

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families et al. on Draft Guidance on Expanded Access to Confidential Business Information under the Amended Toxic Substances Control Act

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Safer Chemicals Healthy Families (SCHF) and the undersigned groups submit these comments on the draft guidance documents developed by the Environmental Protection Agency (EPA) to implement the expanded disclosure requirements for Confidential Business Information (CBI) in sections 14(d)(5) and (6) of the amended Toxic Substances Control Act (TSCA).¹

The signatory organizations listed below are national and grassroots groups committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. We took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

Safer Chemicals Healthy Families
Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
Asbestos Disease Awareness Organization
Breast Cancer Prevention Partners
Center for Environmental Health
Clean and Healthy New York
Clean Water Action
Ecology Center

Environmental Health Strategy Center
Learning Disabilities Association of America
National Center for Health Research
Natural Resources Defense Council
Science and Environmental Health Network
Texas Campaign for the Environment
Vermont Public Interest Research Group
Women's Voices for the Earth

The 2016 TSCA amendments expand the public availability of critical health, safety and environmental information by authorizing EPA to disclose TSCA CBI to state, tribal, and local governments, environmental, health, and medical professionals and emergency responders. These new provisions address a basic need under the law. Although EPA collects extensive data under TSCA authorities on the composition of substances and mixtures, how they are used and released into the environment and their impacts on health and safety, much of this information has been claimed CBI by industry. The rigid prohibitions on disclosure of CBI under the old law prevented public officials and health and environmental professionals from accessing CBI even where it could be invaluable in protecting individuals and communities at risk from chemical exposures. As described in the Senate report on the amended law, sections 14(d)(5) and (6) “will

¹ 83 Federal Register 11748 (March 16, 2018). These comments are focused on the draft guidance documents under sections 14(d)(5) and (6) and do not address the draft guidance for disclosing CBI to states under section 14(d)(4).

help remedy [this] deficiency” by “ensur[ing] that treating physicians, nurses, agents of poison control centers, public health or environmental officials of a State or political subdivision of a State, and first responders have appropriate, timely access to information.”²

In our view, the draft guidance documents represent a missed opportunity. While dutifully paraphrasing the requirements of the law, they fail to address the larger TSCA goal of enabling front-line professionals and public officials to successfully use the new provisions to meet real-life health and environmental needs. This goal requires EPA to take affirmative steps to assist both its own staff and potential CBI requestors in identifying and accessing information that may be critical for medical treatment, spill containment and emergency response in situations where people or the environment are at risk because of chemical exposures. And it requires EPA to establish a process for obtaining CBI in these circumstances that is user-friendly and responsive so that requestors are not deterred from seeking CBI by delays, paperwork and legal complexities.

The intended beneficiaries of sections 14(d)(5) and (6) are physicians, nurses, police officers, firefighters, first responders and emergency medical technicians who are providing care to victims of chemical spills, releases or exposures or are seeking to prevent the spread of chemical contaminants that may threaten nearby communities, drinking water supplies or water bodies. These situations are generally unexpected and provide little time for preparation and analysis. They require on-the-spot decisions under conditions of great stress, as recent spills contaminating drinking water drawn from the Elk River in West Virginia and the Cape Fear River in North Carolina illustrate.

The professionals and local officials who are on the front-lines where such incidents occur will generally lack legal training and sophistication. They may have no idea what TSCA is, little or no experience working with EPA, and limited understanding of what information resources the Agency can make available. CBI may itself be an unfamiliar concept and the constraints on using CBI under the law may seem intimidating and burdensome. If EPA makes no effort to educate these professionals and officials about the TSCA-related information it possesses and how it may be helpful, they are unlikely to avail themselves of the expanded opportunities for access that the law provides. Similarly, if EPA staff are not trained in the new requirements and able to provide rapid and helpful assistance in urgent situations, the statutory goal of providing necessary information to officials on the ground will be stymied by poor communication, delays, and bureaucratic snags.

