

Class 18: Wed. Apr. 3: Toxic Substances Control Act and Cost/Benefit Analysis

Class Project on TSCA

This project element will examine how TSCA will apply to the chemicals and microorganisms involved in the new technologies you are studying. Each project team will focus on the microorganisms and the particular chemicals that are made or used in its technology for which the team has previously compiled available physical chemical, health effects and environmental effects information.

Subsection I, below, leads each project team through the process of identifying which of its chemicals and microorganisms would be subject to TSCA's PMN requirements, as well as the information that would have to be submitted in a PMN. Each project team will share their analysis with the other teams. Then Subsection II asks each team to consider some of the implications of this analysis.

I. Compile the following information, in a form that each project team can share with the other teams, for the microorganisms and for each of the chemicals for which you have previously compiled available physical chemical, health effects and environmental effects information.

You will find useful guidance and resources on the EPA New Chemicals site, which provides materials that industry needs to comply with the PMN process: <http://www.epa.gov/opptintr/newchems/index.htm> You will find useful guidance with respect to any microorganisms involved in your technology on EPA's website at: http://www.epa.gov/biotech_rule/pubs/biorule.htm

1. Identify each microorganism a company commercializing your technology would manufacture. Use the standards articulated by EPA to determine whether an MCAN (PMN equivalent) would have to be submitted for each such organism: http://www.epa.gov/biotech_rule/pubs/fs-001.htm
2. Identify for each chemical whether a company commercializing your technology will manufacture (rather than purchase) the chemical. PMN applications are required only for chemicals the company will manufacture.
3. For each chemical that will be manufactured, determine whether it is a "new" chemical or an "existing" chemical (meaning, on the TSCA inventory). If it is an existing chemical, no PMN is required.

Use EPA's TSCA Chemical Substances Inventory site to find the Inventory itself: <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/basic.html#howto>. Follow the link on that page to the Data.gov site and search for the TSCA Inventory. Determine whether your chemicals to be manufactured are on the Inventory.

Many chemicals on the Inventory are confidential. Consider whether you would recommend filing a formal request to EPA for a Determination If A Chemical is on the Inventory for any of your chemicals you do not find on the Inventory.

4. Determine whether any of the exemptions for the PMN requirement apply to any of your chemicals.

EPA's New Chemicals site describes 5 exemptions from the PMN application requirement:

<http://www.epa.gov/opptintr/newchems/pubs/whofiles.htm#exempt>

Determine whether any of these exemptions would apply to any of your new chemicals to be manufactured during commercialization of your technology and **after** R&D and test marketing is complete.

5. Once you have identified the chemicals for which commercialization of your technology will require a separate PMN, determine the hazard data that will have to be included in each PMN application.

A downloadable PMN application form is available here:

<https://cdx.epa.gov/ssl/pmnm/download.asp> or can be directly downloaded:
https://cdx.epa.gov/SSL/PMN/Outbound/Electronic_PMN_Form_version2.pdf

You might find the PMN Instruction Manual helpful:

<http://www.epa.gov/opptintr/newchems/pubs/tscaman2.pdf>

EPA's PMN application does not specify a minimum or maximum set of PMN data requirements. Rather, as you can see from examination of the PMN application, EPA requires the submitter to provide information to the extent available about the manufacturing process and waste streams, worker and consumer exposures, mammalian and environmental risk, and physicochemical data.

For this exercise, for each chemical for which a PMN will be required, identify the health effects, environmental effects and physical/chemical properties information that is available, as you compiled earlier in the class. This information would need to be included in a PMN application.

6. Share your results with the other project teams.

II. Based on the results you have obtained for your technology, please consider the following questions.

1. Would you recommend that a company commercializing your technology conduct studies to obtain further information about the health effects,

environmental effects and physical chemical properties for any of the chemicals for which a PMN must be submitted? Why or why not? If so, what information?

2. Consider whether the TSCA PMN program creates any preference or disadvantage for your technology, based on health and safety considerations, as compared to (i) the technologies being evaluated by other project teams in the class and (ii) any other technologies that you may be able to compare. In other words, does the TSCA PMN program give a preference to safer chemicals that helps or hurts your technology?