Environmental Protection Network

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Dr. Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Re: New Chemical Review Process

Dear Assistant Administrator Freedhoff:

As you know, the Environmental Protection Network (EPN) is an organization of over 550 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, human health, and the environment. We hope you are well and that this letter provides some helpful ideas for you and your staff regarding EPA's new chemical review process.

Recently, concerns have been raised in the press about the process that the agency has followed in making scientific judgments about the risks of new chemicals subject to premanufacture notification (PMN) under section 5 of the Toxic Substances Control Act (TSCA). The concerns voiced by the EPA scientists in the articles arise against the backdrop of policy changes made by the last administration that prioritized the completion of PMN reviews in 90 days and reduced the issuance of orders placing restrictions on new chemicals and requiring testing. These policy changes may have conveyed the message to EPA staff that the agency was deemphasizing public health, environmental protection, and good science as driving factors in new chemical regulation.

Given the importance of ensuring confidence in the chemical review process, EPN is recommending revisions to enhance transparency, facilitate dispute resolution, and ensure the scientific integrity of new chemical safety decisions.

Our first recommendation is for EPA to reaffirm that the quality of new chemical reviews and the protection of public health and the environment cannot be sacrificed in order to complete PMN reviews in 90 days. EPA has traditionally used a variety of tools to extend (or suspend) the review period when it needs additional information for an informed assessment or more time for EPA staff to come to closure on the potential hazards and exposures of the new chemical. The 2016 TSCA amendments include new requirements for EPA to make a safety determination for every new chemical and provide that no substance can proceed to commercialization until this determination has been made, notwithstanding the completion of the 90-day review period. Although PMN reviews need to be completed expeditiously, EPN recommends that this goal not take precedence over careful consideration of the weight of scientific evidence and adequacy of available data in making determinations on a new chemical's potential risks, especially to

overburdened and vulnerable communities, and that health-protective defaults be used. If important scientific judgments are rushed in the interest of a speedy review, public health and environmental protection will be compromised and confidence in the process undermined.

EPN's second recommendation relates to the use of analogs or Structure Activity Relationships (SARs) in assessing risks. Because data are lacking on most new substances, EPA's risk judgments currently rely heavily on analogs or SARs to predict the effects of a new chemical. Selection of an analog or SAR, however, requires scientific judgment, and it is often uncertain whether available analogs/SARs are, in fact, reliable surrogates for the new substance. The 2016 TSCA amendments strengthen TSCA by directing EPA to require the submitter to conduct testing when the available information is "insufficient" for a "reasoned evaluation" of the new chemical's human health or environmental effects. This will be the case in many instances in which risk judgments are based solely on analogs/SARs. Unfortunately, the last administration failed to exercise its broad authority to require testing under section 5(e) orders when necessary to reduce uncertainty. As a result, the amount of required testing on new chemicals declined significantly as compared to the Obama administration's initial efforts to implement the 2016 amendments.

EPN therefore recommends that EPA underscore the benefits of data development in reducing uncertainties about new chemical risks and the tools that the amended law provides to address gaps in understanding. EPN recommends that OCSPP publish guidance defining the role of testing in the new chemical review process and the criteria for selecting appropriate studies to require under section 5(e). This may be achievable, at least in part, by conducting a major update of the August 2010 TSCA New Chemical Program (NCP) Chemical Categories Document to include additional categories, update the science on categories now included, and provide more detailed discussions of data needs. In previous years, environmental agencies in Canada and Australia that were members of the OECD Clearing House on New Chemicals expressed interest in working with OPPT on such a project. This outside interest may still exist, and EPN recommends that the agency pursue such collaborations in enhancing its new chemical categories document.

Third, to address recent scientific integrity concerns, EPN recommends that EPA undertake a concerted effort to clarify the roles and responsibilities of career staff and managers in arriving at judgments about the risks of new chemicals. EPN recommends that higher-level review of the analyses of frontline scientists be transparent and guided solely by scientific considerations. If there are disagreements—for example, about the selection of an analog or the appropriate endpoint for hazard assessment—these could be resolved (and documented) in an open and collaborative manner that draws on the full range of expertise within the career staff. This was the procedure previously followed at Risk Assessment Division Disposition Meetings. Equally important, EPN recommends that the PMN submitter's interest in a favorable outcome or the political goals of agency management not influence how differing scientific perspectives are resolved, nor should they artificially truncate scientific deliberations before key issues are fully vetted.

EPN recommends reinstating the longstanding practice of convening a meeting of OPPT Division Directors with the entire review team for any PMN that presents contentious risk assessment or risk

management issues. These meetings could be used to talk through and seek consensus on the staff's recommendations and findings; this consensus could then be documented and forwarded to senior decision makers. This will assure greater transparency and consideration of differing views.

If individual scientists still believe that their analyses and judgments have been improperly rejected, EPN recommends that OPPT implement a dispute resolution process. This process could include convening an interdisciplinary panel of EPA experts to address areas of disagreements such as the adequacy of industry submitted data, the selection of an analog to evaluate a new chemical, the choice of the critical endpoints to drive the risk determinations, and studies necessary to fill data gaps. The panel could receive a document that describes the specific issue being disputed and provides the necessary background, including the available data and relevant analyses by the EPA scientists who are reviewing the PMN. Panel members could come to a consensus on how the disagreement should be resolved and explain its rationale. The panel's recommendations could then be forwarded to both the OPPT Office Director and the Division Director responsible for disposition of the PMN. To the extent the panel's work takes more time than is available in the 90-day review period, EPA should prioritize completing the process as quickly as possible.

Fourth, EPN recommends that OPPT enhance the transparency of the PMN review process in order to give career staff and the general public confidence in the legitimacy of EPA's new chemical safety decisions. Right now, the detailed (but Confidential Business Information-sanitized) risk evaluations and supporting technical analyses that form the basis for the disposition of PMNs are not accessible outside EPA unless they are associated with a Significant New Use Rule. The explanations provided in CBI-sanitized Determination Documents and Consent Orders of EPA's safety determinations are limited in detail and thus often uninformative. It could be routine practice to post more detailed risk evaluations and supporting documents on EPA's website upon the completion of PMN review. Where these documents have been revised before public release, EPA's internal records could reflect what revisions were made and why.

Finally, EPN recommends that OCSPP reiterate the need for all managers and staff to document in a central database any contacts they have with industry or others with a financial interest in the outcome. This database could be accessible to all PMN staff so that there is no confusion, misunderstanding, or suspicion about the nature of the interactions between PMN submitters and the agency.

In conclusion, EPN believes these recommendations would enhance transparency, facilitate dispute resolution, and ensure the scientific integrity of new chemical safety decisions.

Please contact Betsy Southerland at 703-350-7508 if you have any questions regarding our recommendations. We would be happy to meet with the agency to discuss these recommendations.

Respectfully submitted on behalf of the EPA alumni volunteers on the EPN TSCA team,

Michelle Roos
Executive Director
Environmental Protection Network