We recommend that EPA take several concrete steps to overcome these obstacles:

Outreach and Education. EPA should develop and disseminate an inventory of TSCA chemical databases that describes the information available, provides Web links to this information and explains its possible relevance to health and environmental professionals in emergency and non-emergency situations. EPA should reach out to associations of state and local officials, doctors and nurses, poison control centers, and emergency responders to share this inventory and expand awareness of the availability and possible benefits of TSCA information resources. As part of

² S. Rep. No. 114–67, 114th Cong. 1st Sess. at 23 (2015).

this outreach, EPA should work with these associations to help them explain to their members the concept of CBI under TSCA, the requirements for accessing CBI under section 14(d)(5)-(6) and the Agency's guidance, and the specific steps for contacting the Agency to request CBI under these provisions.

Designating and Training EPA Points of Contact. The draft guidance for non-emergency situations provides that information requests should be submitted to the Director, OPPT Information Management Division. Requests for CBI access in emergency situations must be submitted to the Director or the TSCA Hotline. Neither of the two guidance documents identifies specific EPA employees responsible for reviewing requests and interfacing with requestors. Without clear points of contact, precious time will be lost as requestors are shuttled from one EPA employee to another and simple questions go unanswered because knowledgeable EPA officials cannot be located. To prevent this, EPA should identify the team of people charged with acting on CBI requests and make their contact information available to the public in an online format that can be easily accessed on the Web. These individuals should be trained in the requirements of sections 14(d)(5) and (6) and educated about the challenges faced by CBI requestors and the concerns and questions they are likely to raise in seeking access to CBI. The TSCA office should consult other programs like the CERCLA emergency response center to learn about best practices for responding to time-sensitive incidents involving threats to health or environmental contamination.

Providing Immediate Access to EPA in non-Emergency Situations. The draft guidance for CBI access in non-emergency situations only allows requests to be submitted by mail or delivery service. No provision is made for contacting EPA by phone or electronically to submit a request, ascertain a request's status or provide additional information.³ Thus, requests could fall into a black hole and languish without response for weeks or even months. Although non-emergency requests may not require immediate turnaround, the circumstances motivating them – treating or diagnosing an individual exposed to a substance or mixture or responding to an environmental release or exposure – are typically time-sensitive and call for expeditious action. The statute recognizes this: section 14(g)(2)(C)(i) shortens the pre-disclosure waiting period to 15 days for CBI requests under section 14(d)(5). At a minimum, EPA should provide for electronic submission of non-emergency requests and specify a phone number for alerting the Agency to the submission of requests and following up on their status.

Setting Deadlines for Responding to Requests. Neither of the draft guidance documents provides a timeline for acting on requests, adding to the risk that requestors will not receive timely responses. To avoid delays, EPA should commit to a fixed deadline – we recommend 20 days – for responding to non-emergency requests. While the guidance for emergency requests allows them to be made electronically and by phone, it similarly lacks a deadline for response, a

³ The draft guidance does indicate that EPA is “considering developing an electronic request and access system for TSCA CBI information, using EPA’s Central Data Exchange (CDX) platform” but there is no firm commitment to adopting this system or timetable for putting it in place. Moreover, the draft guidance indicates that, under such a system, “[p]rospective TSCA CBI requestors will first register for CDX.” This would add an extra step to the process for accessing CBI that is not provided by the law and since the need for CBI in emergency or non-emergency situations often arises without warning, requestors will generally lack any reason to “register” with EPA in advance.

serious omission since these requests by definition require immediate action. We recommend that EPA commit to acting on emergency requests by the end of the business day on which they are made.

Reviewing the Basis for CBI Claims for Requested Information. Even where CBI is shared with medical and environmental professionals and public officials under sections 14(d)(5) and (6), its utility in responding to health and environmental needs may be limited by the handling restrictions imposed under EPA's guidance, such as the bar on disclosure to third-parties and the requirement to use the information only for the specific purpose for which it was requested. In dynamic and rapidly evolving situations following a spill or chemical exposure, adhering to these restrictions may be impractical and reengaging with EPA to broaden the terms of access may be time-consuming or logistically challenging. To enhance the flexibility of CBI users in these situations, the EPA guidance should specify that the Agency will examine whether the requested information is in fact entitled to CBI treatment at the same time it considers requests for disclosure.

