

June 19, 2020

Alexandra Dunn
Assistant Administrator for Chemical Safety and Pollution Prevention
US Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460

Re: *Unannounced Changes in EPA Model Consent Order Under Section 5(e) of TSCA*

Dear Assistant Administrator Dunn:

We were distressed to learn recently from [INSIDE EPA](#) that EPA has revised its longstanding model consent order under section 5(e) of the Toxic Substances Control Act (TSCA) without any public announcement. According to INSIDE EPA, the revised model was developed with “input from industry and others.” However, none of the undersigned groups were asked, or were offered the opportunity, to provide input, despite the fact that all of our organizations have been actively involved in virtually every aspect of the implementation of TSCA since the Lautenberg Act was adopted. That EPA sought input on this important regulatory initiative only from industry groups is unacceptable and defies the intent of Congress to assure transparency and public participation in implementing TSCA. Unfortunately, this is only the latest example of the lack of transparency and accountability in EPA’s implementation of the TSCA new chemicals program.

Section 5(e) orders are required under TSCA for new chemicals that EPA finds may present a risk of injury to health or the environment, lack sufficient data for a reasoned determination of risk, or will be produced in substantial quantities and have the potential for significant or substantial human exposure or environmental release. These orders place enforceable requirements on submitters of premanufacture notices (PMNs) to ensure that commercialization of new chemicals does not present unreasonable risks of injury. These requirements may include use restrictions or other conditions, including production volume limitations, controls on environmental releases, testing obligations and worker protections. Violation of section 5(e) orders is a “prohibited act” under section 15 of TSCA and may result in suits to compel compliance as well as civil and criminal penalties.

Congress expanded the use of section 5(e) orders in the 2016 Lautenberg Chemical Safety Act (LCSA), imposing a new requirement for risk determinations on all new substances and directing EPA to issue orders unless it determines that a new chemical is “not likely to present an unreasonable risk of injury.” Following enactment of LCSA, EPA initially increased its use of section 5(e) orders in accordance with the new law but then reversed course in response to industry pressure. Now, EPA is skirting the law by bypassing determinations that new chemicals may present unreasonable risks where such determinations are compelled by TSCA. As a result, the Agency is issuing far fewer orders than the law requires.

The new model consent order represents a further weakening of this important tool. The new order replaces standard consent order provisions that, with minor updates, have been used for new chemical regulation since the 1990s. The new provisions lack detail, specificity and clarity and give PMN

submitters latitude to cut corners on basic protections. The result will be less effective consent orders and greater difficulty enforcing their obligations against non-complying manufacturers.

As just one example, the new model order creates confusion and uncertainty by eliminating the detailed hazard communication provisions in the previous model order and substituting a vague directive to comply with the OSHA hazard communication standard. This standard was not designed to address the unique circumstances of new chemicals and its precise application to these chemicals is open to debate. Manufacturers will undoubtedly interpret the OSHA standard so as to reduce or eliminate the applicability of labeling, MSDS and worker training requirements that are now spelled out explicitly in section 5(e) orders and EPA will have little enforcement recourse since these specific requirements no longer apply.

According to the INSIDE EPA article, the new model order was informed by consultations with PMN submitters. However, these consultations were not part of a public process; EPA did not solicit comment by all stakeholders and failed even to disclose that the model order was undergoing revision.

Despite the absence of any public announcement or opportunity for input, the new order is a fait accompli and is in use across the PMN program. EPA's webpage on which the boilerplate was quietly posted recently [states](#): "The updated version of the boilerplate is expected to be used for Orders starting in April 2020."

It is also troubling that the new model order does not address the concerns identified in a [report](#) issued less than a month ago by EPA's Office of Inspector General (OIG), which found "insufficient communication and coordination" between OCSPP and EPA's Office of Enforcement and Compliance Assurance (OECA) with respect to enforcing consent order requirements. The OIG made specific recommendations for establishing and implementing processes to ensure that section 5(e) orders are enforced by regional offices and OECA. Despite these concerns and recommendations, it is uncertain whether OCSPP consulted OECA about the new order's impact on enforcement and, if so, how it responded. To address the OIG's concerns, it is important, at a minimum, for EPA to commit that, once signed, all section 5 (e) orders will be sent to OECA and the relevant regional office within 14 days. OECA may have additional ideas for how to strengthen the model order to maximize effective enforcement and should be consulted for this purpose in parallel with the public comment process on the new model order.

In sum, it is not acceptable for EPA to make major changes in its implementation of section 5 of TSCA without a transparent public process. We call on EPA to suspend use of the new order, explain how it changes the old order and why these changes were made, and afford an opportunity for public comment.

We look forward to your response.

Please contact SCHF counsel Bob Sussman at bobsussman1@comcast.net or Richard Denison of EDF at rdenison@edf.org with any questions about this letter.

Sincerely yours,

Liz Hitchcock, Director
Safer Chemicals Healthy Families

Patrick MacRoy, Deputy Director
Environmental Health Strategy Center

Richard Denison, Lead Senior Scientist
Environmental Defense Fund

Eve Gartner, Managing Attorney, Toxics Program
Earthjustice

Daniel Rosenberg, Director, Federal Toxics Policy
Natural Resources Defense Council

cc: Lynn Dekleva, Associate Deputy Assistant Administrator for New Chemicals, OCSPP
Yvette T. Collazo, Director, OPPT
Madison Le, Director, Chemical Control Division, OPPT
Lynn Vendinello, Deputy Director, Chemical Control Division, OPPT
Greg Schweer, Chief, New Chemicals Management Branch, OPPT