REACHing out to the world

The adoption of the Chemicals Regulation in December 2006 has forced the EU's main trading partners into action so that Europe's doors do not slam shut on their chemical industries. In very different ways from one world region to the next.

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Bhopal survivors want the site cleaned up. Thirty years on from the disaster, the authorities are just starting to overhaul chemical laws.
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In the run-up debates to its adoption, REACH was variously portrayed as the death-knell of the European chemical industry and a protectionist plot to give EU industry an edge. EU chemical industry bosses sang from both hymn sheets depending on their target audience.

The anti-REACH alliance was spearheaded by chemical industry multinationals with key backing from the United States government. US President George Bush and the President of the American Chemistry Council (ACC) lobbied actively from 2002 to 2006, including through covert actions revealed by an NGO – the Environmental Health Fund – from confidential records secured under the Freedom of Information Act[1].

The campaign culminated in June 2006 with a joint statement by diplomatic missions of different countries to the European Union, organised by the United States and backed by Australia, Brazil, Chile, South Korea, India, Israel, Japan, Malaysia, Mexico, Singapore, South Africa and Thailand, to influence the European Parliament's thinking. The US was prompted to go on the front foot by its perceived loss of leadership. Whereas in the past, US laws had often prompted new EU rules on chemical safety, REACH turned the situation around and the EU rules are now the benchmark in international debates[2].

A change of tone

Things have toned down over five years. The chemical industry's hired consultants had forecast doom and gloom but no-one now places credence in the scaremongering studies about the devastation REACH would wreak. Threats to haul the EU up before the World Trade Organization have given way to technical discussions in WTO committees on specific aspects of the new legislation.

There are two reasons for this about-turn. The final version of REACH is less far-reaching than the Commission's original October 2003 proposal, and the chemical industry has won on some points. Especially, though, the need for a radical shake-up of national laws is now recognized in many countries.

The adoption in 2002 of a Globally Harmonized System (GHS) for the classification and labelling of chemicals prompted most countries to review their laws. Being a creature of the United Nations, the GHS is limited in scope: it deals neither with authorisation, restrictions or public checks and enforcement. What it mainly does is spell out the basic information that producers must supply in order to place hazardous chemicals on the market. The GHS has often been implemented beyond this minimum, however, giving rise to more far-reaching reforms.

> In the USA, industry is fighting a successful guerrilla war against new regulation through the courts.

Apart from the window of opportunity offered by this regulatory environment, a growing awareness of the dangers of under-regulated production of chemicals has also been a factor. Major disasters like Bhopal (see box) and a growing body of studies on the long-term effects of exposures that are hazardous to health and the environment are altering society's firm views about what the chemical industry should deliver. Blind faith in the benefits of progress is giving way to uncertainty. Then, too, Europe is a major importer. Foreign producers need to invest in REACH compliance to preserve their access to the market, so the costs of their own countries' reforms are already substantially covered.

What invariably happens first is that an inventory is made of chemicals placed on the market. There are two options here: collect information from public authorities or research bodies (as Mexico did with an initial inventory between 2009 and 2011), or ask manufacturers to register their chemicals (most usually).

An inventory is obviously only a first link in the chain. Its value depends on the information it gives on the hazards of chemicals, their conditions of use and preventive measures. The next step is to evaluate the risks of each and every chemical identified. Again, there are two ways (which can be combined): by the industry itself or by independent public agencies.

Finally, decisions have to be taken to eliminate the most hazardous chemicals and promote replacement. Here again, there are options: require pre-marketing authorisation (as in the EU for pesticides, food additives and medicines), or after-the-event action based on the risks or damage observed. The complex REACH authorisation system operates only ex post and only for listed substances, but is supplemented by the ability to prohibit or restrict marketing (also retrospectively).

The US is now behind the game

The main **United States** legislation is the Toxic Substances Control Act (TSCA) passed in 1976 after five years of fierce debate. Responsibility for enforcing it lies with a federal organisation, the Environmental Protection Agency (EPA). Thirty-five years on, its record is fairly dismal. Industry has successfully dodged bans on most of the most hazardous chemicals and much of the information submitted to the EPA is locked by confidentiality clauses. It is fighting a successful guerrilla war against new regulation through the courts, which is how it got the asbestos ban reversed in 1991. The TSCA Inventory lists 84 000 chemicals, but comprehensive exposure conditions and toxicity data are available for fewer than 200.

1. See: Waxman H. (2004) The chemical industry, the Bush administration, and European efforts to regulate chemicals, Washington, US House of Representatives; and Ackerman F., Stanton E., Massey R. (2006) European chemical policy and the United States: The impacts of REACH, Medford, Tufts University.
2. Shapiro M. (2007) Exposed: The toxic chemistry of everyday products and what's at stake for American power, White River Junction, Chelsea Green.
3. Schifano J., Tickner J., Torrie Y. (2009) State Leadership in Formulating and Reforming Chemicals Policy: Actions Taken and Lessons Learned, Lowell University.

