

## HOW IS EPA HANDLING NEW CHEMICALS UNDER THE NEW TOXIC SUBSTANCES CONTROL ACT (TSCA)?

Updated TSCA directs the U.S. Environmental Protection Agency (EPA) to evaluate new chemical notices and make a determination whether a new chemical is safe, including for susceptible subpopulations, prior to allowing its manufacture and use.<sup>1</sup>

### WHAT ARE NEW CHEMICALS?

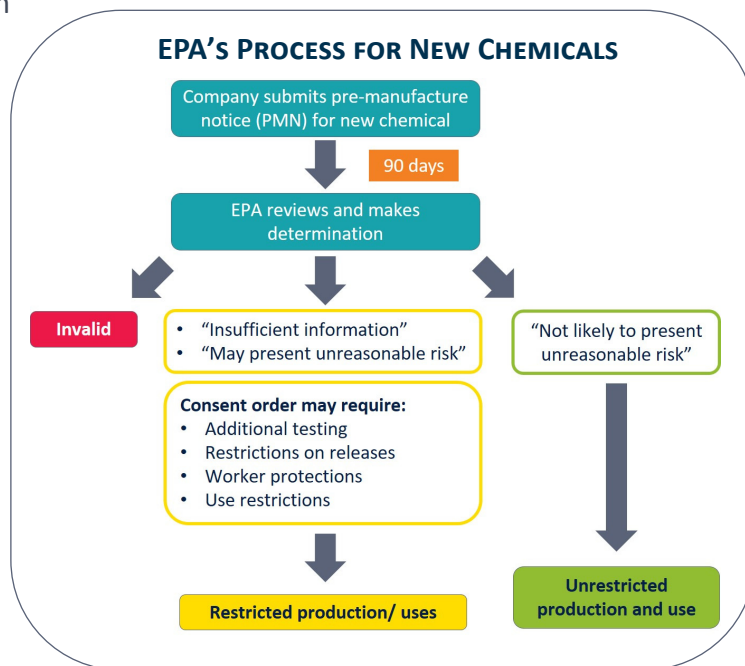
New chemicals are not yet authorized for use in commerce and are not listed on the existing TSCA inventory. To make and use new chemicals, companies must submit a pre-manufacture notice (PMN) to EPA. EPA reviews hundreds of new chemicals a year used in everything from cleaning products to baby clothes.<sup>2</sup>

### WHAT DOES TSCA REQUIRE EPA TO DO ABOUT NEW CHEMICALS?

Updated TSCA mandates that EPA cannot allow a new chemical to be introduced unless it concludes it is low-risk (in the words of the law, “not likely to present an unreasonable risk of injury to health or the environment”) under the conditions of use of the chemical. The “conditions of use” means the circumstances under which the chemical is intended, known or reasonably foreseen to be manufactured, processed, used and disposed. This includes uses that companies may not specifically list in the PMN, but which EPA can reasonably anticipate would occur given its experience with the type of chemical, application etc.

*The law requires EPA to issue a TSCA Section 5(e) order if it determines a chemical may present an unreasonable risk, there is insufficient information to make a determination, or the chemical may have substantial production and exposure or release.*<sup>3</sup> An order prescribes legally binding conditions that a company must comply with when

producing the new chemical. For example, if a chemical has the potential to cause birth defects, EPA could prohibit its use in everyday products to protect pregnant women, and require further testing. Or, if a chemical may be toxic to fish, EPA may restrict the chemical’s release to water. Section 5(e) orders are typically called “consent orders” because PMN submitters agree to sign them. In November 2017, EPA issued a “New Chemicals Decision-Making Framework” outlining changes to how the Agency is making new chemical determinations.<sup>4</sup> There is litigation over this framework.



