Guidance on Determining Potential Reporting Requirements Under EPA’s TSCA Section 8(a) Rule for Chemical Substances Manufactured or Processed as Nanoscale Materials

40 CFR 704.20

Flowchart

This flowchart applies primarily to reporting under 704.20(b)(1), the 3-year “look back” requirement. Entities who may have a reporting obligation under 704.20(b)(2)—proposed manufacture (including import) or processing after the final effective date of the rule—may find the flowchart useful as well.

IMPORTANT NOTICE: The following flowchart is provided as guidance that may assist your organization as it evaluates its reporting obligations. Neither ACC, its Nanotechnology Panel, or any of ACC’s employees, subcontractors, consultants or other assigns makes any warranty, expressed or implied, or assumes any liability or responsibility for any use, or the results of such use, of any information contained in this flowchart. Nothing in this document is intended to constitute legal advice.
Does your company have a reporting obligation? Small manufacturers and processors (defined for this rule at 704.20(a)) are exempt (see 704.20 (c)(3)).

**704.20(a), “reportable chemical substance”**

1. Did your company manufacture, import or process any substances that are solid at 25°C and atmospheric pressure (S25AP) in the three years prior to the final effective date of the rule (August 14, 2017)?

   - **NO**
   - **YES**

2. Your company has no reporting obligation.

3. Are any of the following among the S25AP substances your company manufactured, imported or processed in the three years prior to August 14, 2017:
   - Chemical substances manufactured at the nanoscale as part of a film on a surface;
   - DNA; RNA; proteins; enzymes; lipids; carbohydrates; peptides; liposomes; antibodies; viruses; microorganisms;
   - Chemical substances that dissociate completely in water to form ions that are smaller than 1 nanometer (nm)?

   - **NO**
   - **YES**

5. Your company has no reporting obligation for the types of substances listed in box 3. Did your company also manufacture, import or process any S25AP substance(s) in addition to the types listed in box 3 in the three years prior to August 14, 2017?

   - **NO**
   - **YES**

10. Your company has no reporting obligation for any S25AP substance for which the answer to boxes 4, 5, or 8 are “No”; the answer to boxes 6 or 11 is “Yes; and for which information is neither known or reasonably ascertainable to answer the questions in boxes 4, 6, or 8.

8. Was the substance manufactured, imported or processed to exhibit unique and novel characteristics or properties because of particle size?

   - **NO**
   - **YES**

9. Such information is neither known nor reasonably ascertainable.

11. Do any of the TSCA 8(a) reporting exemptions at 40 CFR 704.5(a)-(e) apply?

   - **YES**
   - **NO**

12. Your company may have a reporting obligation. Go to box 13 on the next page.
13. For each S25AP substance that has made it this far in the flow chart, did your company submit to EPA a TSCA chemical notice under the PMN or SNUR regulations (40 CFR part 720, 721, or 723) on or after January 1, 2005?

14. Has the substance described in box 13 been modified in any way (e.g., shape, coating, size, properties)?

15. Your company has no reporting obligation for a substance noticed as described in Box 13 that has not modified since that notice.

16. You must determine whether you may have reporting obligations for more than one “discrete form” of each reportable S25AP substance.

17A. Has there been a change in an industrial process to affect a change in size, a change in one or more of the properties in box A (bottom of page), or both?

17B. Does your company manufacture, import or process forms of the substance for which the mean particle sizes differ by more than 7 times the standard deviations of the mean?

18. Such information is neither known nor reasonably ascertainable.

19. Does your company manufacture or process different morphologies (e.g., sphere, rod, fiber, hollow cage) of the substance?

20. Does your company, as part of your manufacturing or processing, coat the substance with another chemical substance or mixture?

21. Such information is neither known nor reasonably ascertainable.

22. You answered “Yes” to questions 17A, 17B, and 17C, or to either question 19 or 20. Your company manufactured or processed multiple, reportable “discrete forms” as defined by the rule.

23. Such information is neither known nor reasonably ascertainable.

24. Because you answered “No” to question 17A, 17B, or 17C, and to questions 19 and 20, your company has not manufactured or processed multiple reportable “discrete forms” of the substance.

25. You neither know nor can reasonably ascertain information to know whether your company manufactured, imported or processed multiple reportable “discrete forms” of the substance.

26. Your reporting obligation is for one “discrete form” of the substance.

Box A. Zeta potential, specific surface area, dispersion stability, surface reactivity.