To that end, when processing a request under section 14(d)(5) relating to an "active" substance, EPA should ask the CBI claimant to substantiate the basis for the claim under section 14(f)(1)(B). If the claimant fails to respond or provides inadequate substantiation, the CBI claim should be voided and the information requestor should be advised that there are no limitations on use or dissemination of the information. EPA should follow the same approach in emergency situations under section 14(d)(6) if, after being contacted by the Agency, the CBI claimant does not ask the requestor to provide a written statement of need or sign a confidentiality agreement in accordance with section 14(d)(6)(B). Non-action in these instances should be deemed a waiver of the CBI claim and the requestor should be advised that the information is no longer subject to CBI restrictions.

Finally, upon receiving requests for CBI under sections 14(d)(5) and (6), EPA should consider whether other, less restrictive grounds for disclosure apply. For example, EPA could conclude under section 14(d)(3) that disclosure of CBI is required to protect health or the environment against an unreasonable risk of injury. Disclosure under this provision would avoid the need for the handling restrictions required under sections 14(d)(5) and (6).

Eliminating Acknowledgement of Criminal Penalties. Under the draft guidance for non-emergency situations, confidentiality agreements signed by requestors must state that:

I understand that under TSCA section 14(h), 15 U.S.C. 2613(h), I am liable for a possible fine and/or imprisonment for up to one year if I willfully disclose TSCA CBI to any person not authorized to receive it.

In emergency situations, the potential for criminal penalties will be conveyed orally to the requestor and restated in a written confidentiality agreement if one is required by the CBI claimant.

Nothing in amended TSCA requires written acknowledgement by requestors that they are subject to criminal penalties if they do not fully observe CBI restrictions. Highlighting the threat of such

penalties for even minor CBI breaches will have a chilling effect on medical and environmental professionals and emergency responders who lack legal sophistication; the fear of criminal liability may dissuade them from seeking CBI even when it could provide important benefits in protecting health or the environment. Confidentiality agreements should be sufficient to safeguard CBI if they include a clear statement of the protected status of the information and a commitment by the requestor to maintain its confidentiality. No mention of criminal liability is necessary.

Informing Patients of CBI Protections. Under section 14(h)(1)(C), treating medical professionals may disclose information subject to sections 14(d)(5) and (6) to patients or persons authorized to make medical or health care decisions on their behalf. The guidance provides that confidentiality agreements must state that:

When disclosing TSCA CBI to a patient or person authorized to make medical decisions on behalf of the patient, I will advise that person that the information has been claimed confidential by a business and should not be further disclosed except as authorized by that business or by TSCA section 14.

The statute neither requires patients to protect CBI if shared with them for treatment purposes nor obligates health professionals to advise patients that they are receiving CBI and cannot disclose it. Moreover, it is overreaching for EPA to dictate what medical professionals must communicate in often stressful treatment environments where health care needs take precedence and nurses or doctors must make immediate on-the-spot decisions for the benefit of patients.

Affirmation that the CBI Requestor is Certified. The draft guidance requires a “representation that the requester is certified to perform the services relevant to the requester’s position.” This wording is unclear but seems to contemplate that, in addition to describing her title and place of employment, the requestor will confirm that she is board certified or has other credentials establishing that she is qualified to perform the medical or other services for which CBI access is being sought. Information requestors will likely not understand what EPA is looking for and the exact nature of the requestor’s professional qualifications should not be germane to whether access to CBI is granted. This requirement should be dropped.

We appreciate this opportunity to share our views on the draft guidance documents. Please contact Bob Sussman, SCHF counsel, with any questions at bobsussman1@comcast.net.

Respectfully submitted,

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