REACH: halfway there or half-baked?

How is REACH doing five years after the Regulation went live? The European Commission and ECHA, the European Chemicals Agency, think things are going well. The trade unions are less enthused, and point to a string of failings in the new system that must be addressed in short order for the expected health benefits for workers, consumers and the environment to happen.

Tony Musu
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The European Union (EU) chemicals market is worth nearly 540 billion euros a year – around about the public debt of Greece and Portugal combined. No wonder, then, that it took nearly ten years of acrimonious negotiations to get REACH onto the books. The regulation lays down the rules on the marketing and use of chemicals in Europe based on the precautionary principle. It is hugely complex and replaces up to 40 old directives and regulations with a single, more efficient system for the registration, evaluation, authorisation and restriction of chemicals on the EU market1. Central to the system is the reversed burden of proof: pre-REACH, the public authorities had to assess the risks of a chemical before they could ban it from sale if needed; now, manufacturers have to provide information before they can place their products on the market. More specifically, if they want a registration number, without which they cannot put their chemicals on the market, manufacturers and importers must provide ECHA, the European agency responsible for supporting the implementation of REACH, with data to show that they are safe to use throughout their life cycle. These data are provided in a registration dossier which is required to get market access (the "no data, no market" rule).

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The timetable for registration of chemicals already on the EU market runs up to May 2018 (see chart), so halfway there seems a reasonable point to take stock of the reform’s rollout. The European Commission was also meant to publish a general report on the experience acquired from the operation of REACH by 1 June 2012. It was actually published several months later in February 20132.

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Figure 1 REACH registration timeline

Commission awards itself a pat on the back

The European Commission has concluded that REACH is functioning well and delivering on all the objectives that can be assessed at present. Some adjustments may well be needed to certain provisions of the regulation, but to ensure stability and predictability for industry, no changes are being considered. Nevertheless, the Commission considers that the regulation’s impact on small and medium-sized enterprises (SMEs) ought to be reduced, and therefore proposes to cut the amount of registration fees they have to pay and provide practical guidance to help them fulfil their obligations.

While the Commission acknowledges that it is still too early to quantify the benefits to human health and the environment, it does note that the additional data supplied by the registration dossiers has helped to identify and classify more chemicals as hazardous, improve safety data sheets and pass on more appropriate risk management measures throughout the production chain. The inclusion of some substances of very high concern on the candidate list for authorisation has also encouraged switching to safer alternatives. All these indicators show that progress towards meeting the human health and environmental objectives of REACH is materialising.

The European trade union movement accepts that registration has gone well in technical terms, and probably better than might have been feared.

Industrial operators have prepared their registration dossiers on time and ECHA has processed them promptly to allocate registration numbers and enable the European internal market to function properly. By the end of November 2010 — the first deadline for existing substances produced in quantities of more than 1,000 tonnes per year — more than 3,600 substances had been registered with ECHA. By the second deadline of the end of May 2013 for existing substances produced in quantities of 100 to 1,000 tonnes per year, nearly 3,000 further chemicals had been registered. That adds up to 6,600 chemicals already on the European market for which ECHA should now have information on their properties, uses, risks and how to manage them in order to avoid adverse effects to human health and the environment.

Data quality is an issue

The unions are more critical of other parts of the reform.

Evaluation

The Agency uses dossier evaluation firstly to examine testing proposals submitted by registrants in case of missing data, and secondly to check whether the dossiers actually contain the information required for registration. The latter, known as a ‘compliance check’ is done on only 5% of dossiers and can be used as an indicator of the quality of data provided by the industry. Apparently, however, a third of the dossiers examined in 2012 were significantly deficient in quality.

This includes, for example, inadequate or incomplete information on substance identity, its intrinsic dangers, uses and/or estimated exposure levels. This therefore makes it impossible to ensure that the risks for the substances concerned are properly identified and controlled in order to protect workers and the public at large.

