



Lowell Center for Sustainable Production

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Update on the European Commission's REACH Proposal – Registration, Evaluation, and Authorization of Chemicals

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On October 29th, 2003, the European Commission officially adopted a legislative proposal that fundamentally restructures chemicals regulations in the European Union, responding to many of the limitations of the current system of chemicals control. Whereas the last several months of negotiation have seen several important modifications of the original draft, the basic framework and principles for the Registration, Evaluation, and Authorization of Chemicals (REACH) proposal have remained solidly intact.

The REACH proposal still responds to many of the limitations of current chemicals management policies. Whereas under current legislation, all chemicals on the market before 1980 were considered safe until proven harmful and had no toxicity information requirements, REACH requires that manufacturers to register (provide data on uses, exposure, and toxicity) the most widely used chemicals in commerce over a 11 year period or their manufacture and use will be prohibited. For those chemicals of highest concern, manufacturers and users will be required to seek “authorization”, permission to use the chemical for a defined use. Authorization will only be given if there are no other alternatives, if the substance is necessary, or if the company can demonstrate it is safe to use.

The October 29th proposal marks the end of an intensive and transparent five-year process whereby the European Commission engaged stakeholders on technical committees, convened conferences, and conducted an Internet consultation.

To understand the implications of the European Commission's proposal, some background on the European legislative process is necessary. First, in Europe, only the European Commission (the European Union's administrative body) has the right to initiate legislation. Because responsibility for chemicals management is currently split between Directorate General Environment (the environment agency) and Directorate General Enterprise (like a commerce department), it was these two agencies that jointly drafted the legislation. They began the legislative drafting process in February 2001, with the publication of a “White Paper on a New Chemicals Strategy” which outlined the limitations of current chemicals legislation as well as the foundations of a new approach. In the subsequent two years, DG Environment and DG Enterprise worked to craft a piece of legislation to implement the REACH scheme. A draft of the legislation was published on May 7th for a seven week Internet consultation. The Commission then reviewed some 6000 comments, making changes to the

draft legislation. Changes to the draft legislation were finalized by DG Environment and DG Enterprise in early October 2003 and then was sent for Interservice Consultation, where other European Commission agencies reviewed and commented on the legislation. It was finalized as a European Commission proposal (meaning it is fully supported by all government officials) on October 29th.

The proposal will now go to the European Parliament and Council of Ministers (the European Union's two legislative bodies) for debate and modification. It is important to note that historically the vast majority of legislative proposals adopted by the European Commission ultimately become European Union law. In a majority of those cases, only minor changes were primarily made to the Commission proposals. Given the amount of effort and political capital that has gone into REACH, it is highly likely that the proposal will be enacted by 2006. This provides a strong signal of requirements that industry will have to fulfill in coming years. In the interim period, the European Commission is already working to establish its new chemicals agency and working with industry and other stakeholders on "strategic partnerships" to test and conduct demonstration projects on the REACH system.

What is the status of REACH?

There have been some news stories indicating that the REACH proposal is not moving forward or that it has been so weakened by lobbying of some governments and regulated parties as to be ineffective. Some modifications to the initial proposal for REACH outlined in the 2001 White Paper on Chemicals have been made – in some cases substantial modifications. It is to be expected that with a proposal this major, the lobbying process would reduce the burden to industry. In some cases modifications in hopes of streamlining the system so that it can more effectively achieve its health and innovation goals. Some of the modifications to the REACH proposal of concern to some stakeholders and governments include:

- Reduction of registration requirements for chemicals produced from 1-10 tonnes per year per manufacturer.
- Elimination of a chemical safety report for downstream users of chemicals.
- Elimination of polymers and most intermediates from the registration requirements.
- The requirement that authorization be granted if "adequate control" of the chemical is demonstrated by industry. Adequate control has been defined as exposure minimization.
- Greater protection of confidential business information (including chemical production volumes and some use information).

Despite these modifications, the basic framework and principles for the REACH proposal remain intact. Companies will be responsible for registering chemicals and for those of high concern, industry will have the burden of demonstrating their safety, like drugs. In particular, companies will have to submit toxicity, use, and exposure information for a large number of chemicals; government authorities will evaluate registrations of chemicals produced in high volumes or those of concern for additional data needs or risk management efforts; companies will have to seek time limited authorizations for chemicals considered of high concern – carcinogens, mutagens, reproductive toxicants, very persistent and very bioaccumulative chemicals, persistent and bioaccumulative toxics, and other substances of high concern (sensitizers, endocrine disruptors) – and these will be considered problem chemicals by the European commission and

can only be used if companies can demonstrate their safe use or there is a need for their continued use; the European Commission will be able to restrict chemicals of high concern on an expedited basis.

The proposal remains a fundamental restructuring of chemicals regulation, far beyond anything feasible at this point in the United States. The process of arriving at the draft has ensured that chemicals regulation is a critical environmental and health issue in Europe and already many companies are beginning to initiate changes in production practices and substances.

In press materials released on October 29th, a group of European environmental organizations (organized by the European Environment Bureau) working on chemicals has noted many concerning modifications to the policy. Nonetheless, they have noted that REACH still contains all elements necessary and provides stronger control of industry than anything we have now. The groups note that changes to restore elements of the proposal are paragraph substitutions of the 1200 page proposal. These groups have described the modifications to the proposal through the analogy of a house that remains standing despite the removal of some of its furniture.

Margaret Wallstrom, the Swedish Commissioner of Directorate General Environment and the leading government proponent of the new chemicals policy agreed to the changes in the proposal as necessary for the ability to achieve the restructuring of policy. She stated in a November 5th Letter to the Editor of the Financial Times, that:

“The chemicals reform is a test case for the principle of sustainable development. To be sustainable, any policy has to reconcile economic, social and environmental concerns. Achieving this balance is particularly important in the case of chemicals, where the stakes are so high on all three sides. It is high time that European citizens get the high level of protection for environment and health they have the right to expect. This is why we need a new strategy for chemicals management, and we should never forget this. The measures and scope that have been detailed in extensive consultation with all stakeholders, including industry, are entirely in line with what we announced in the white paper on chemicals reform two years ago and the cost estimates are roughly the same as then. In designing the system we have paid particular attention to the need to allow the important European chemicals industry, particularly the many small to medium-size enterprises, to enhance competitiveness, without compromising environment and health concerns. This will safeguard the trust in the European chemicals industry and their products, providing both a competitive business edge and benefits for the health of our citizens.”

In the coming months, the proposal will be discussed by the European Council of Ministers (likely what is called the Competitiveness Council) and the European Parliament. The Parliament's first reading may take place before European Union expansion and elections take place in June 2004. In the past the European Parliament has tended to be more “green” than the Commission, which means that certain provisions may be reintroduced into the proposal. It will be useful in coming months to follow these developments to observe what changes are made to the proposal. The Lowell Center will continue to provide updates and analysis in as the discussions on the draft legislation move forward.