



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF THE  
ADMINISTRATOR

The Honorable Thomas R. Carper  
United States Senate  
Washington, D.C. 20510

Dear Senator Carper:

This letter serves to highlight steps the Environmental Protection Agency is taking to address issues you have recently raised as further priorities. As always, I appreciate the continued dialogue between my staff and your staff on these issues and look forward to working together to achieve our shared environmental goals.

I fully appreciate that you want to know that the bipartisan work which went into the enactment of the Frank R. Lautenberg Chemical Safety Act for the 21st Century is fully reflected in its implementation by the EPA. I would like to commit to providing additional public information for the review of chemicals under this statute.

EPA receives approximately one thousand new premanufacturing notices (PMNs) from chemical manufacturers each year. These represent new products which manufacturers would like to place on the U.S. markets. EPA commits to ensuring that starting no later than May 31, 2019, all new PMNs, their attachments, including any health and safety studies, any modifications thereto, and all other associated information are placed online into electronic dockets accessible via ChemView within 45 days of their receipt following an evaluation of sensitive confidential business information. Each month, EPA will also publish in the *Federal Register* a notice of receipt of all PMNs, test marketing exemptions (TMEs) and notices of commencement (NOCs) received in the preceding calendar month. For PMNs, these notices will include at least the case numbers, amendment number and version, date received, manufacturer (if not CBI), use (specific, or generic if CBI), and chemical substance (specific and CAS number if not CBI, or the generic name if CBI). For TMEs we will make available the case, submission type, version, date received, manufacturer (if not CBI), use, and chemical substance. For NOCs we will also make available the case, date received, commencement date, if an amendment, the type of amendment (amendment to generic name, specific name, technical contact information, etc.), and chemical substance. EPA will also make available, via ChemView, each PMN reviewed and subject to a final determination, and will make available all underlying documents supporting EPA's risk determinations, as soon as practicable, with a goal of making this information public as close in proximity as possible to when a final determination is communicated to the PMN submitter.

EPA released a draft framework this year to guide the evaluation of PMNs and requested public comment. EPA will commit to working with the Committee on considering those public comments in our evaluation. EPA will publish its next version of this framework, and will hold a public meeting to solicit additional public comment and describe our working approaches within 60 days of its publication. EPA's framework will specify: (i) the statutory and scientific justifications for the approaches described, (ii) the policies and procedures EPA is using/plans to use in its PMN reviews, and (iii) its responses to public comments received.

I also understand that substantiation of new and re-substantiation of long-standing CBI claims is another concern. EPA commits to providing you with a report describing how the Agency is complying and will comply with Section 14 of the Frank R. Lautenberg Chemical Safety Act for the 21st Century within the next 180 days, with specific information and statistics related to the Agency's implementation of Section 14(g), as well as information on how and when the public will be able to track the status of EPA's reviews of CBI claims and have access to EPA's CBI determinations and associated documents on EPA's website. Additionally, before that time, EPA will describe how the Agency is requiring substantiation or re-substantiation of and reviewing CBI claims on chemicals undergoing risk evaluations, including EPA's plans to ensure both that the public is made aware of the outcome of those reviews and is provided access to any information no longer entitled to CBI protections (i) within 6 months of the release of a final determination regarding risk under TSCA section 6(b)(4)(A) for any chemical substance currently undergoing a risk evaluation, and (ii) before the release of the scope of the risk evaluation for other chemical substances.

The Agency has been developing proposals concerning the Agricultural Worker Protection Standard (WPS) rule, including changes to the designated representative and minimum age provisions, and application exclusion zone (AEZ) provisions. The Agency has also been developing changes to the Certification of Pesticide Applicators (CPA) rule. Although the subject matter associated with these potential changes has been subject to wide ranging public stakeholder meetings and public comments, EPA will withdraw its OMB submission to propose revisions to these rules and will not make any changes to the designated representative and minimum age provisions. It may consider proposing revisions to the AEZ provision in the WPS rule, but to no other substantive provision in the WPS rule. If such a proposal is issued, it would be subject to a public notice and comment period of no less than 90 days.

It is important that all of the Agency's chemical safety efforts comply with the requirements in the law as well as the regulations implementing the law regarding the Agency's use of the best available science. Consequently, the Agency will, promptly submit the methodology for deciding how to collect and evaluate scientific research related to a chemical's safety that was recently developed by the Office of Chemical Safety and Pollution Prevention (OCSPP) to the National Academy of Sciences (NAS) for peer review and feedback and, at the same time EPA will use the Frank R. Lautenberg Chemical Safety for the 21st Century Act Section 26(o) mandated advisory committee, a FACA committee, whose purpose is to provide independent advice and expert consultation with respect to the scientific and technical aspects of issues related to TSCA, to provide its independent advice on the methods used by OCSPP to collect and evaluate scientific research in the first ten risk evaluations. I also commit to make public the review, feedback and any recommendations received from both the NAS and the

advisory committee within 30 days of their receipt. Finally, EPA will incorporate feedback and recommendations as appropriate.

Additionally, I will ensure that for each of the first ten existing chemicals being reviewed under the new law, there will be at least 60 days made available for public comment on the draft risk evaluations with consideration of extensions as appropriate, and an effort will be made to stagger some of their public release in order to maximize the opportunity for review and thorough comments to be prepared and submitted.

EPA proposed a PFAS significant new use rule (SNUR) in 2015. The EPA is considering the public comments received as well as the new statutory requirements added by the Frank R. Lautenberg Chemical Safety for the 21st Century Act as it is moving forward to issue a supplemental proposed SNUR on PFAS.

I appreciate your continued interest in the implementation of the Frank R. Lautenberg Chemical Safety Act for the 21st Century. I want to assure you it is a mutual interest, and appreciate the opportunity to work with you on these and other matters of interest.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Wheeler", with a long horizontal flourish extending to the right.

Andrew R. Wheeler  
Acting Administrator

cc: The Honorable John Barrasso  
Chairman