What this means is that workers who use these chemicals are being provided through manufacturers’ safety data sheets with risk management measures and conditions of use that are in practice not fit for purpose. This is why in just such cases ECHA calls for additional information from registrants, who must produce it within a specified period. Unfortunately, the Agency’s powers stop there and if additional data are not supplied, only the – chronically understaffed – national policing and enforcement authorities have power to take action against offenders.

The quality of data provided by industry is recognised as a problem by ECHA, which has made it a key strategic objective of its work programme for the years ahead. Arguably, the solutions are not far-reaching enough. The European Trade Union Confederation thinks ECHA is using too much carrot and not enough stick to get registrants to up the quality of their registration dossiers. The ETUC wants two key measures brought in. First, the outright withdrawal of the

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registration number (and therefore the right to be on the European market) for a virtually empty or very poor quality dossier. And second, an increase in the number of dossiers compliance-checked by the Helsinki Agency.

Authorisation

The authorisation strand of the Regulation aims to foster innovation by having the most hazardous chemicals on the EU market gradually replaced by ones that are less dangerous to human health and the environment. So, if firms persist in using substances identified as of very high concern (e.g., carcinogens, mutagens or reprotoxins – CMRs), they will have to get authorisation from the European Commission. Such authorisations are granted on a case-by-case basis for a limited time. Since REACH came into force, only 22 substances have been subject to authorisation and 144 identified as candidates for authorisation. The full authorisation procedure can take up to seven years and the first application files were received by ECHA only in August 2013.

The trade union complaint is that with an estimated 1,500 or so substances of very high concern currently on the European market, the system is too sluggish. At this rate it will take over a century to get manufacturers to replace their substances of the highest concern with safer alternatives. That said, they do still fully support the objectives of the authorisation system. In fact, they have drawn up their own list of widely-used hazardous chemicals that need to be eliminated from workplaces at the earliest opportunity. In response to criticisms about the slow-moving system from NGOs and trade unions, the choice of candidate substances by industry, the Commission and Member States have recently adopted a roadmap for identification of substances of very high concern (SVHCs) which aims "to have all relevant currently known substances of Very High Concern (SVHCs) included in the candidate list by 2020". This unquantified target brings little cheer to the unions because it will not necessarily speed up the slow-moving procedures and gives too little incitement to substitution and switching to safer chemicals.

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Restriction

The Regulation also enables the Commission to restrict the manufacture, use or placing on the market of certain chemicals in case of unacceptable risks for human health and the environment. The ability to impose restrictions has been part of EU law since 1976 (e.g., the banning of asbestos or certain heavy metals in batteries) and was kept in REACH. Comparing the number of substances (or groups of substances) covered by a restriction procedure post-2009 – the start of restriction procedures under REACH – is disheartening to see that the rate at which new prohibitions are adopted in the EU has halved. Under the old system, about two prohibitions were made a year on average compared to about one a year under REACH. One possible reason is the long and complex procedure (two to three years between a proposal being made and adopted – if it is) involving two ECHA scientific committees tasked with preparing an opinion for the Commission. The Member State proposing the Community-level restriction has to convince the committees of its merits, both in terms of the unacceptable risk and the proportionality between the costs of the restriction and the expected benefits to society. While the public consultations and presence of observers throughout the restriction process are clear improvements over the old system, it is reasonable to wonder whether the same applies to the socio-economic analysis. Equating the costs to business with the benefits to human health and the environment is surely comparing apples and oranges?

8. Under the old system, 59 entries were added to the EU list of prohibitions in 33 years compared to four new entries in four years with REACH. Notable among these recent prohibitions was one on the use of an anti-mould substance used to protect shoes or clothing during transport and storage which caused allergic reactions in exposed workers and consumers.
ECHA under fire from NGOs

3 questions to Vito Buonsante, lawyer with NGO ClientEarth’s Health and Environment programme

Interview by Denis Grégoire, Brussels, 2 October 2013

In May 2011, ClientEarth filed a complaint against the European Chemicals Agency with the Court of Justice of the European Union. What has ECHA done wrong?

