October 4, 2016

The Honorable James Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington DC 20460

Re: *Failure to Comply with TSCA Section 14 (Confidential Information) in the Current Chemical Data Reporting Cycle and Other Information Collection Programs*

Dear Mr. Jones:

We write regarding the implementation by the U.S. Environmental Protection Agency (EPA) of the Confidential Business Information (CBI) protections in section 14 of the reformed Toxic Substances Control Act (TSCA). Section 14 as revised enhances transparency by more clearly differentiating between protected CBI and information that must be disclosed, requiring CBI submitters to better justify why information should be protected, and directing EPA to be more proactive in reviewing CBI claims and assuring the rigor and integrity of the CBI process. Your staff has helpfully explained how EPA is implementing the new CBI requirements and we support many of the steps the Agency is taking. However, we are concerned that EPA is failing to require industry to comply with a critical, express element of the new CBI provisions -- substantiation of the basis for CBI claims at the time information is submitted.

While the substantiation requirements apply to all of EPA's information collection activities, we are particularly concerned about the absence of adequate substantiation for some data elements required for submissions under the Chemical Data Reporting (CDR) rule (40 CFR part 711). The quadrennial reporting cycle under this rule is now in progress, with reports currently due on October 31, 2016. Without the safeguard of substantiation, industry will likely make numerous unjustified CBI claims and this will block public access to the valuable information on chemical uses and exposures that industry will submit. Since CDR reporting will not occur again for another four years, this lack of access will have significant implications for the transparency of the TSCA program.

We are also concerned that the current CDR reporting form provides an opportunity for submitters to assert CBI claims for general descriptions of processes used in manufacturing and processing and a chemical's industrial, commercial or consumer functions and uses. This is information that, under the express terms of section 14(b)(3)(B), is not protected from disclosure.

As EPA collects more information from industry and evaluates a larger universe of chemicals, the public's access to data on chemical uses and exposures will be increasingly critical for informed participation in the expanded TSCA program. That is why it is essential that the Agency implement the law's CBI improvements from day one.

A further extension of the CDR reporting deadline will afford time to provide notice to industry of the required scope of substantiation and the data elements that cannot be shielded as CBI under the new law. Industry could then amend CDR submissions to comply with the requirements of the reformed TSCA. During an extension, EPA would also be able to revise the CDR reporting form so that it does not indicate

that general descriptions of processes used in manufacturing and processing and a chemical's industrial, commercial or consumer functions and uses can be claimed CBI. As we explain in more detail below, we urge EPA to take immediate action to achieve these goals.

Substantiation under Amended Section 14. Section 14(c)(3) provides that "a person asserting a claim to protect information under this section *shall substantiate* the claim . . ." (emphasis added). All information submitted to EPA is subject to this requirement unless it falls within the narrow categories of information listed in section 14(c)(2). A broad range of previous unsubstantiated claims must now be specifically justified at the time the submitter requests CBI protection. This includes, for example, the identity of the submitting company, the site of manufacture, processing or use, the number of workers and types of worker protections, and the nature and magnitude of environmental releases and the controls used to limit such discharges. Much of this information, like the name of the manufacturer, is important to meaningful public oversight of the TSCA program, but, in our judgment, has in the past been withheld as CBI not because of legitimate commercial interests but to block public knowledge of the company's activities.

Application of Substantiation Requirements to CDR. The CDR rule is EPA's primary vehicle for determining the production volumes and use and potential exposure profiles of commercially significant chemicals (those manufactured or imported at a given site in amounts of 25,000 pounds or more per facility in a given reporting year). The CDR reports will perform an important role in the new prioritization process under section 6(b)(1) and shape the review and analysis of exposure in risk evaluations conducted under section 6(b)(4).

Form U, which submitters must use for reporting, contains boxes that can be checked to request CBI protection for particular data elements. Consistent with the underlying CDR rule, Form U requires submitters to substantiate CBI claims for chemical identity, site identity and processing or use information. However, several other data elements are not subject to substantiation. Part II of Form U does not seek substantiation for the following manufacturing/importation information:

1. Name and title of official who signed the certification;
2. Name and address of parent company;
3. Name and address of the listed technical contact;
4. Number of workers likely exposed at the manufacturing or importing site;
5. Maximum concentration of the chemical;
6. Whether the chemical is being recycled;
7. Whether the chemical is domestically manufactured, imported or never physically at the site; and
8. Physical form of the chemical.

None of these data elements are included in the list of information not generally subject to substantiation in section 14(c)(2). Thus, they require substantiation under section 14(c)(3). Form U must be revised to seek the required substantiation.

Delay in Implementing the Substantiation Requirements Is Not Permissible. During our September 23 meeting with your staff, we expressed our disappointment that the Agency is not requiring substantiation of CBI claims for all data for which it is required under Section 14(c)(3). We emphasized that EPA's non-compliance is of particular concern for CDR rule submissions because this information is provided only every four years. We were told by your staff that EPA is uncertain whether it can or should implement the new CBI substantiation requirements before adopting implementing regulations.

We do not agree that EPA is free under the law to postpone immediate compliance with the express requirement that all CBI claims (other than for information listed in section 14(c)(2)) must be

substantiated. The language in section 14(c)(3) stating that substantiation "shall be in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section" does *not* allow submitters to avoid statutorily required substantiation if the existing rules do not provide for it. Rather, this language simply means that, where existing or future EPA regulations prescribe the form or manner of substantiation, submitters must comply with these requirements. There is no indication that EPA can postpone the immediately effective statutory substantiation obligations of submitters until some future date when EPA "may promulgate" regulations. Indeed, because Congress did not mandate the promulgation of regulations on substantiation, it could not have intended to condition the mandatory substantiation requirement on the issuance of such regulations. This is confirmed by section 14(i)(2), which states that "[n]othing in this Act prevents the Administrator from . . . requiring substantiation . . . before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment" of the new law.

