February 18, 2020

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001


Dear Sir or Madam:

We welcome the opportunity to comment on the issue of new chemicals, as it relates to protecting workers under the amended Toxic Substances Control Act (TSCA). The AFL-CIO is a federation of 55 national and international unions and represents more than 12.5 million working people in their workplaces. Our unions represent workers in a broad range of industries including manufacturing, construction, healthcare, education, transportation, utilities, retail and service, and others; in private and public sectors; in stationary and mobile workplaces. Our members work side-by-side millions of non-unionized workers. These comments submitted by the AFL-CIO also are being submitted on behalf of the International Association of Machinists and Allied Workers, International Chemical Workers Union Council, North America’s Building Trades Unions, and Utility Workers Union of America.

The AFL-CIO has been integrally involved with both the passage and implementation of the original 1976 TSCA and the 2016 Frank R. Lautenberg Chemical Safety Act for the 21st Century Act (LSCA), which amended the original TSCA law. The AFL-CIO previously commented on EPA’s proposed New Chemicals Framework in 2018, urging the agency to use their mandate under TSCA to protect workers from chemicals and fully evaluate risks to workers before assuming the use of controls, rather than ignore their duty under the law.1 In our comments on the document TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5 (Working Approach), we continue to stress the importance for EPA to appropriately assess worker exposures, the need for effective, enforceable
workplace protections, and issue warning to the agency that this new working approach moves EPA’s workplace protections backwards in time to the early 1970s, against its mandate under the amended TSCA law.

I. EPA is intentionally disregarding their mandate to protect workers from unreasonable risk to new chemicals.

A. TSCA Section 5 requires EPA to provide workers with protection from new chemicals.

Under TSCA Section 5, EPA is required to regulate all new chemicals unless the agency finds that a chemical is “not likely to present an unreasonable risk of injury to health or the environment,” a “not likely” determination. Additionally, EPA is required to take particular consideration to potentially exposed or susceptible subpopulations, specifically identifying workers as one of these. Moreover, EPA is required to regulate new chemicals’ known, intended, and reasonably foreseen conditions of use. Therefore, EPA must consider all the potential ways that workers may be exposed to a new chemical and then determine if the exposures are likely to result in unreasonable risk, which triggers regulation.

Before the amended TSCA in 2016, EPA already issued requirements to employers to prevent and mitigate worker exposures, particularly in the area of new chemicals. The Working Approach rolls this back. When TSCA was originally enacted in 1976, the law was intended to be a gap-filling statute, giving EPA co-existing and compatible authority with other agencies over chemical exposures. While TSCA became essentially ineffective in protecting people from some of the most toxic existing substances (e.g., asbestos), new chemicals was one area of TSCA that retained protective, upstream mechanisms to prevent or mitigate chemical exposures in the workplace. For decades under the authority of TSCA Section 5, before a company could introduce a new chemical to the market, EPA could require, through 5(e) orders, that employers install specific controls, including engineering controls and work practice controls—and often did. Many 5(e) orders stated:

When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

This practice was largely influenced by labor unions and other stakeholders who called for EPA to incorporate the hierarchy of controls as the established approach to protect workers against unreasonable risk.

When TSCA was amended in 2016, the spirit of the law did not change. In fact, LSCA more clearly defined EPA’s role to regulate toxic substances in the workplace through a more

---

5 For an example, see 78 FR 48063.
6 See EPA-HQ-OPPT-2010-0279-0130.
comprehensive approach across populations, routes of exposure and jurisdictions. Congress used the successes of the upstream and broad coverage approach of the new chemicals area of the law to establish a preventive system for all chemical exposure control. It is counterintuitive for EPA now to assume Congress intended to move backwards, away from the successes of the original law. In its amendments, lawmakers recognized the need to address gaps in coverage and effectiveness in overall chemical regulation by requiring more comprehensive measures throughout the risk evaluation and risk management stages of chemical assessment. But gap-filling never meant piecemeal—the law was meant to take into account other deficiencies, not rely on them. Given its history and experience in the area of new chemicals, EPA’s approach used for decades only required minor adjustments; the language of the amended act specified the approach EPA shall take to address new chemicals instead of the Agency developing its own framework.

