

## 米国における化学物質管理政策最新動向セミナー（平成 29 年 11 月 13 日開催）

- 1. Regarding the document below, when was it released? What review did it have? Concern: International users are not familiar with CDX, and are having trouble. I'm told this guidance was not available day 1 of the reporting period.**

The Central Data Exchange, or CDX, is the Agency's electronic reporting portal. CDX enables EPA reporting systems to receive legally acceptable data in various formats, including confidential data. Within CDX, the "Submissions for Chemical Safety and Pesticides Programs" (CSPP) service provides the software modules and forms for submitting TSCA notices, including the "TSCA Section 8(b) – e-NOA" module for submitting Notices of Activity under the TSCA section 8(b) Inventory rule.

<https://cdx.epa.gov/> , <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn>

The "*Section 8(b) e-NOA User Guide - Primary Authorized Official*" was posted in the docket for the rule on August 11, 2017 (the date of the publication of the rule in the Federal Register). It was also available in the electronic reporting application on August 14, 2017. Reporting was scheduled to begin after the publication of the rule in the Federal Register on August 12. As August 12 was a Saturday, EPA released the electronic reporting application on Monday, August 14, in order to assure a smooth rollout and staff available for any troubleshooting. This document was updated in the docket and reporting application with the "*Section 8(b) eNOA Application User Guide - Primary Authorized Official Updated*" on October 11, 2017.

The "*Section 8(b) eNOA User Guide - Secondary Support*" was available in the docket and application on October 11, 2017.

The "*Section 8(b) e-NOA User Guide – Secondary Authorized Official*" was available in the docket and application on October 16, 2017.

These documents underwent internal review prior to finalization.

- 2. How does one maintain CBI for something that will remain on the inactive inventory, is that form A?**

A CBI chemical substance, identified as an inactive substance on the TSCA Inventory, cannot have its CBI status altered outside adherence to the forward looking reporting process. That process provides that when a manufacturer or processor acts to reintroduce the chemical back into commerce, using the forward looking reporting form (NOA Form B), the CBI claim for the substance identity can be maintained (or not) by following the procedures set forth in 40 CFR 710.37(a)(2). Those procedures, in summary, provide that a manufacturer or processor may request to maintain a CBI claim for chemical identity, and substantiate the same within 30 days of filing an NOA Form B.

**3. Once you have done a Form B, and have a CDX receipt, can you commence activity immediately?**

Yes, activity can commence immediately. The statute and the rule stipulate that, for future reporting, a Notice of Activity (NOA) Form B is required to be submitted prior to the date that an inactive substance is reintroduced into U.S. commerce for a non-exempt commerce purpose. Once a valid NOA Form B is submitted, a company has met its obligation and activity can commence immediately.

**4. Not on inventory, but for PMNs, how are impurities, which are CBI, reported? Is there a reporting requirement?**

Impurities are exempt from Premanufacture Notification (PMN) requirements under TSCA section 5 (see 40 CFR 720.30(h)(1)). Although impurities are exempt from separate PMN reporting, they must be identified in a PMN on a reportable new chemical substance if the impurities are present in that new chemical substance. The manufacture or processing of a chemical substance described in 40 CFR 720.30(h) is also exempt from Notice of Activity (NOA) reporting under TSCA section 8(b). Impurities are therefore exempt from NOA reporting.

**5. Can non-US companies utilize the CDX application for reporting and include a request that EPA maintain the company's confidentiality claim in their Form A or Form B submission?**

Non-U.S. companies can submit a Form A or a Form B via the electronic reporting application and CDX. Any company submitting an NOA Form for a substance whose chemical identity is confidential on the TSCA Inventory can request in their Form that EPA maintain the confidentiality claim.