TSCA Inventory Notice of Activity Form B Ouestions and Answers

1. Question. Will EPA allow a person to rely on a letter from their supplier certifying that one or more confidential chemical substances (e.g., in a formulation or mixture) are active, and therefore not require submission of a Notice of Activity (NOA) Form B?

Answer. Generally, yes. TSCA section 8(b)(5)(B)(i) requires that "[a]ny person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed." Manufacturers and processors can determine whether a substance is active or inactive by accessing the TSCA Inventory on EPA's website at https://www.epa.gov/tsca-inventory and searching for the substance by either its specific chemical identity or, when the specific chemical identity is confidential, by EPA accession number and generic name. If a manufacturer (including importer) or processor cannot determine a substance's commercial activity designation because its specific chemical identity is held confidential by a supplier and its EPA accession number and generic name are unknown to the manufacturer or processor, as may be the case in the context of a formulation or mixture, then the manufacturer or processor may rely on a letter or email confirmation from the supplier certifying that the confidential substance is already designated as "active" on the TSCA Inventory and therefore not subject to NOA Form B reporting. Alternatively, if a manufacturer or processor is unsure of the commercial activity status of a substance because of third-party confidential business information (CBI) and does not know the substance's EPA accession number or generic name, the manufacturer or processor may initiate a joint submission of NOA Form B pursuant to 40 CFR 710.29(d)(4)(i)-(iii). The electronic reporting application includes an option for a supplier to document that confidential substance(s) are active and therefore not reportable.

Where it is actually known to or reasonably ascertainable by the manufacturer or processer that a substance has been designated as "inactive" on the Inventory, a letter from a supplier that incorrectly identifies the inactive substance as "active" will not relieve the manufacturer or processor from their obligation to submit an NOA Form B, or from liability for failing to file an NOA Form B, prior to manufacturing or processing the inactive substance.

In the event that a supplier communicates to a manufacturer or processor that a substance is active but it is actually inactive, EPA may hold liable the person or persons responsible for filing an NOA Form B for failure to submit the notice prior to the anticipated date of manufacturing or processing. Manufacturing or processing a chemical substance on or after the effective date of an inactive designation for that substance, without first sending in an NOA Form B, is unlawful. [See Comment 35 in the Response to Comments Document for more information (https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0086).]

EPA encourages persons to share non-confidential identifiers for confidential chemical substances, such as EPA accession numbers and generic names, with their customers so

that their customers can independently verify a substance's commercial activity status on the Inventory.

2. <u>Question</u>. If a supplier fails to respond to an NOA Form B joint submission request, has the person that initiated the joint submission met its forward-looking reporting obligation?

Answer. The joint submission requirement is to properly ask that suppliers provide secondary submissions to EPA. However, in order for EPA to re-designate an inactive substance as active, a complete, valid Form B must be submitted. This prerequisite applies to scenarios where the person responsible for filing an NOA Form B cannot provide the information required in 40 CFR 710.29 because of third party CBI. In these scenarios, the person responsible for filing should initiate a joint submission per 40 CFR 710.29(d)(4)(i)-(iii). With a joint submission, an inactive substance cannot be re-designated as active until all parties provide the required information. A person that initiates a joint submission has met their forward-looking reporting obligation for the manufacturing or processing activity that is anticipated to begin within 90 days following the initiation of the Form B joint submission. However, if a substance remains inactive because a supplier fails to complete the joint submission, subsequent manufacture or processing of that substance (i.e. commercial activity beginning within 90 days from initiation of the Form B) will require submission of a new NOA Form B. For example, if an importer initiates a joint submission of an NOA Form B in anticipation of importing a shipment of an inactive chemical substance, and the supplier fails to complete the joint submission by providing the specific chemical identity directly to EPA, then the substance would remain inactive, and the importer would need to submit a new NOA Form B (or initiate a new joint submission) prior to importing a new shipment of the inactive chemical substance. EPA intends to notify submitters of incomplete joint submissions.

Persons are encouraged to share non-CBI identifiers, such as EPA accession numbers and generic names, with their customers for confidential substances. Persons that do not know the specific chemical identity of a confidential substance can still file an individual NOA Form B if they have the substance's EPA accession number and generic name by selecting the accession number from the pick list in the electronic reporting application. Filing via a joint submission is not necessary if a person has the accession number and generic name for a confidential substance.

