AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

January 19, 2018

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: Implementation of the New Chemicals Review Program under the Toxic Substances Control Act as Amended (Docket No. EPA-HQ-OPPT-2017-0585)

Dear Administrator Pruitt:

On behalf of the American Public Health Association, a diverse community of public health professionals that champions the health of all people and communities, I appreciate the opportunity to comment on implementation of the New Chemicals Review Program by the U.S. Environmental Protection Agency under section 5 of the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the Lautenberg Act). These comments have been informed by a review of the Lautenberg Act and EPA's "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under section 5 of TSCA."[1]

Every year, hundreds of new chemicals come onto the market.[2] Historically, these chemicals entered commerce with little – and sometimes no – data to support their safety. A major aim of the Lautenberg Act is to ensure that new chemicals are reviewed for safety before they end up on store shelves and before the public, including many vulnerable populations like children, pregnant women and workers, may be exposed. We are concerned that EPA's implementation of TSCA section 5, as outlined in the framework, fails to ensure that new chemicals will be fully evaluated and properly regulated to protect Americans' health. We urge the agency to consider the following issues so that the public is protected, as the law requires.

<u>TSCA section 5 requires EPA to protect public health from risks presented by new chemicals</u>

TSCA section 5, as amended, requires EPA to take action to protect the public from the risk presented by a new chemical unless the agency determines that the chemical is "not likely to present an unreasonable risk of injury to health or the environment." Specifically, section 5(a) requires EPA to review information contained in notices submitted by manufacturers of new

[1] 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 (accessed January 12, 2018) (hereafter, "Framework").
[2] 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 (accessed January 16, 2018).

chemicals (pre-manufacturing notices or PMNs), make a determination about the risk of injury to health or the environment presented by the chemical, and then take action based on this determination. With one exception – when EPA determines that a chemical is "not likely to present an unreasonable risk" under section 5(a)(3)(C) – every determination that the agency may make under section 5(a) requires agency action under section 5(e) or section 5(f). For example, even if there is insufficient information for EPA to make a determination about a chemical, section 5(e) requires EPA to be cautious and to protect against unreasonable risk by prohibiting or limiting the manufacture, processing, distribution in commerce, use or disposal of the substance.

EPA cannot seek amendments to pre-manufacturing notices in place of issuing section 5(e) orders

If the agency determines that a chemical "may" present an unreasonable risk, that the information available is insufficient to permit a reasoned evaluation, or that the chemical is produced in substantial quantities and environmental releases or human exposures may be high, TSCA section 5(e) requires the agency to issue an order imposing prohibitions or other limitations "to the extent necessary to protect against an unreasonable risk of injury to health or the environment." The framework suggests, however, that the agency may forego issuance of a section 5(e) order if the manufacturer amends the PMN submitted to the agency to incorporate recommended limits on release and exposure.[3]

This approach would not protect public health. A PMN, including any stated limits on exposure and release, is voluntary. By contrast, a section 5(e) order is binding and enforceable: under section 5(e)(1), after issuance of an order, "the submitter of the notice may commence manufacture of the chemical substance...only in compliance with the order." We urge EPA to issue section 5(e) orders, rather than seek amendments to PMNs, whenever the agency believes that a chemical may present an unreasonable risk, the information available is insufficient, or environmental releases or human exposures may be high.

EPA cannot invent a lower standard for a "not likely" determination

EPA has attempted to invent a lower standard for making a "not likely" determination and thereby avoiding the duty to take action that TSCA section 5 otherwise would impose. In the framework, EPA claims that "the level of uncertainty in a reasoned evaluation to inform a "not likely" determination could be greater than that in an evaluation to inform a "presents" determination."[4] This claim is based on the agency's contention that the word "presents" is "less equivocal" than the words "not likely."[5]

EPA's interpretation ignores the fundamental nature of scientific inquiry and inference that underlie determinations about risk. In this context, use of the words "not likely" merely acknowledges that while scientists can identify some risks presented by a chemical, they cannot determine definitively that a chemical does not present a risk because new research informed by

[3] Framework at 4.
[4] Framework at 1n3.
[5] *Id.*

new scientific knowledge and methods may identify new hazards or lower levels of exposure that can threaten public health. In essence, scientists cannot prove a negative.