Vito Buonsante — Our complaint aims to get the principle of public access to information generated by implementation of the REACH Regulation applied in practice. We found that the data put out by ECHA did not give the identity of a lot of the producers of chemicals on the SIN list, the list of carcinogens, mutagens, reprotoxins and endocrine disruptors drawn up by the Swedish NGO ChemSec. It was unacceptable for ECHA not to show transparency on a matter so important to European consumers. A year after our complaint was filed, ECHA decided to publish the identity of most of these producers. It’s a first victory, but we decided to maintain our complaint because there is still no way of knowing what exact quantities these highly toxic substances are produced in.

You have also complained about the quality of ECHA registration dossiers. ClientEarth thinks the dossier checks are not up to scratch. VB — ECHA checks registration dossiers using an automated computer system that does not check the data supplied in the Chemical Safety Report. As a result, the agency is giving registration numbers, and therefore access to the European market, to chemicals with a poor or near empty dossiers - so-called “google dossiers” that look as though they’ve been cobbled together in a couple of minutes from web searches. This is an unacceptable practice which undermines REACH’s basic principle of “no data, no market”. It is estimated that in practice, only one in twenty dossiers undergoes thorough scrutiny by ECHA. Registrants soon realized that there was little chance of their dossier getting a detailed compliance check, and that even if it did, there is no sanction - the agency just sets them a new deadline to improve it. In July, we published a report analysing the dossiers submitted by the producers of five endocrine disruptors. Most did not even mention some toxicological studies that are readily available in the scientific literature. ECHA is aware of the problem but has told us that it has no plans to review its automated checking system. It has, however, promised us that it would require more detailed information from 2015.

You paint a fairly gloomy picture of the early years of REACH. Any reasons to be cheerful?

VB — Yes, of course. REACH has already made a lot of improvements. Around 700 carcinogens, mutagens and reprotoxins have not been registered. Looking on the bright side, you could assume that users of these chemicals have simply given up on them (see also article p. 20). We have also found that whenever a chemical is put on the list of “substances of very high concern”, its production decreases rapidly. Obviously, this list contains only 144 substances at present as opposed to the 1 500 or so it should do. The biggest benefit of REACH so far may be to have caused a real “cultural revolution”. Consumers are no longer willing to accept products being put on the market that pose serious threats to their health or the environment. The circle of those who think substitution is the best option has widened compared to those who argue that “chemical risk management” is enough to protect people, although that idea is still very much the thinking among some national governments and trade unions.

Further reading

The ClientEarth reports on REACH implementation are downloadable from http://www.clientearth.org/health-environment/publications

Availability of data

To fill the big gap in public information on chemicals on the European market, ECHA has to publish on its website much of the information it collects through the different REACH procedures. Data like the classification and labelling of substances, the levels of exposure to the substance above which humans should not be exposed – Derived No-Effect Levels, DNELs –, and risk management measures recommended by registrants must always be publicly available. The regulation also requires other information like the identity of the manufacturer and production volumes to be made public except where the firm makes a justified request for confidentiality.

ECHA has been extremely concerned to preserve the commercial interests of registrants at the expense of the transparency required by the Regulation. Trade unions and NGOs have fought long and hard to get the Agency to publish this vital information for consumers and workers (see box p. 18). Having the identity of registrants made public allows us to know who is manufacturing or importing the chemicals that we are exposed to, but even more, encourages registrants to provide good quality data in their registration dossiers.

One area where the Regulation falls badly down on improving public information about exposure to potentially hazardous substances around us is nanomaterials. The REACH registration criteria are unfitted to this kind of substance and the "no data, no market" principle is being flouted for many nanomaterials manufactured and marketed in Europe.