3. Question. Is EPA allowing Form A's to be corrected at this time? Is EPA allowing Form A's to be submitted at this time by persons that failed to file a Form A by the reporting deadline(s)?

Answer. No. The 180-day submission period for required retrospective reporting was the maximum time provided for by the statute. [See TSCA section 8(b)(4)(A)(i)]. EPA therefore is not allowing original Form A's to be corrected or new Form A's to be submitted now that the reporting deadline has passed. EPA did allow Form A's to be withdrawn when persons discovered errors in their original notices, provided that the request to withdraw was made not later than the October 5, 2018 deadline. [See Comment 20 in the Response to Comments Document for more information

(https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0086).]

If a person discovers that they failed to file a required NOA Form A for a substance that they commercialized for non-exempt purpose during the retrospective reporting period, they should self-disclose according to EPA's Self-Disclosure policies. [See https://www.epa.gov/compliance/epas-edisclosure.] If the person anticipates continuing to commercialize the substance for non-exempt purpose into the forward-looking reporting period, and the substance's commercial status on the TSCA inventory is "inactive," the person has a forward-looking reporting obligation and should file an NOA Form B.

4. Question. For persons who commercialized a substance at any time during the transitional period between the Form A and Form B reporting periods (i.e., on or after June 22, 2016, and before the effective date of inactive designations), and who anticipate that their activity will continue into the forward-looking reporting period, what manufacture or processing commencement date should be recorded in an NOA Form B submission?

Answer. Persons who have already commenced manufacturing or processing for a nonexempt commercial purpose (e.g., during the transitional period prior to the effective date of a substance's inactive designation) may provide the most recent date of manufacturing or processing in lieu of an anticipated future date, if the forward-looking notice is submitted prior to the effective date of the substance's inactive designation. See 40 CFR 710.29(c)(2).

Note that persons do not have a commercial activity reporting obligation if they cease all manufacture and processing of the substance before the Form B reporting period begins. However, persons who commercialized an inactive substance during the transition period and anticipate that their activity will continue into the forward-looking reporting period, must file an NOA Form B and may record the most recent date of manufacturing or processing in lieu of an anticipated future date. This also may apply to persons who commercialized a substance with recent inactive identification during the retrospective reporting period but who did not file an NOA Form A because, for example, reporting was voluntary and they chose not to file or reporting was required and they failed to file. If such persons continued their commercial activity into the transition period and anticipate that their activity will continue into the forward-looking reporting period, they must file an NOA Form B and may record the most recent date of manufacturing or processing in lieu of an anticipated future date.

5. Question. The forward-looking reporting requirements in the rule require manufacturers and processors to report inactive substances prior to commercialization, but not more than 90 days prior. If inactive substances are now not designated as inactive until August 5, do persons that already filed an NOA Form B have to re-file the notice in order to be within 90 days of August 5?

<u>Answer</u>. No. EPA is accepting all notices that are submitted during the transitional period that ends on August 5.

6. Question. What is the effective date of an NOA Form B submission?

<u>Answer</u>. The effective date of a valid Form B submission is the date that it is received by EPA electronically. A submission received in CDX at 11:59 PM EDT or EST, for example, is considered received that day, while a submission received in CDX at 12:01 AM EDT or EST would be considered received in the first minute of the new day.

7. Question. If a substance is anticipated to be manufactured or imported under a TSCA section 5(h)(4) exemption (e.g., polymer or Low Volume Exemption) during the forward-looking reporting period, and the substance is not on the TSCA Inventory due to the TSCA section 5(h)(4) exemption, is the substance required to be reported under the forward-looking reporting requirements of the rule?

<u>Answer</u>. Chemical substances that are not on the TSCA Inventory are not subject to commercial activity reporting. Substances that are not on the TSCA Inventory are not included in the electronic application pick list. Persons therefore will be unable to report substances that are not on the TSCA Inventory. See response to comment 1 in the Response to Comments document for more information (https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0086).

8. Question. If a substance is inactive and is anticipated to be manufactured or imported under a preexisting TSCA section 5(h)(4) exemption (e.g., polymer or Low Volume Exemption) during the forward-looking reporting period, and the substance is on the TSCA Inventory because it was submitted by another person in a Premanufacture Notice and commenced, is the substance required to be reported under the forward-looking reporting requirements by the person that anticipates manufacturing or importing the substance under a TSCA section 5(h)(4) exemption?