The committee report on the Senate bill, which was the primary basis for the CBI provisions in the final law, notes the widespread criticism of TSCA for "for failing to require a systematic review of confidentiality claims, or upfront substantiation of confidentiality claims," resulting in an "overabundance of confidentiality claims, some of which may not be legitimate." Senate Rpt. No. 114-67, 114th Cong. 1st Sess. (June 18, 2015) at 5. While recognizing that certain traditional proprietary information "does not require the same degree of substantiation . . . as other types of information . . . that must be substantiated and reviewed by EPA", the Report makes clear that "*all* new claims for protection of information not presumed to be protected from disclosure *must be substantiated* by the claimant." *Id.*, at 22 (emphasis added). This intent is manifest in the plain language of section 14(c)(3) and reinforces that EPA is not free to ignore the substantiation mandate.

CDR-Reported Information That Must Be Disclosed. Form U also does not conform to the scope of information that may be protected as CBI under the reformed TSCA. Rather, it improperly indicates that CDR submitters may assert CBI protection for general information describing the manufacturing volumes expressed in aggregated form or in ranges, as well as for a general description of a process used in the manufacture or processing -- information that Congress mandated be disclosed to the public.

Specifically, Part III of Form U calls for processing and use information at downstream sites. Section A applies to industrial processing and use and requires the submitter to:

1. Indicate whether the type of operation falls into one of five general categories – such as processing as a reactant, incorporation into a formulation or mixture, or incorporation in an article.
2. Identify the industrial sector where the processing or use occurs, picking from a "drop down" menu of standard industrial categories such as agriculture, mining, construction and wholesale and retail trade.
3. Identify the number of sites where the use occurs, expressed as a range.
4. Provide the industrial function category of the processing or use operation, picking from a menu of general categories such as agricultural chemicals, dyes, solvents and fuels and fuel additives.
5. Describe in general ranges the number of use sites and workers likely exposed.

Section B is for consumer and commercial use and calls for similar information, including:

1. The product category, identified using a menu of standard codes, such as personal care products, apparel and footwear products, paper products and electrical and electronic products.
2. Whether the use is a consumer and/or a commercial use.
3. Whether the use is in a product intended for use by children.

4. The typical maximum concentration of the chemical, expressed in range form.
5. The number of commercial workers likely to be exposed, again as a range.

The information requested in Sections A and B characterizes processing, use and exposure in broad categorical terms, using general, commonly accepted descriptors and in many instances expressing indicators of exposure in the form of ranges and not specific values. Thus, it is to be differentiated from "specific" processing and use information, which is exempt from substantiation under section 14(c)(2),[1] and instead falls under the category of "information not protected from disclosure" under section 14(b)(3), which covers:

> "(A) *any general information* describing the manufacturing volumes, expressed as specific aggregated volumes or . . . in ranges; or
>
> "(B) *a general description* of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . . " (Emphasis added).

As Congress recognized, information that does not disclose the technical details of a manufacturing process and describes chemical uses in broad terms that do not identify the specific product in which a chemical is present or the precise role the chemical plays in that product are both extremely unlikely to be CBI and highly informative to the public.

By allowing all the use and processing information that must be reported under the CDR rule to be claimed as CBI, the current Form U does not correctly reflect the narrow scope of information that may be protected as CBI under the reformed TSCA. Rather, the Form U improperly suggests that CDR submitters may assert CBI protection for information that Congress mandated be disclosed to the public.

Implementation of the CDR Rule Must Comply with Section 14. In sum, the CDR Form U is inconsistent with the reformed TSCA in multiple respects, as described above. This is unacceptable. We believe the best approach is for EPA to revise Form U, ensure that submitters are aware of their legal requirements, and extend the CDR reporting period to allow submitters to revise their submissions based on the revised Form U. To allow manufacturers to submit flawed CDR reports based on an incorrect interpretation of Section 14, and then to attempt to undo the damage through later CBI reviews of individual submissions, would not only create a huge workload for EPA and industry but lead to long delays in public disclosure of information that does not qualify for CBI protection. The far preferable approach is for EPA to briefly suspend and then extend the CDR reporting period to bring the program into compliance with the revised Section 14 so that the CDR reports comply with the reformed TSCA.

Applying Section 14 to Other TSCA Information Collection Programs. Beyond the CDR, EPA collects a variety of information under TSCA that must conform to the amendments to Section 14. For example, the form for PMN submissions under section 5 is extensively used by industry and is the essential foundation for new chemical review. In addition, EPA routinely receives information under the reporting requirements of sections 8(a), 8(d) and 8(e), the export notification requirements of section 12 and the import certification requirements of section 13.

[1] EPA addresses this issue in the General Q&As relating to CBI under amended TSCA recently posted on its Website. In response to Q.7., EPA states that the "general use and process information collected under 40 CFR § 711(b)(4) of CDR . . .is not the type of specific information referenced in TSCA § 14(c)(2)."

All of these information collection mechanisms require immediate review and revision so they properly implement the substantiation provisions of section 14(c)(3) and the disclosure mandate for general volume, processing and use information in section 14(b)(3).

We appreciate the challenges EPA is facing as it implements the complex new law and would be pleased to work with EPA as it develops a practical path forward to meet the new CBI requirements.

We would like to meet with you as soon as possible to discuss the issues laid out above and will contact your office to find a convenient date. In the meantime, do not hesitate to contact Bob Sussman (bobsussman1@comcast.net) with any questions.

Sincerely yours,

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