In 2018, EPA proposed a new chemicals framework that dismissed their strengthened role in the workplace. In public comments to the agency at the time, the AFL-CIO and other unions strongly critiqued that framework and demanded that EPA provide workers with more protections from chemicals, not less. However, EPA has continued to ignore decades of agency practice of regulating new chemicals in the workplace and instead of building upon these processes to strengthen protections, significantly weakens them. This approach contradicts the Congressional mandate under TSCA as it considers extremely limited uses of new chemicals in order to circumvent findings of unreasonable risk—especially in the workplace.

**B. EPA is misconstruing occupational risk evaluations to camouflage unreasonable risk to workers.**

TSCA requires the EPA to conduct a risk evaluation and make a determination of unreasonable risk before it considers how such risks may be managed. It is statutorily required because it is an established scientific protocol. During a risk evaluation, established industrial hygiene practice requires EPA to measure risk without regard to whether control measures are used. Workplace controls are risk management tools and not risk evaluation tools. Only once risk is assessed can the appropriate management control be determined. Chemicals require different levels of risk management based off each of their individual toxicities and properties. For example, some organic solvents evaporate rapidly into the air requiring controls to prevent them from entering a worker’s breathing zone. Other chemicals, such as isocyanates, are powerful irritants and cause sensitization, requiring controls to prevent an allergic reaction. EPA must consider each chemical’s properties and how it will be processed and used throughout its lifecycle.

In this working approach, instead of evaluating risk, making a risk determination, and then mitigating risk, EPA is assuming the mitigation of risk prior to evaluating risk, then making a risk determination that shows there is not likely to be risk. This contrariwise approach results in the EPA issuing “not likely” determinations when there is unreasonable risk to workers, disregarding its duty under the law and effectively hiding the dangers of toxic chemicals from workers, the public, and manufacturers other than the Pre-manufacture Notice (PMN) submitter.

---

C. EPA is treating the hierarchy of controls as inconsequential.

The hierarchy of controls are the longstanding, well-established and widely accepted industrial hygiene practice to effectively mitigate workplace hazards. According to the hierarchy, the most effective method for controlling workplace hazards begins with substitution with a safer chemical, product or process; followed by engineering controls such as isolation or installation of local exhaust ventilation; administrative and work practice controls such as limiting time during which a particular task is performed; and only as the final line of defense, personal protective equipment (PPE), including respiratory protection, gloves and protective clothing. EPA has received exhaustive comments on the importance of the hierarchy of controls and proper implementation. Moreover, EPA has effectively used the hierarchy to protect workers from dozens of new chemicals in the past.

Despite this knowledge and understanding, EPA’s current working approach pays lip-service to the hierarchy of controls while simultaneously turning it on its head. While EPA describes that the initial assessment includes consideration of engineering controls, it does not independently assess if risk can be mitigated by anything other than the use of PPE, the least effective control method.

Instead, after making a risk determination, if unreasonable risk is found to workers, EPA must independently evaluate control methods to mitigate risk beginning with engineering controls, followed by administrative and work practice controls, and finally PPE. However, even if EPA begins to properly implement the hierarchy of controls, it cannot be used as justification for issuing a “not likely” risk determination. The risk still must be evaluated without regard to non-health factors, as the law explicitly states, and the agency should require that employers install controls following the hierarchy, as it had been doing previously.

D. EPA’s reliance on PPE is misdirected and does not protect workers.

Personal protective equipment has always been at the bottom of the hierarchy of controls because it is the least effective way to protect against toxic substances. Respirators and other forms of personal protective equipment do nothing to address bystander exposure and leave wide variability in the times they are worn, their fit, working conditions such as temperature, communication between workers, and the ability of workers to do their job tasks without compromising the fit and efficacy of the respirator. The limitations of PPE have been thoroughly explained to EPA many times including most recently in comments on the 2018 proposed New Chemical Framework.

---

9 See 78 FR 48065; 79 FR 8273; 79 FR 38464; 79 FR 39268; 79 FR 63821; 80 FR 5457; 80 FR 32003; 80 FR 59593; 81 FR 30452.
EPA must evaluate what type of PPE employers should be required to provide in order for the PPE to be effective. For example, different glove materials resist different chemicals, so no one glove can be universally protective. The glove material, thickness, length, degradation, breakthrough time, and permeation are all considerations for a glove to be protective against a chemical. Additionally, in some cases the incorrect protection can result in an increase of dermal exposures when they are donned, doffed or used for too long. Simply recommending gloves, even impervious gloves, or other PPE generally, is not sufficient and can give a false sense of protection to the user, the employer and the public.