Answer. Yes, unless the presence of the inactive substance on the confidential portion of the Inventory is not known to or reasonably ascertainable by the person. EPA does not believe that manufacturing or processing under a low volume, low releases/low exposures, or polymer exemption (1984 or 1995 polymer exemption) qualify as exempt commercial purposes under TSCA section 8(b), despite the exemptions from reporting under TSCA section 5(h)(4) for such substances. Be advised that under 40 CFR 710.25(c), forward-looking reporting is not required where "the presence of the inactive substance on the confidential portion of the Inventory is not known to or reasonably ascertainable by the person." EPA anticipates that the presence of a substance on the confidential portion of the Inventory may be information that is not "known to or reasonably ascertainable by" a person who is operating under a TSCA section 5(h)(4) exemption and who did not submit the confidentiality claim for the specific chemical identity of that substance. However, EPA anticipates that the presence of a non-confidential substance on the public portion of the Inventory would be information that is "known to or reasonably ascertainable by" a person who is operating under a TSCA section 5(h)(4) exemption. See response to comment 1 in the Response to Comments document for more information (https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0086).

- 9. Joint Submissions.
 - a. <u>Question</u>. How are multi-party supply chain scenarios reported in an NOA Form B joint submission?

Answer. As a multi-party scenario example, Company A manufactures a substance for Company B who processes the substance for Company C who is the importer of the substance; Company B and C do not know the chemical identity of the substance, and Company C does not know the identity of Company A. In such a scenario, Company C initiates a joint submission which involves sending an email with the unique ID to Company B. Company B then forwards the email with the unique ID to Company A, and Company A responds to the joint submission.

b. <u>Question</u>. If a supplier receives an NOA Form B joint submission request where some or all the chemical substances are designated as "active" on the TSCA Inventory, how does the supplier report?

<u>Answer</u>. In response to an NOA Form B joint submission request, a supplier should check the "Contains Non-Reportable Substances" box in the application in order to document that some substances that the supplier is being asked to report are already "active" and therefore not reportable. If all substances that a supplier is being asked to report are not reportable, the supplier should communicate such to the person that initiated the joint submission and request that the joint submission be withdrawn by that person.

c. <u>Question</u>. Does the person that initiates an NOA Form B joint submission request receive an email or other communication when their supplier submits the secondary form in response to the joint submission request, either from EPA or their supplier?

<u>Answer</u>. No, the person that initiates an NOA Form B joint submission request will not receive an email or other communication from EPA if, and when, their supplier submits the secondary form in response to the joint submission request. EPA intends to notify submitters of incomplete joint submissions.

10. <u>Question</u>. If I search for an inactive chemical substance in the electronic reporting application and receive an error message that the substance is not found, what should I do?

Answer. If persons cannot locate a substance that they are trying to report, they should contact EPA. EPA will address the status of a chemical substance in the electronic reporting application pick list and make any corrections necessary. When contacting EPA, communications with no CBI content can be emailed to tscainventory@epa.gov. Communications with CBI content should be mailed to the Document Control Officer in EPA's Office of Pollution Prevention and Toxics.

<u> Maıl</u>:

Document Control Officer (7407M)

Office of Pollution Prevention and Toxics Environmental Protection Agency 1200 Pennsylvania Ave., NW Washington, DC 20460–0001

Attention: Industrial Chemistry Branch

Hand Delivery/Courier:
OPPT Document Control Officer
EPA East Bldg., Rm. 6428
1201 Constitution Ave., NW
Washington, DC.

Attention: Industrial Chemistry Branch

11. Question. What is the limit for uploading more than one chemical substance in a batch submission?

<u>Answer</u>. The electronic reporting application has not limited the number of substances that can be uploaded in a batch submission. Submitters should be advised, however, that they may experience "time-outs" when uploading large batches due to the capacity of the browser that they are using.

12. Question. Can an authorized agent (e.g., consultant) submit a Notice of Activity Form B for a company?

<u>Answer</u>. Yes. An authorized agent can submit a Notice of Activity Form B for a company, based on the agreement between the two parties. The electronic reporting application allows an authorized agent to submit Notices of Activity on behalf of a company.

13. <u>Question</u>. Can an authorized agent or a secondary authorized official submit a secondary Notice of Activity Form B in response to a joint submission request?

<u>Answer</u>. Yes. The electronic reporting application allows an authorized agent or a secondary authorized official to submit a secondary Notice of Activity Form B in response to a joint submission request.