data using our authority under section 8(d) and critically review each study to determine its inadequacy before we could require testing for a particular endpoint. Under optimum conditions, we could issue the final rule to require testing two years after we started the process. Typically, it was years longer. A proposal developed by the Natural Resources Defense Council and the Chemical Manufacturers Association to substitute Negotiated Consent Agreements for this long process helped somewhat, but disagreements between the agency and industry sometimes generated no time savings at all. The situation was so dire that when data were needed by another office in EPA or another agency, we effectively ceded routine testing of industrial chemicals to the National Toxicology Program (NTP) because we could not meet our potential client's timelines. This testing by the NTP was paid for by the taxpayer instead of being paid by industry under TSCA, which was the intent of Congress in passing the law.

This is no longer the situation. The Lautenberg Amendments gave EPA authority to require testing by rule, order, or consent agreement if data were needed to conduct a risk evaluation or even to establish the priority of a chemical for risk evaluation. Many commenters have noted the paucity of studies in the PV29 database. There is, in my mind, a disconnect between EPA's selection of PV29 for the TSCA work plan and the conclusions of the draft risk evaluation that PV29 is relatively inert and presents no unreasonable risks. Several commenters, including EPN, have expressed concern that EPA relied on inadequate data to reach this conclusion, and that the studies that they did rely on were not fully disclosed to the public as required by TSCA.

For PV29, EPA has based its conclusion of "no unreasonable risk" on claims of low exposure, low bioavailability, and low toxicity observed only in short-term studies. These data seem to support a hypothesis of low risk, but are woefully insufficient to establish it. As tiered testing is encouraged by TSCA, EPA should confirm this hypothesis by requiring workplace monitoring, basic pharmacokinetic (PK) data measuring levels of PV29 in blood and distribution in fat, and a 90-day subchronic test as directed by the PK results. Further testing may be necessary based on the outcome of these tests. In addition, EPA noted that PV29 was expected to partition to soil and sediment. It therefore has no basis to conclude that there is no unreasonable risk to the environment without biodegradation data and data on the toxicity to benthic organisms.

The risk evaluation of PV29 is critical because it will be seen as precedent setting. EPA needs to establish criteria to determine the minimum data set necessary to make a risk determination. Without such criteria, it looks like an arbitrary judgment call on each chemical. With the new authority EPA has under TSCA, EPA has an obligation to require testing for PV29 to meet the minimum data requirements and fill critical data gaps before making a risk evaluation.

EPA's primary obligation is to ensure that any finding of "no unreasonable risk" is based on data that actually show no risk, as opposed to being based on the absence of data. Mandating testing is one way to fill data gaps, and we urge EPA to do this, but the most critical point for the SACC is that EPA cannot make risk determinations without actual data showing no unreasonable risk.

As EPN's formal comments submitted on May 17, 2019, expressed, we are concerned about the following:

1) The lack of transparency in this risk evaluation will create a precedent of making "no unreasonable risk" determinations based on proprietary information.

2) The most critical study in this evaluation was heavily redacted, which removes the ability to do an independent analysis.

3) A potentially useful and important study was not included in the draft risk evaluation, with no explanation.

Thank you for the opportunity to speak today.