TSCA reform has been on the agenda since a first bill sponsored in 2005 by Democratic Senator Frank Lautenberg. The current CSIA (Chemical Safety Improvement Act) bill is a compromise reached in May 2013 between Sen. Lautenberg and Republican Senator David Vitter. If this bipartisan text is passed, the reform will not be far-reaching. Some of its provisions have attracted a welter of criticism since they would limit states' powers to pass more progressive laws. At present, 29 states have enacted tougher rules than the federal legislation to restrict or ban the use of certain chemicals. These more enlightened laws have played greatly into the development of sustainable chemistry in some areas of activity[3].

The CSIA's general approach is to avoid "unreasonable risk of harm to human health or the environment" rather than eliminate risks that might be. That said, the CSIA does arguably represent some progress. The EPA could delay new substances coming to market if there were doubts about their safety. In 1976, the TSCA had foregone a thorough evaluation of the 62 000 substances already on the market at that time.

Using the CSIA, the EPA should be able to set programmes going to make up for lost time and evaluate some of these chemicals. The big unknown is how fast the work will go. Even more than essential changes in the law, it means overcoming central government reluctance to implement appropriately-resourced public controls on the chemical industry ... which, let it be said, is a generous donor of campaign funds. In February 2012, the EPA selected 83 chemicals (one thousandth of the inventory) for priority risk assessment. Even this limited programme is advancing at a snail's pace: 7 evaluations started in 2012, and the evaluation process for 18 more will get under way in 2013-2014.

Asia on the move

There are signs of movement in the law in **China**. Growing labour and social unrest is challenging official policies that sacrificed health and the environment to rapid, predatory industrialization. A raft of legislation was introduced between 2006 and 2009 to implement the GHS. In January 2010, more ambitious regulations were enacted, entering into force on 15 October 2010. These impose tighter rules on registration of new chemicals (compared to the 45 000 that had already been recorded since 2003).

There are some big differences from REACH. There is no quantity limit for the registration of new substances (but the information required for quantities less than one tonne is fairly basic). Some tests not provided for in REACH are required and some of them have to be done in China. There is a duty not to sell substances to downstream users who cannot implement risk management measures. To its discredit, China maintains relatively lax rules for chemicals already registered.

New rules on the safety of hazardous chemicals came into force in December 2011. They cover just over 3 700 substances and require the firms concerned to have official authorisation. The authorities have also announced a planned update of the catalogue of hazardous substances (which will probably include around 7 000 chemicals).

The Environment Ministry adopted a new chemical hazards prevention and control plan in January 2013 identifying 58 priority substances and seven industry sectors. Occupational health was only a marginal criterion in selecting these substances for official risk assessment. Any restrictions or prohibitions are unlikely to be adopted before late 2015. In August 2013, the Ministry of Industry and Information Technology announced plans to tighten up the rules on the use of toxic substances in the electronics industry.

The ruling and opposition parties in **Taiwan** have agreed legislative changes, but put off enacting them until 2014. Producers and importers will then have to notify the authorities about all chemicals in quantities above 10 kg per year. The information required will depend on the quantity and risk level. The Taiwanese legislation expressly refers to the inventories of chemicals created by six other regulatory systems (Australia, China, United States, European Union, Canada and Japan). Notification of any chemical already listed in two of these inventories must be accompanied by more detailed information. At the opposition's urging, government agencies will have new regulatory powers, in particular as regards nanomaterials and toxic chemicals contained in manufactured articles.

Among the most far-reaching reforms is that of **South Korea** whose new law, passed on 30 April 2013, has been dubbed K-REACH. It will come into force in 2015 and sets a time frame of eight years within which chemicals produced or imported in quantities of at least one tonne per year must be registered. Chemicals that are hazardous to the environment or human health and new substances must be registered regardless of the production volume. Annual reports will update the registry information. This reform is particularly important because the Korean chemical industry ranks seventh worldwide. That the legislation is so far-reaching is due to public opinion, galvanised by a very serious accident in the industrial city of Gumi in September 2012 and the publication of a Health Ministry report on lung cancer caused by chemicals commonly used to sterilize humidifiers.

India also announced a law reform review in April 2012. A muted beginning was made in 2013 by drawing up an inventory of chemicals. Health and environmental campaigners are critical of the partial reforms introduced in recent years focused mainly on pesticides and electronic waste. The situation regarding both remains dire and the Indian government has not resourced any systematic monitoring of the situation. The European chemical industry employers (CEFIC) was quick to step into the debate, calling on the government not to take its lead from REACH but trust in the chemical industry's voluntary initiatives – displaying some cynicism given the scale of the health problems caused by the lack of control over that industry in India.

