Testimony of Gary E. Timm

July 17, 2018

Good morning. My name is Gary Timm. I worked at EPA for 38 years and retired in 2011. I was chief of the Chemical Testing Branch of 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).

Today my remarks will focus on the effects of the proposed transparency policy in three areas:

- On studies traditionally used to support regulation,
- Its interaction with TSCA Section 4, and
- Its interaction with our obligations to accept studies conducted in accordance with OECD test guidelines.

Effect on studies traditionally used to support regulation

If EPA had adopted this data transparency limitation in past risk assessments, EPA would not have been able to take many of its historic actions to protect children, families, and the environment such as reducing or eliminating the exposure of children to lead in paint, gasoline and drinking water and promulgating protective air quality standards for particulate matter and other air pollutants.

The proposed policy would affect assessments that will soon be carried out under TSCA Section 6. TSCA gives EPA the authority to regulate the manufacture, processing, distribution in commerce, use and disposal of chemicals. The problem formulation documents which set forth EPA's approach for assessing the first 10 chemicals under the amended TSCA are open for public comment now. How these chemicals are assessed will be the model for future assessments. The proposed policy would in fact make it impossible for EPA to consider the full array of well conducted and peer reviewed scientific studies of the health and environmental effects of pollution. It would bias the body of information in favor of industry supplied studies since they would have the means to provide the underlying data. Assessment of all relevant scientific information is essential in making sound judgments about protecting public health and the environment and is a legal requirement in all major environmental legislation.

Interaction with TSCA Section 4

TSCA also contains provisions to require chemical manufacturers to test the chemicals that they manufacture or process. To require industry to test chemicals under Section 4, EPA must make a set of legal findings.

It is the data inadequacy finding that we are interested in today for it is the nexus between TSCA and the proposed transparency policy. To make this finding, EPA conducts a thorough literature search and usually issues a rule to require studies that have not been published be submitted to the Agency. The bulk of the information considered, however, is typically studies published in peer-reviewed scientific journals. Despite being accepted by the scientific community, these studies do not meet the proposed transparency requirements of the proposed rule, since it requires that all raw underlying data and the models used to analyze data supporting the study are available for public review. Thus, if the transparency rule were in effect, EPA would have to judge studies from peer reviewed journals as inadequate. Ignoring this large category of information would cost industry hundreds of millions of dollars to repeat perfectly good, scientifically acceptable studies, which the public would ultimately pay for through higher prices. And it would significantly delay or, in some cases, preclude assessment and regulation of risks to human health and the environment.

Interaction with our obligations to accept studies conducted in accordance with OECD test guidelines

Another aspect not addressed by the proposed transparency policy is the obligation of the US to accept data generated in accordance with the Organisation for Economic Cooperation and Development (OECD) Test Guidelines and Good Laboratory Practice Standards. The US and other OECD member countries realized that differences in testing requirements among countries meant that companies would in some cases have to retest a chemical in order to market it in other areas. This was needlessly costly and resulted in a delay in obtaining information needed for regulatory assessment. As a result, the OECD member nations agreed to accept for regulatory purposes data generated in accordance with the OECD test guidelines, GLPs and quality assurance program. The GLPs specify the information that must be reported; underlying data is not one of them. Therefore, the proposed policy which requires underlying data to be made available would run counter to our obligations under the Mutual Acceptance of Data treaty.

I can only conclude that this proposal constitutes fraud--as it is deceptive, waste--for rejecting perfectly valid studies, and abuse for it is arbitrary and capricious.

Thank you for giving me the opportunity to provide comments this morning.