The upside for workers

The timetable for REACH implementation runs up to 2018, and halfway there it has to be said that the benefits to workers’ health are not easy to put figures on. With more than 100,000 deaths a year, chemicals remain the leading cause of workplace deaths in Europe. The best indicator that the reform is working is that the number, and the number of chemical-induced occupational diseases, go down. Unfortunately, it is too early to see any such changes. Less than a quarter of the 30,000 substances that should be registered under REACH have been, and it will take time for the new knowledge on chemical hazards and risks to filter down to workplaces.

The new safety data sheets containing more information on prevention and risk management are starting to trickle into workplaces. Employers and workers need to learn to use them better, and they are still on a learning curve. Many firms do not even know about the reform, which is why unions are developing workplace information campaigns (see box).

However, there are signs that REACH is starting to influence how firms act, including SMEs. Replacing carcinogens with safer alternatives (a legal requirement since the 1990s in worker protection legislation) has always been a complex process that firms are reluctant to get into. Since the regulation came in, some sectors that use carcinogens on the list of substances subject to authorisation have developed less hazardous substitutes in record time to avoid the high costs of getting an authorisation granted (see report p. 31). Proof that this system designed to encourage businesses to innovate is doing its job.

Then, too, the many university training programmes in REACH appearing across Europe driven by strong demand from firms in all sectors looking for knowledgeable employees evidences the growing number of businesses concerned with the reform across Europe.

Industry claims that the REACH reform was impractical, unrealistic and bad for the European economy are belied by the clear fact that the system is working. The doom forecast to bell the European chemical industry has not happened – it is still thriving.

The Commission’s evaluation report bears out that although its relative share in the global chemicals market has declined, the European chemical industry is still the world’s biggest exporter with a turnover that
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has risen steadily in absolute terms since the reform came in. The new rules have led to further harmonisation of the internal market, which has been good for the European chemical industry. Where innovation is concerned, the Commission notes that the reporting obligations between suppliers and users under REACH have given producers a better understanding of their customers’ uses and needs, thereby helping to bring innovative substances to market. The annual number of new substance registrations has actually gone up since the Regulation came in.

Interestingly, other non-EU countries have actually taken a cue from REACH to reform their own legislation (see article p. 37). Obviously, not everything is working to best effect at this mid-point. SMEs are still complaining about the burden and cost of the system. The European trade unions have pointed to failings in the Regulation and ECHA’s operation which are holding back the expected benefits to human health and the environment.

The massive industry lobbying that overshadowed the entire negotiation phase of the Regulation continues to beleaguer its implementation. ECHA must make efforts to find a better balance between the defence of corporate interests and those of society at large.

Given the difficulties in getting this reform brought into existence and adopted, the Commission’s reluctance to reopen the Pandora’s Box halfway through is understandable. Even so, it would be well advised to make good some defects, like the failure to cover the risks of nanomaterials, the inadequate provisions for ensuring data quality, and the slow-moving authorisation and restriction procedures.

If the benefits of REACH to workers’ health and the environment are to materialise, therefore, the labour movement must not only continue to support the reform, but also prepare for its future developments.

Illegal CMRs on the EU market?

All substances that are proved or assumed to be carcinogenic, mutagenic or toxic for reproduction (CMRs) in humans and are produced in quantities greater than one tonne per year in Europe are supposed to have been registered with ECHA by 30 November 2010. However, comparing the official list of the 1100 or so CMRs with a harmonised classification at European level against the list of 406 CMRs registered in REACH, the question is: what happened to the missing 700 CMRs?

In a May 2012 report on CMRs, ECHA says that the main reason why so many CMRs are unregistered is because they have been replaced with safer alternatives and so are no longer being marketed on the Community market. It claims this as evidence that REACH is working very well and encouraging companies to use substances that are less dangerous for human health and the environment.

It would be nice to take as rosy a view as the ECHA, but what the Agency’s report sadly does not mention is that some CMRs may still be present on the market without having been registered, and so be being sold illegally. Some unscrupulous companies may be wagering that the chronic understaffing of national enforcement authorities means the odds are against them being caught and punished. The European Trade Union Institute has commissioned a survey on this which is due to be published soon.