Lead, and specifically the level of lead in blood known to harm the developing nervous system, provides a telling example. Before 1970, the blood lead level of concern was 60 µg/dL.[6] As new evidence associated lower levels with neurodevelopmental harm, the level of concern declined from 60 to 40 µg/dL in 1971, to 30 µg/dL in 1978, to 25 µg/dL in 1985, and to 10 µg/dL in 1991.[7] In 2012, citing evidence that no blood lead level was safe, the term "level of concern" was jettisoned altogether and replaced with a reference value pegged to the upper 97.5th-percentile blood lead level among children ages 1 to 5.[8] This value was 5 µg/dL in 2007-2010.[9] In 1960, it would have been accepted that a blood lead level of 5 µg/dL did not present an unreasonable risk of injury to health, but with the benefit of additional scientific research, it is clear that such a determination would have been incorrect.

The language of TSCA section 5(a) recognizes that scientific knowledge evolves by limiting any determination that a chemical does not appear to present a risk to a determination that the chemical is "not likely to present an unreasonable risk." It does not, as EPA suggests, support a lower standard for a "not likely" determination.

EPA cannot make a "not likely" determination based on vague "risk-related factors"

The framework indicates that, even when EPA determines that the risk associated with exposure to a chemical exceeds benchmarks of unreasonable risk traditionally used by the agency, EPA nonetheless may determine that such risks "are not likely to be unreasonable" based on vague "risk-related factors."[10] The agency does not elaborate on these factors, except to list several examples: "severity of endpoint, reversibility of effect, or exposure-related considerations (duration, magnitude, population, etc.)".[11]

The use of vague risk-related factors in place of traditional benchmarks raises troubling questions. For example, how does EPA intend to determine that the severity of an endpoint makes the risk of the endpoint "not likely to be unreasonable"? The framework does not answer this question and fails to provide an example of an endpoint that EPA believes is not severe. It is doubtful that EPA should determine that the endpoint associated with a chemical exposure is not severe – and therefore that risk of the endpoint is not likely to be unreasonable – on behalf of those individuals who experience the endpoint.

Similarly, how does EPA intend to determine that the reversibility of an effect makes the risk of the effect "not likely to be unreasonable"? Workers who are exposed to formaldehyde-containing compounds may experience irritation to their respiratory system, including chest pain and

[6] Lanphear, B.P., R. Hornung, J. Khoury, et al., Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environmental Health Perspectives, 2005, 113, 894-899 at 897.
[7] *Id*.
[8] CDC, Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention, 2012, https://www.cdc.gov/nceh/lead/acclpp/final_document_030712.pdf (accessed January 12, 2018) at 3.
[9] CDC, What Do Parents Need to Know to Protect Their Children?, https://www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm (accessed January 12, 2018).
[10] Framework at 4.
[11] Framework at 4.

shortness of breath.[12] Respiratory irritation, chest pain and shortness of breath may resolve after exposure – that is, these effects may be reversible – but they are not inconsequential. Formaldehyde is also a sensitizing agent that can elicit an immune response, including allergic asthma and dermatitis.[13] It is one of more than 300 agents have been designated as work-related asthma agents.[14] Once the immune response is activated, future exposure to formaldehyde-containing compounds and other asthmagens will trigger a biological response. EPA should not dismiss such a response simply because it is reversible.

While pesticides generally do not fall within the definition of chemical substances regulated under TSCA, it is instructive to consider the neurological effects of carbamate insecticides. These effects are caused by the reversible inhibition of acetylcholinesterase enzymes that regulate signaling between the nerves and muscles.[15] If an exposure is not fatal, a worker or bystander poisoned by a carbamate may recover after several hours of vomiting, difficulty breathing, and other symptoms as the inhibition slowly reverses.[16] The framework suggests that EPA believes an elevated risk for the reversible neurological effects of carbamate poisoning is not likely to be unreasonable. If this is not EPA's belief, the agency must clarify. If it is, the agency should justify its belief.

