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SOLUTIONS FOR SPECIALTIES

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EPA Docket Center
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Docket No. EPA-HQ-OPPT-2022-0218-0001

Via regulations.gov submission

RE: TSCA Collaborative Research Program to Support New Chemical Reviews

Dr. Michal Freedhoff:

The Society of Chemical Manufacturers and Affiliates (SOCMA) is pleased to submit the following comments on the Environmental Protection Agency's TSCA Collaborative Research Program to Support New Chemical Reviews.

SOCMA is supportive of the effort to revise the New Chemical Review process and meet the statutory deadlines for review. SOCMA supports the development of the Collaborative Research Program and seeks to work alongside EPA in the development of the program. Additionally, SOCMA has strong recommendations to resolve New Chemical Review Program problems that are not addressed by the program.

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture new and innovative chemistries used in a wide range of commercial, industrial, and consumer products. SOCMA maintains a strong record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote industry stewardship.

SOCMA is supportive of the program but there are major problems that cause EPA to miss legislative deadlines that are not addressed by the program.

EPA looks beyond "reasonably foreseen conditions of use" to those that are unreasonable. Looking beyond reasonable uses leads to looking at non-existent exposures and environmental impacts, which leads to testing requirements far outside the scope of chemical reviews. SOCMA members regularly experience a signicant slow-down in the process.

Additionally, EPA should assume compliance with OSHA PPE requirements for a number of reasons, among them the chemical industry, and specifically SOCMA members, have a strong history of compliance. Further, those bad actors that are not complying with OSHA regulations are no more likely to comply with PPE requirements in a Significant New Use Rule (SNUR).

SOCMA also suggests that a lack of information or data poor environments are a problem for PMNs and LVEs, but in the case of SOCMA members, it is not the prime reason for delays in review. Additionally, lack of information is frequently a communication issue. In the case that specialty manufacturers do not provide EPA with the necessary data it is because EPA has not properly conveyed the need for such information.

This is problem with a simpler solution than the Collaborative Research Program. Pre-submission meetings must be a two-way conversation. In most cases, SOCMA members report that it is more of a briefing from the submitter to EPA. This does not serve the purpose of the meeting. Additionally, most report that a risk assessor is not present for the pre-submission meeting; without the risk assessor the meeting cannot accomplish its goal.

The swiftest, best step that EPA can take to resolve lack of data is mandate that the risk assessor attend pre-submission meetings. Additionally, the assessor must have a dialogue with applicants to understand potential risks and help the submitter understand additional tests that EPA needs to properly complete an assessment. While this will not resolve all data gaps, and additional testing may be required in some PMN and LVE processes, this step alone could save months in the review process.

COLLABOARITVE RESEARCH PROGRAM

One of the top priorities of SOCMA is the preservation of confidential business information. This is the life blood of an innovative industry. Specialty chemical manufacturers thrive on by developing new products and getting to market early with that product. This initiative by EPA must protect CBI.

The Problem Statement as drafted:

> Using the best available science involves OPPT's use of methods, approaches, and tools to evaluate new chemicals prior to their entrance into US commerce, and refining and updating them where appropriate. Any changes should align with statutory deadlines, be operational in a data poor environment, make effective use of new data sources and approaches, and be transparent to the extent practicable given that TSCA CBI may be used in the development of these approaches.

is strong but not perfect. The clause "[a]ny changes should align with statutory deadlines" is unclear. The changes do not need to "align" with statutory deadlines since the proposed program does not make changes to specific portions of the review process that have statutory deadlines. Additionally, "should" is

not appropriate when referring to statutory deadlines; statutory deadlines *must* be met. SOCMA suggests that the problem state should change "[a]ny changes should align with statutory deadlines" to "Any changes must align to dimmish review times to meet 90-day PMN and 30-day LVE statutory deadlines".

FOCUS AREAS

SOCMA is supportive of the five focus areas and the approaches that EPA identifies.

1. Update and Refine Chemical Categories

SOCMA strongly supports the use of best available data. Development of updated and refined chemical categories must be done in conjunction with industry. Though it must be noted that even after having redefined chemical categories, EPA must work closely with submitters and understand the submitter analogs and submitter suggested read across data.

2. Develop and Expand Databases Containing TSCA Chemical Information

The primary concern of SOCMA is "[s]afeguards for CBI will be maintained as appropriate in this process." The language is too vague and implies that EPA may decide, independently, to disclose CBI. Preservation of CBI must be a high priority and "as appropriate" is not a proper descriptor. The phrase should simply read "safeguards for CBI will be maintained in this process."

SOCMA is strongly supportive a cooperative process on the development of this program as industry insight will be integral to a successful effort. This is a step in the right direction and with the additional suggestions outlined EPA can achieve the legislatively mandated review periods.

Thank you very much for your willingness to seek feedback from stakeholders. SOCMA has appreciated the opportunity to provide advice and recommendations on improving EPA's New Chemical Review Program. If you have any questions about these comments, please contact me at rhelminiak@socma.org.

Respectfully,

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Society of Chemical Manufacturers & Affiliates