It is unlikely that PPE will be mandated or is universally and properly used by the PMN submitter. Proper use includes correct type, proper fit, training, consistent use, proper use according to manufacturer's instructions, and possibly medical testing. However, it is even less likely that PPE will be universally or properly used by other manufacturers and downstream users of the chemical.

It is common for employers not to provide PPE for known toxic substances and extremely common for employers not to provide the proper fit or training for PPE use. One of OSHA’s most commonly violated standards is 1910.134(c), respiratory protection program and 1910.134(e), medical evaluations. Therefore, respirators are frequently not worn properly, even when required by OSHA. Moreover, a NIOSH study found that 42 percent of employers who provided respirators did not have a training program and less than half of employers performed the required medical assessment. Therefore, it is absurd for EPA to rely on the assumption that PPE will be voluntarily, universally and properly used to sufficiently reduce risk of harm from toxic chemicals and leaves workers in danger of significant health effects. The entire intent of the amended law was not to create additional gaps in effectiveness or coverage or to leave another agency to clean up EPA’s mess, but to design a system that corrects these potential gray areas, prevents future loopholes and is protective to the subpopulations identified in the law. It is worth noting that avoiding these gray areas through prevention also would be the most efficient use of government resources and would reduce its burden in the future.

Therefore, by relying on PPE to prevent exposure to toxic chemicals, EPA is leaving workers at increased risk of exposure than if the hierarchy of controls were properly implemented. Yet EPA’s failure to protect workers does not stop there, as the reliance on PPE occurs before a risk determination is made, EPA’s “not likely” determinations makes it less likely that other manufacturers or downstream users will be aware of the unreasonable risks that PPE use is assumed to address. The only way to ensure that all manufacturers of a new chemical and downstream users are using proper protections to prevent hazardous exposure levels is for EPA to mandate that employers provide protections.

---

E. Safety Data Sheets are not an effective, consistent way to communicate or enforce workplace protections.

EPA has made another erroneous assumption on the communication and flow of hazard information and necessary protections in the workplace to justify issuing “not likely” determinations. EPA is planning to require the original submitter’s Safety Data Sheet (SDS) reflect agency recommendations to protect workers from the risks EPA found in the initial assessment, including PPE and hazard communication, rather than use the enforcement mechanism specifically described in detail by lawmakers through TSCA. Relying on PPE voluntarily listed on the SDS by the manufacturer, the agency assumes that future users of the chemical, including other manufacturers and downstream users, will have accurate and sufficient information to protect their workforce or themselves against the hazardous chemical. 14

EPA’s assumptions are fundamentally flawed and not consistent with well documented limitations of SDSs. A published literature review concluded there are significant problems with the accuracy and completeness of SDSs, that many workers are not able to understand the complex language used in SDSs generally, and that a lack of training and poorly enforced regulations may contribute to low use and awareness of SDS across a range of industries.15 This was also found more recently in a 2018 report by the European Chemicals Agency stating “serious shortcomings in the quality of the information in [SDSs].”16 EPA has even previously recognized the limitations of SDSs citing a study which concluded that approximately one-third of SDSs were incomprehensible.17

Additionally, SDSs are ineffective at consistently communicating hazard information because each sheet is created by each individual manufacturer. The original manufacturer may include Agency recommendations, but other manufacturers may not. However, the Agency’s recommendations are not sufficient or specific enough to be protective. Previously discussed in these comments are the limitations of PPE and the specifications that are essential for PPE to reduce exposure. SDSs are not intended to convey the level of information needed to protect against toxic chemicals to the average lay person and only offer guidance that is too vague to be meaningful. In the workplace, the reality of SDSs is that they are collected, placed in a binder, and sit in an office drawer—only to be looked at if an emergency occurs or health effect is seen. SDSs cannot be assumed to be relied on for the consistent protections that TSCA requires to actually reduce workers’ risk from harm.

personal protective equipment, and engineering controls, there is no requirement for employers to implement the recommended controls. EPA has sufficient evidence that SDSs do not require, nor voluntarily result in, protections being universally or properly used.

II. EPA is distorting OSHA regulations.

A. OSHA’s worker protection standard does not protect workers from new chemicals.

In the Working Approach, EPA states that “[t]he requirements set forth by [OSHA], including OSHA’s worker protection standard require employers to provide and have affected employees use PPE wherever it is necessary by reason of hazards present in the workplace.” However, this interpretation is far removed from OSHA practice.