In addition, EPA cannot determine that an estimate of risk that exceeds a traditional benchmark is not unreasonable based on exposure-related considerations such as duration and magnitude because these considerations already are taken into account when risk is estimated. For example, cancer risk is estimated by multiplying a "lifetime average daily dose," which is an estimate of the level (or *magnitude*) of daily exposure to a chemical averaged over a lifetime (a *duration*), by a "unit cancer risk." The estimate is compared to a benchmark. As the framework notes, $1x10^{-6}$ (or 1 additional case of cancer per 1 million people exposed) "has often been considered a "benchmark" above which EPA has concerns for exposure to the general population."[17] As duration and magnitude are reflected in the risk estimate, it is unclear how EPA could determine that an estimate of risk that exceeds $1x10^{-6}$ (or another benchmark, as appropriate) is not unreasonable based on duration and magnitude.

<u>EPA must protect workers from exposures to new chemicals under TSCA section 5</u>

Workers unwittingly have served as the "canary in the coal mine" for adverse health effects stemming from exposure to toxic chemicals. Indeed, workers are often exposed to the highest concentrations of chemicals and chemical mixtures. An estimated 96,000 U.S. residents die every year from work-related illnesses – more than 260 every day.[18] This number includes deaths from lung cancer due to exposure to asbestos, arsenic, chromium, nickel, and diesel exhaust;

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[12] ATSDR, Addendum to the Toxicological Profile for Formaldehyde, October 2010, https://www.atsdr.cdc.gov/toxprofiles/formaldehyde_addendum.pdf (accessed January 16, 2018).
[13] *Id*.
[14] Rosenman, K.D. and Beckett, W.S., Web based listing of agents associated with new onset work-related asthma, *Respiratory Medicine*, 2015, 109, 625-31.
[15] Rosman, Y., Makarovsky, I., Bentur, Y., et al., Carbamate poisoning: treatment recommendations in the setting of a mass casualties event, *American Journal of Emergency Medicine*, 2009, 27, 1117-1124 at 1119.
[16] *Id*.
[17] Framework at 4.
[18] Takala, J., P. Hämäläinen, K.L. Saarela, et al. Global estimates of the burden of injury and illness at work in 2012, *Journal of Occupational and Environmental Hygiene*, 2014, 11, 326-37.

hematopoietic diseases from exposure to benzene, radiation, and formaldehyde; and adverse reproductive effects from exposure to perfluorinated compounds. By enacting the Lautenberg Act, Congress intended EPA to use its authority to address occupational exposure to chemicals. Indeed, Congress explicitly identified workers as a "potentially exposed or susceptible subpopulation" under the law.

EPA must evaluate occupational exposure across both intended and reasonably foreseen uses

Workers are exposed to chemicals and chemical mixtures along a chemical's life cycle. Yet the framework suggests that, when reviewing a PMN, EPA will consider only those uses identified by the manufacturer in the notice (the "intended" uses) and not other uses that the agency believes are "reasonably foreseen."[19] EPA's New Chemical Review Program must more fully integrate Congress's intent into the framework by recognizing that workers are exposed to chemicals in settings and during applications which are beyond those listed by a manufacturer in the PMN submitted to EPA. These settings and applications may occur during production, processing, distribution, use and/or disposal of a chemical. EPA must ensure that chemicals in the workplace that present unreasonable risks are controlled.

It also is important for EPA to understand that families of workers historically have been exposed to deadly workplace chemicals because of contaminated clothing, equipment and belongings that come home from work with them. EPA should consider such "take-home" exposures as it makes determinations about the risks presented by new chemicals.

EPA should not defer to the Occupational Safety and Health Administration

While TSCA section 5(f)(5) requires EPA to *consult* with the Occupational Safety and Health Administration to the extent practicable prior to adopting a prohibition or other restriction on a chemical that EPA has determined presents an unreasonable risk to workers, there is no indication in the statute that Congress intended for EPA to *defer* to OSHA. This is prudent, as it is well recognized in the public health community that OSHA does not have the capacity to assess and regulate the tens of thousands of chemicals in commerce. Indeed, OSHA has comprehensive health standards on just a few dozen chemical agents.[20] The majority of these standards were issued before 1990.[21] Furthermore, OSHA's ability to regulate chemical hazards is constrained by legal restrictions and inadequate resources. The Government Accountability Office reported in 2012 that it takes an average of seven years for OSHA to issue a standard to protect workers.[22] The result is that millions of U.S. workers are exposed to chemicals that pose an unreasonable risk of injury to health.