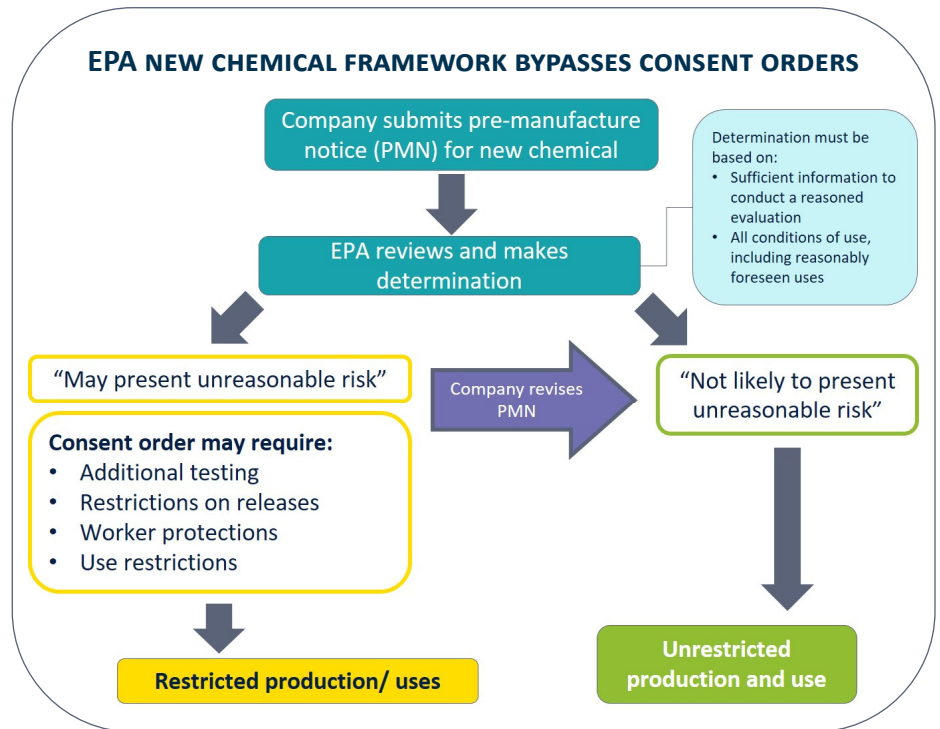
## CONCERNS WITH EPA'S IMPLEMENTATION OF TSCA FOR NEW CHEMICALS

**Determinations:** New TSCA does not allow new chemicals to proceed to manufacture in the absence of sufficient information to conduct a reasoned evaluation of risk.<sup>5</sup> EPA has not clearly defined what constitutes “sufficient information” for evaluation, such as desired information on health hazards like carcinogenicity. If EPA makes determinations without sufficient information on toxicity to human health, the public could be at risk from unknown or inadequately understood chemical hazards.

New TSCA also mandates that EPA make determinations after considering the full extent of the chemical's conditions use-- *including reasonably foreseen uses*.<sup>6</sup> But EPA's framework inappropriately narrows the scope of uses that EPA plans to consider, and ignoring dangerous uses could leave the public at risk.

**Consent orders:** To safeguard public health, new TSCA requires that EPA issue a consent order if a chemical may present an unreasonable risk;<sup>7</sup>

but EPA's framework introduces a huge loophole. Now, when a PMN application raises risk concerns, EPA is allowing companies to revise and resubmit the PMN. This enables chemical companies to receive a low-risk determination by editing PMN sections to address risk concerns on a voluntary basis, instead of EPA issuing legally binding consent orders which ensure the protection of the public.



## RECOMMENDATIONS

- ⇒ **EPA should gather sufficient data to determine if chemicals pose unreasonable health risks, including to susceptible subpopulations, by using its TSCA authorities to request existing data and additional testing.**
- ⇒ **EPA should consider all uses of a chemical, including reasonably foreseen uses, when making its determination.**
- ⇒ **EPA should issue consent orders as the law requires if a chemical may present an unreasonable risk or lacks sufficient information, EPA should not allow companies to revise PMNs and make unenforceable commitments to address potential risks.**

## REFERENCES

<sup>1</sup> 15 U.S.C. § 2604

<sup>2</sup> US EPA. Statistics for the New Chemicals Review Program under TSCA. <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>.

<sup>3</sup> 15 U.S.C. § 2604

<sup>4</sup> US EPA. New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA. November 2017. [https://www.epa.gov/sites/production/files/2017-11/documents/new\\_chemicals\\_decision\\_framework\\_7\\_november\\_2017.pdf](https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf)

<sup>5</sup> 15 U.S.C. § 2604

<sup>6</sup> 15 U.S.C. § 2604

<sup>7</sup> 15 U.S.C. § 2604