OSHA requires a clear and significant burden of proof in order to regulate workplace hazards. In the absence of a permissible exposure limit or comprehensive standard to identify a hazard, OSHA requires strict criteria to establish a violation under the General Duty Clause. OSHA must show that (1) the employer failed to keep the workplace free of a hazard to which employees of that employer were exposed; (2) the hazard was recognized; (3) the hazard was causing or was likely to cause death or serious physical harm; and (4) there was a feasible and useful method to correct the hazard. Due to this, OSHA rarely issues a 5(a)1 violation for airborne chemical exposures, and when they do it is most often related to an acute fatality from airborne exposure.

With this extraordinarily high burden of proof, OSHA regulations leave employers with significant discretion to determine what constitutes a hazard. This is true for all OSHA standards, but also 1910.132 which provides employers with discretion to determine the type of hazard, the PPE required, and any documentation of their decisions. The preamble specifically states “[t]he Agency believes that the employer will be capable of determining and evaluating the hazards of a particular workplace…. It should not be necessary for employers to prepare and retain a formal written hazard assessment.” The main purpose of 1910.132 is not to require PPE, but to assure that if the employer decides to provide PPE, it is maintained and paid for by the employer and training is provided.

B. OSHA does not have the ability to regulate new chemicals.

As stated above, OSHA’s high burden of proof required to issue a general duty clause citation means it rarely relies on this mechanism to cite employers for chemical exposures. This is true

18 See 77 FR 17574-17693.
22 See 59 FR 16334-16364.
even for chemicals where the risk to workers has been long-established, and even more so for a new chemical with limited information. To issue citations under any standard, OSHA must meet significant risk thresholds that require disease or death estimates associated with that particular chemical. Even where that information exists for long-established chemicals, OSHA’s rulemakings can take years or decades to complete.

Additionally, OSHA does not have the enforcement coverage or resources to protect all workers from new chemicals. Many workers in the U.S. are not covered by the OSH Act. Currently 8 million public sector workers, 15 million self-employed workers, thousands in the mining industry, and many agricultural workers on small farms are not afforded safety and health protections under the OSH Act. However, these workers are considered potentially exposed or susceptible subpopulations covered under TSCA.

Even where OSHA has coverage, OSHA is staffed with so few resources that it would take federal OSHA inspectors 165 years to visit every workplace in the U.S. once. With strapped resources and staff, OSHA prioritizes well-understood hazards and issues citations using standards with a long history, and tragically, for chemicals with a long history of making people sick.

Moving forward, it is even more unrealistic that OSHA will regulate new chemicals. Not only has the Trump administration removed chemical exposures from OSHA’s regulatory agenda, it recently implemented a new OSHA enforcement weighting system that places less emphasis on significant non-PEL chemical exposures, likely to result in even less action than in previous years. But it is not simply that OSHA is a small agency with very limited capabilities in chemical regulation, which is true, but even under existing structure and authority, the agency does not have the abilities to regulate new chemicals that EPA has.

C. **OSHA’s regulations are less protective than EPA’s authority to reduce risk.**

The Supreme Court has limited OSHA’s authority to regulate only significant risks and OSHA generally uses significant risk to mean a risk posed to one in one thousand workers. Under TSCA, workers must be protected from exposures that “may present unreasonable risk” defined as one in one-hundred thousand. The level of risk OSHA regulations are intended to address are magnitudes less protective than the level of risk EPA must consider. Additionally, if EPA finds that a chemical presents an unreasonable risk, may present an unreasonable risk or there is insufficient information to make a determination, EPA is required to issue a 5(e) order. There is no similar concept under the OSH Act. Therefore, even when employers comply with relevant OSHA standards to protect workers against new chemicals, EPA has no basis to conclude that workers are protected from unreasonable risk.

---

25 Id.
D. EPA’s requirements to consult with OSHA reaffirms their authority in the workplace.

TSCA Section 5 requires EPA to “consult” with OSHA regarding workplace chemicals and exposures “to the extent practicable”, but does not give OSHA deference.26 This mandate makes it clear that Congress intended that EPA would be dealing with occupational exposures and workplace protections. However, this requirement to consult with OSHA does not intend for EPA to rely on current or potential OSHA regulations to justify “not likely” determinations or avoid taking regulatory action. Instead, EPA must utilize OSHA’s expertise in occupational exposures in order to require effective workplace protections.