We urge EPA to reject assertions, such as those by the New Chemicals Coalition, a group of companies, that EPA should have a very limited role in addressing occupational exposure to chemicals. NCC recommends that the agency simply consult with OSHA about a chemical risk

[19] Framework at 2.
[20] AFL-CIO, Death on the Job: The Toll of Neglect, April 2017, https://aflcio.org/sites/default/files/2017-04/2017Death-on-the-Job.pdf (accessed January 16, 2018) at 106.
[21] *Id.*
[22] U.S. Government Accountability Office, Workplace Safety and Health: Multiple Challenges Lengthen OSHA's Standard Setting, April 2012, https://www.gao.gov/assets/590/589825.pdf (accessed January 16, 2018).

and inform the chemical use notifier of its evaluation.[23] NCC suggests that EPA's responsibility ends at this point, and that the "general duty clause" (GDC) of the Occupational Safety and Health Act of 1970 (the OSH Act) and the respiratory protection standard (1910.134) impose sufficient requirements to protect workers from chemical exposures.[24]

NCC's assertion that OSHA's GDC functions as an effective tool to protect workers from chemical hazards is incorrect. Under both Republican and Democratic administrations, OSHA has been reluctant to enforce the GDC for many hazards, especially chemical hazards, because of the high burden of proof required to substantiate a GDC citation. Violations issued under the GDC and litigation to defend them are resource intensive.[25] Furthermore, despite representing the regulated industry, NCC fails to mention that there is strong opposition within industry to OSHA's use of the GDC for chemical hazards. In congressional testimony, the U.S. Chamber of Commerce said doing so "…would be the equivalent of de facto rulemaking."[26]

EPA likewise should not rely upon OSHA's respiratory/personal protective equipment standard to protect against chemical hazards. The *hierarchy of controls* is widely recognized as the most effective form of protection against workplace hazards, including chemical exposures.[27] The hierarchy emphasizes elimination, substitution, engineering controls, work practice controls and administrative controls, in that order, all before considering personal protective equipment as the last resort option for protection.[28] Personal protective equipment is not always adequate, appropriate or effective. It will not reduce the burden of disease associated with chemical exposures.

A decision by EPA to defer to OSHA would be improper for another reason. A substantial portion of U.S. workers are not covered by the OSH Act. This includes 15 million individuals who are self-employed workers; 8 million state and local government employees; workers in agriculture who are employed on small farms; and 350,000 workers in the mining industry who fall under the Federal Mine Safety and Health Act of 1977. These workers deserve protection as well, but they will not receive it if EPA defers to OSHA and fails to use its authority under TSCA section 5 as required.

Conclusion

The enactment of the Lautenberg Act marked an important step forward for environmental and occupational health in the U.S. The requirement that EPA make determinations about the health and environmental risks presented by new chemicals and take action as necessary to protect

[23] Kathleen M. Roberts, New Chemicals Coalition. Letter to Jeffrey Morris, December 1, 2017, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0028 (accessed January 16, 2018).
[24] *Id.*
[25] David Michaels, Assistant Secretary of Labor, OSHA, Testimony before the Committee on Education and the Workforce, Subcommittee on Workforce Protections, October 7, 2015, https://www.osha.gov/news/testimonies/10072015 (accessed January 16, 2018).
[26] U.S. Chamber of Commerce, OSHA's regulatory agenda: Changing long-standing policies outside the public rulemaking process, House Committee on Education and the Workforce, Subcommittee on Workforce Protections. February 4, 2014, https://edworkforce.house.gov/uploadedfiles/hammock_revised_testimony.pdf (accessed January 16, 2018).
[27] CDC, Hierarchy of Controls, https://www.cdc.gov/niosh/topics/hierarchy/default.html (accessed January 16, 2018).
[28] *Id.*

public health is one of the new law's most important advances. It is essential that EPA fulfill the promise of the Lautenberg Act by robustly implementing these requirements. We hope the comments above will help the agency in this regard. Please feel free to contact me with questions regarding our comments on this important public health issue.

Sincerely,

Georges C. Benjamin, MD
Executive Director