

**Class 19: Wed. Apr. 8: The EU's REACH Regulation and the Precautionary Principle**

**Class Project on REACH**

This project element will examine how REACH will apply to the chemicals and microorganisms involved in the new technologies you are studying. We will focus on the microorganisms and the particular chemicals for which the teams have previously compiled available physical chemical, health effects and environmental effects information.

Subsection I, below, leads us through the process of identifying which of chemicals and microorganisms would be subject to the Registration and Authorization provisions of REACH, as well as the information that would have to be submitted in a registration submission. Then Subsection II asks each team to consider some of the implications of this analysis.

**I. Compile the following 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 REACH, as well as the text of the law itself, at: <http://echa.europa.eu/web/guest/regulations/reach/>

1. Identify each microorganism a company commercializing your technology would manufacture. Determine whether that organism would be considered a “substance” subject to REACH under the definition at Article 3(1) or a “mixture” under Article 3(2). You can find the REACH regulation on the above site where you can download a pdf of the English (EN) language version of the REACH law itself.

If manufacture of your microorganism is not subject to REACH, is there an EU law that it is subject to?

2. Assume that for each chemical whether a company commercializing your technology will manufacture the chemical in the EU, buy it from an EU manufacturer or import it into the EU.

Would you be a manufacturer or a downstream user of the chemical?

Take a look at the list of exemptions from REACH as they are described in the following document: <http://www.hse.gov.uk/reach/resources/exemptions.pdf>  
Do you think your chemical might be exempt from the REACH registration requirements?

3. Determine what tonnage level you would make or use the chemical at: under 1 tonne, 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or over 1000 tonnes per year.

There is on bSpace for Class 19 a document compiling the REACH data requirements for different tonnage levels called “Denison, EDF REACH DATA Requirements.” Use that compilation of data requirements to compare the data you have for your chemicals to the data that would be required to be submitted at your expected tonnage level.

Would you have to generate additional data for a REACH registration submission for each chemical?

4. Is/are your chemical(s) already on the market in the EU or would your company be manufacturing a new chemical not yet on the market? If a chemical you are making or using is already on the market, you will need to join a Substance Information Exchange Forum (SIEF).

Read about SIEF’s on the ECHA website:

<http://echa.europa.eu/regulations/reach/substance-registration/substance-information-exchange-fora>

Can you anticipate some of the difficulties encountered by companies that form a SIEF?

Why do you think the EU created this mechanism within REACH?

5. Registration submissions for chemicals made or imported at over 10 tonnes/year must include a Chemical Safety Report. Guidance on CSR’s can be found on this ECHA site: <http://echa.europa.eu/regulations/reach/registration/the-registration-dossier/chemical-safety-report>

If you are a manufacturer or lead SIEF registrant, you will have to prepare the CSR. Take a look at the guidance for preparing a CSR at the bottom of the above site and identify some of the requirements of a CSR.

If you are a downstream user, do you have any obligations to assist in the preparation of a CSR? If so, what are they? Find the answers in the guidance for downstream users at the bottom of the above-identified site.

6. Chemicals that are identified by ECHA as “substances of very high concern” (SVHC) will be subject to Authorization. No chemicals have yet been formally

designated as SVHC's, but 138 chemicals have been identified as candidates for such designation and are on the Candidate List, which you can find on this site:  
<http://echa.europa.eu/regulations/reach/authorisation/the-candidate-list>

Are any of your chemicals on the Candidate List?

The government-supported NGO ChemSec ([www.chemsec.org](http://www.chemsec.org)) has published a list of chemicals that it believes will eventually be designated as SVHC's. Are any of your chemicals on the SIN list?

Should you be concerned if your chemical is on the SIN list but not the Candidate List? What if you can't tell if your chemical is dangerous because of extensive datagaps. Should you try to fill in some of those gaps?

**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 relevant chemicals? Why or why not? If so, what information?
2. Consider whether REACH 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 REACH program give a preference to safer chemicals that helps or hurts your technology?