

# The European Dream

*This guest editorial is by Guy Villax, chief executive officer of active pharmaceutical ingredient manufacturer Hovione.*

**R**EACH (REGISTRATION, EVALUATION & Authorization of Chemicals) is currently being discussed in the European Parliament, in Brussels. The bill is more than 1,000 pages long. REACH is an attempt to legislate regionally an industry that is global. Its goals are necessary, but its approach will further damage Europe's chemical industry.

REACH replaces the current system for new and existing chemicals and extends the requirements for new substances to existing ones. Since 1981, the competent authority in each European Union member state has had to be notified of new substances before a substance could be marketed. Existing substances available commercially between Jan. 1, 1971, and Sept. 18, 1981, were compiled into the European Inventory of Existing Commercial Chemical Substances (EINECS), which contains 100,116 entries. EINECS-listed products could be produced and sold without meeting the comprehensive and stringent data requirements demanded for new substances. In other words, the notification requirements for new substances have affected primarily the companies that were bringing out new products; that is to say, those that innovated.

REACH has been the object of a great deal of debate. A key point is the uncertainty of the economic impact of the legislation. Industry claims an impending calamity; politicians claim to be saving the world. What is certain is that the current program has had two effects:

■ In order to avoid the restrictions, the manufacture of many new chemicals slowly moved out of the EU. As a result, Swiss process chemistry has grown tremendously, and kilo-labs and pilot plants have mushroomed in the U.S. and Canada, not to mention India and China.

■ The suffering of the pharmaceutical R&D industry does seem to have been heard in Brussels. This is probably the one industry that will be far better off with REACH than with the current system; indeed the lower limit for testing R&D intermediates will no longer be set at 10 or 100 kg, it will be 1 ton with multiple waiver opportunities. Intermediates, if sold to few manufacturers under long-term agreements, may also enjoy substantial relief.

If the past is any measure of the future, more clumsy regulation will add to the long list of handcuffs placed on the EU chemical industry before common sense prevails. By then, it will be too late. REACH will probably be law in 2007; by then, 30,000 substances (say, most of the Aldrich Catalog) will either have toxicity data generated on them (costing from \$100,000 to more than \$1 million apiece), or they will be available from India, China, Japan, or the U.S. at no extra cost.

The side effects of these "save the world laws" are not always obvious: In China, the current explosive growth of the chemical industry seems to be going hand in hand with a horrendous increase in the frequency of tragic chemical accidents involving fatalities and serious environmental damage.

The negative impact is not only on traditional industries—chemicals, fertilizers, polymers, paints, and the like—but also in the knowledge-based activities of the future—those same industries that Brussels claims to be promoting and encouraging. The same European fine chemicals industry that is being attacked is also the workhorse of modern biotechnology. Do the Brussels politicians and bureaucrats know that whenever a biotech company invents a new cancer drug, a new HIV fusion inhibitor, a new peptide, or a new oligonucleotide the development and production of the active ingredient take place in Europe? Europe has 90% of the world's merchant industrial capacity for all these new technologies, those very jewels of European industry that every day face a tougher regulatory environment—and migrate away.

Unwise EU legislation is turning valuable assets into industrial graveyards and is squandering know-how and expertise. José Manuel Barroso, the new president of the EU Commission, tells us he has a dream: He has reaffirmed the objectives of the European Council's Lisbon Agenda, a 10-year strategy to make the EU the world's most dynamic and competitive economy. If REACH is enacted as it is currently constituted, that seems unlikely.

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