III. EPA is leaving workers without enforceable protections against unreasonable risk.

EPA’s Working Approach’s goal seems to be to issue as many “not likely” determinations as possible to limit their requirements to issue enforceable protections. This is particularly evident in EPA’s statement “unless case-specific facts indicate otherwise, EPA believes that a chemical is generally not likely to present unreasonable risks to workers if the use of PPE and/or other exposure controls would mitigate potential risk.”27 This broad determination allows chemicals to go into production without any required protections in place.

The recommendations EPA makes for the submitter to receive a “not likely” determination are based solely on the voluntary use of PPE, the bottom of the hierarchy of controls, written on a non-enforceable SDS. However, TSCA specifically gives EPA the authority to go beyond recommendations and issue 5(e) orders to ensure employers are providing adequate protections. As previously mentioned, EPA has previously issued enforceable workplace protections when unreasonable risk to workers is determined, yet now has backed away from their re-authorized duty.

EPA has seemed to attempt to acknowledge that their approach leaves workers at risk by discussing Significant New Use Rules (SNURs) that precede or follow determinations. However, a SNUR does not require protections before a new chemical is placed on the market; a SNUR only requires a person who intends to manufacture or process a chemical substance for a significant new use to notify EPA 90 days before commencing that activity.28 Additionally, in practice, SNURs have only been proposed with “not likely” determinations with very few finalized, no matter if it was considered a SNUR preceding or following the risk determination. Therefore, EPA’s acknowledgment of a risk to workers through issuance of a SNUR is nothing more than a paper tiger in practice.

The mandated and effective approach to protecting against unreasonable risk, EPA is supposed to issue 5(e) orders when risk is found and the orders must integrate the hierarchy of controls. As discussed previously, the only way to provide effective protection against toxic substances is to

28 Id. Pages 5-6.
codify engineering controls requirements, then administrative and work practice controls, and lastly PPE. Any other approach, such as the one laid out in EPA’s Working Approach, violates the TSCA requirements and leaves workers at risk.

IV. EPA’s recent actions have disrespected the intent of TSCA.

Originally, TSCA was intended to protect people from toxic substances, including before chemicals were allowed on the market. When TSCA was amended, this intention was further defined and their role to regulate toxic substances in the workplace was strengthened. However, before the release of the Working Approach, EPA had already applied the approach when reviewing new chemical applications. A review of EPA decisions since July 2018 shows that EPA has issued around 300 “not likely” determinations. These determinations have been made with the large majority finding unreasonable risks to workers until EPA camouflaged the risk to workers by including universal and proper PPE use into the risk evaluation. EPA’s interpretation of the statute has resulted in weaker implementation of Section 5 of TSCA than before the law was amended. EPA’s actions prior to presenting the approach for public comment completely disrespects the bipartisan intent of TSCA to protect workers from toxic substances.

Moreover, EPA included a statement in the Working Approach Document which attempts to absolve itself from the Agency’s duty to provide a transparent and scientific approach to protecting Americans from toxic substances, “EPA may choose to depart from this approach with respect to any specific submission as the Agency deems appropriate.” While the Working Approach is not a formal rulemaking, EPA is clearly trying to deflect their responsibility authorized under TSCA, pointing to a lack of political will to hold chemical companies responsible for exposing workers to toxic substances.

Conclusion

The magnitude of disease from work-related chemical exposures is not insignificant, but EPA’s Working Approach is another failure to the United States worker. It is not inevitable that workers develop diseases because of the chemicals they are required to work with; where proper controls are required or safer alternatives are used, these diseases are preventable.

Congress passed the original TSCA law to give EPA authority to address chemical exposures in commerce. To address a broken system that has resulted in lack of protections for working people and other particularly susceptible subpopulations, Congress reauthorized and strengthened EPA’s authority on toxic substances in the workplace by amending TSCA in 2016. EPA’s Working Approach, which the Agency has already been implementing, undoes decades of protective measures by EPA in workplaces where new chemicals are produced, conceals risk to workers, distorts OSHA regulations, and insults the intention of TSCA. EPA must correctly evaluate risk, properly implement the hierarchy of controls, and issue enforceable protections to fulfill their mandate to protect workers and the public from chemical exposure. EPA mistakes the implementation of the amended TSCA as striking a balance between the chemical industry and advocates for susceptible subpopulations, such as unions, but the agency’s only requirement is to follow the law the way Congress intended it to be—more protective, not less.
For more information, please contact:

MK Fletcher, MSPH  
Safety and Health Specialist, AFL-CIO  
mfletcher@aflcio.org

Rebecca L. Reindel, MS, MPH  
Safety and Health Director, AFL-CIO  
rrreindel@aflcio.org