



Reason and expertise— not emotion

It is frustrating to see the debate around sustainable development, which is set to determine Europe's future industrial policy, being shaped by environmental experts rather than members of industry. Everyone agrees that the issues are eminently technical, and that solutions can only come through reason and expertise—not emotion.

Over the past two decades the situation has changed—the majority of the chemical industry now adheres to Responsible Care type programs, with the focus on transparency and accountability. Those companies that don't toe the line become outcast, an example being the exclusion of non-subscribers from industry associations. Unfortunately, the burden of the past that earned the industry a deservedly poor reputation is relentless and still appears to leave the chemical industry no respite despite the massive improvements and measurable results achieved during the last decade.

Cefic and the various national chemical industry associations in Europe are working hard to demonstrate to legislators that the chemical industry is part of the solution to their problems—not the problem. Annually, the sector generates €519 billion (\$561 billion) of added value, and generate for the EU a trade surplus of €65 billion. The industry makes sure that at the end of the month three million people see a pay packet.

The EU's proposed chemical policy and its Registration Evaluation and Authorisation of Chemicals program (Reach) is the key regulatory issue of the day. The debate on this matter would easily be decided upon if the 'gnomes' of Brussels were to look clearly at the impact of the European Inventory of Existing Commercial Chemical Substances (EINECS)/European List of Notified Chemical Substances (ELINCS)/Process Oriented Research and Development derogation (PORD) system—they would soon realize the harm that such legislation has done to the competitive position of the European pharmaceutical fine chemicals industry. At pains to provide every possible support to its laggard biotechnology industry, the EU is now totally ignoring the jewel in the crown of European industry—its active pharmaceutical ingredients manufacturing sector. But this may not be the case for much longer: The local application of EU directives is inconsistent, those responsible for its application are short in competences and/or resources and paperwork seems to get in the way of the critical path of new drug development. The response from the active phar-

ma ingredients manufacturers is not hard to understand: Plants are relocating outside of Europe.

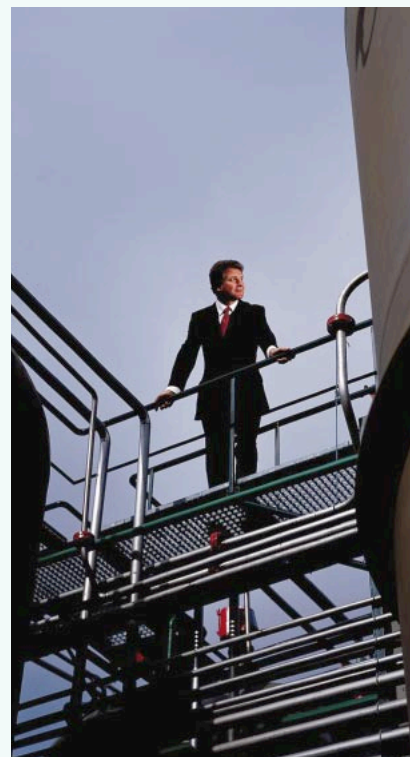
In the space of 18 months, Hovione has recently built—and has since opened—a kilo-lab and pilot-plant in New Jersey, a greenfield site. This is faster than it took a local municipality to review, discuss and issue a planning permit for a similar plant in Portugal at an existing site. Like Hovione, many other companies are moving, and new competitors are emerging in the U.S., in India and in China.

Reach makes no sense. It will cause resources to be wasted, small companies to fail, lead to bans on needed products and will further tip the uneven playing field across the globe. Those using emotional language to make their case should listen to those with reason and expertise.

The EU also needs to respond to what is happening on the global stage. The pharmaceutical industry established the International Conference on Harmonization (ICH), a global system of regulations to accelerate new drug approval. This is an industry-led effort that has been welcomed by the FDA and Japanese authorities. It sets a level playing field on a global scale. It is a fair deal that satisfies everyone. Only the EU has yet to bring the ICH Q7a GMP guidelines for APIs into Law! Yet Europe does not even have a system for GMP compliance inspections for the API in place.

The European health authorities free-ride on the standards imposed and policed effectively by the FDA. Yet European companies are hard at work training their staff and improving their systems, even the European Directorate for the Quality of Medicines (EDQM) has started an informal inspection system.

The chemical industry really is being run by people with more emotion than reason. Fortunately, serious things like pay-packets are dealt with by people in the industry.



For further information on "Legislating to death" by Brussels over the chemical industry, please visit: www.hovione.com/h_press/Legislating_to_death.pdf (pdf file - 130KB)