Japan brought in a law reform in 2009. The government said it would be looking closely at banning the most hazardous chemicals. Producers or importers will have to provide an annual report on the quantities placed on the market and the use of different chemicals. A key aim of the reform is to make more information available to downstream users. The amended Chemical Substances Control Law requires a risk assessment to be done by public agencies by reference to priority criteria. Producers and importers must in principle notify all substances from quantities of one tonne per year.

A mixed score sheet

This brief overview is by no means comprehensive. **Turkey** enacted a new law not dissimilar to REACH at the end of 2008. In 2009, **Malaysia** decided to require registration of hazardous chemicals produced or imported

Industry defensive measures: self-regulation and good laboratory practice

In the night of 2-3 December 1984, a 40-tonne tank of methyl isocyanate exploded in Bhopal, India at a plant owned by Union Carbide (subsequently bought by Dow Chemical). The disaster killed an estimated 20 000 people and left some 200 000 seriously disabled. Union Carbide and Dow offered only paltry compensation and have not paid for site clean-up work.

In the months following the disaster, the Canadian chemical industry launched the Responsible Care initiative, purportedly to improve industry safety. The movement spread rapidly worldwide and now operates under the auspices of the ICCA (International Council of Chemical Associations). Its aim – industry-driven improvements in the management of chemical risks – is praiseworthy. A close reading of the charter reveals the limits of the initiative: it contains no commitment to replace substances of the highest concern.

Responsible care is also a public relations programme to promote self-regulation. Companies that join it link up in associations to lobby systematically to fend off major legal restrictions. As Canadian researchers observe, "One of the main objectives of Responsible Care was to foster a less adversarial relationship with government and to pre-empt or at least influence the content of additional regulation".*

Other partners (NGOs, trade unions) may be associated but remain subordinate to industry top management. A number of national studies have shown that companies that sport the Responsible Care label were not necessarily exemplary where risks to workers, the public and the environment are concerned. In 2006, one of them – the Czech company Draslovka – caused a disaster by discharging cyanide that poisoned an 80 kilometre stretch of the River Elbe.

The OECD's role is an ambiguous one here. This international organization now includes 34 countries and is gradually opening up to the emerging countries most receptive to the ultra free-market policies it propounds. The OECD has been worrying away at the issue of chemicals since the 1970s, on which it has adopted a score of recommendations and decisions. Its central focus is on simplifying the regulatory framework for the chemical industry, chiefly through urging all States to endorse a common set of benchmark rules on "good laboratory practices" for recognition in each country of the test results produced by a given country. EU laws refer to the OECD criteria. The main requirements relate to standardised procedures and detailed test documentation. That is not enough to resolve conflicts of interest stemming from industry-funded research done by private laboratories. Various studies suggest that referring to these GLPs alone lets through studies that seriously underestimate the risks.**

* Moffet J., Bregha F., Middelkoop M.J. (2004) Responsible Care: A case study of a voluntary environmental initiative, Webb K (Ed), Voluntary codes: private governance, the public interest and innovation, Ottawa, Carleton University.
** Myers J.P. *et al.* (2009) Why public health agencies cannot depend on good laboratory practices as a criterion for selecting data: the case of Bisphenol A. Environmental Health Perspectives, 117, 309-315.

REACH is now a benchmark for the rest of the world.

in quantities of 0.1 tonne per year. Major reforms have been announced in **Russia.** Other countries (e.g., Australia, Canada, Brazil and Vietnam) are more cautious and content for the moment to tweak specific aspects of their regulations.

The overall score sheet is mixed. REACH has been beneficial in breaking through some no-go areas: proscribing chemicals for which there is insufficient information (no data, no market); making the industry help to pay for the operation of regulatory agencies; asserting that chemical manufacturers have a responsibility to the entire production chain – these are undeniable plus points. It would have been unrealistic to wait for some unlikely global agreements to regulate these areas. The first step had to be taken. On the evidence, it was a gamble that paid off: REACH has become a benchmark for the rest of the world.

Major challenges still await answers: ensuring transparent information and seeing that industry does not abusively claim data confidentiality; developing public expertise in institutes of toxicology that are independent from industry to check the quality of the information provided; ensuring market controls to enforce the rules; strengthening the specific rules on worker protection in line with those on marketing (on which the EU's record is becoming worrying).

One basic inconsistency remains: the rules treat each individual chemical in isolation whereas in reality health and the environment are bombarded by multiple exposures that interact with one another. The only joined-up responses to these "risk cocktails" are: a ban on substances of the highest concern; innovation; voluntary production restraint; and research based on a precautionary principle. The example of asbestos alone – still authorised in countries where approximately 90% of the world population live – shows that much remains to be done. ●