REACH: first reading verdict – "could do better"

The European Parliament and Council are still wrangling over the future REACH regulation (Registration, Evaluation, Authorisation of Chemicals). The two institutions have been working in parallel since October 2003 on a draft text formally adopted by the European Commission. They have to agree on the final version through a co-decision procedure.

REACH will make sweeping changes to current European legislation on the use and marketing of chemicals. The reform will force producers to register chemicals that they manufacture or import in quantities of one tonne or more a year to show that they can be used safely. Also, producers of substances that are CMR[1] or likely to accumulate irreversibly in the body and environment[2] must obtain an authorisation for each use regardless of its production volume.

Rarely has any legislature been subjected to such intensive industry lobbying against proposed law reforms[3]. MEPs and Member State governments were strong-armed into radically trimming down produ-cers' REACH obligations as the process went on.

A curate's egg of a compromise

However, a major milestone was passed on 17 November 2005, when MEPs passed a fairly heavily amended first reading text by a majority of 407 votes for, 154 against and 41 abstentions as a result of an eleventh-hour political compromise between the big three groups in the European Parliament (conservatives, socialists and liberals). Compared to the European Commission's original proposal, the text significantly reduces the information producers have to supply to register almost all the 30 000 substances covered by REACH.

Even so, the first reading text does keep intact some major advances secured earlier by the Environment Committee, Parliament's lead scrutiny body on the draft, like the mandatory substitution of the most dangerous substances, chemical safety reports for all substances covered by REACH, and the "duty of care" for all substances produced or imported into Europe.

Less than a month on, the Extraordinary Competitiveness Council of 13 December 2005 found the Member States striking their own political agreement on the text. It closely mirrors the amendments adopted by Parliament on Registration and Evaluation, but diverges on Authorisation.

Apart from slashing the amount of information that manufacturers will have to supply in the registration phase, both Parliament and Council adopted the OSOR (One Substance, One Registration) principle requiring different producers of the same substance to share the information they have in order to submit a single registration dossier.

Both the institutions beefed up the role of the European Chemicals Agency that will be set up to manage the new REACH system in the evaluation phase of dossiers and substances.

In the authorisation phase, by contrast, Council has thrown out the principle adopted by Parliament that an authorisation for a substance of very high concern will always be refused where a safer alternative is available (mandatory substitution principle) in favour of keeping a system where an authorisation can be granted if the applicant can show that the risks related to the use of the substance are "adequately controlled". The Council nevertheless ruled out granting authorisations on this basis for PBT and vPvB substances. It has also gone with the principle that authorisations granted should be reviewed, but after a period set case-by-case rather than after five years in every case as decided by Parliament.

These different approaches by Parliament and Council to the implementation of the substitution principle in the authorisation phase will be central to the debates in the second reading, scheduled to take place on 24 October 2006.

Evening up the cost-benefit ratio

The European Trade Union Confederation (ETUC) believes that the REACH project has passed major milestones in Parliament and Council, given the fears that powerful industry pressures could have led to the reform simply being quietly scrapped. This first reading result means that the reform will see the light of day, and will set Europe firmly on the road to an economy that takes greater account of the health and environmental impacts of the chemicals industry.

However, the ETUC believes that both the text adopted by Parliament and that negotiated by the governments could have achieved a better balance between economic demands and health protection for workers, citizens and the environment.

[1] Carcinogen, mutagen, reprotoxic.
[2] PBT (persistent, bio-accumulative and toxic) and vPvB (very persistent, very bio-accumulative toxins).
[3] See: "REACH: industry's meltdown predictions groundless, but fierce lobbying goes on..." *Hesa Newsletter*, No. 27, June 2005, p. 5-6. Downloadable from http://hesa.etui-rehs.org > Newsletter.

The ETUC's key demands for the second reading of REACH

1. Application of the mandatory substitution principle in the authorisation phase.
2. More exacting information requirements for the registration of low volume substances (between 1 and 10 tpa) and chemical safety reports for all substances covered by REACH.
3. Adoption of a "duty of care" for all chemicals produced or imported into Europe.
4. A quality assurance mechanism for the information provided by manufacturers and importers.
5. More coherence between the REACH obligations and those in the health and safety at work directives.
6. Introduction of measures to help SMEs discharge their REACH obligations.

One plus point is that both texts confirm the key principle of reversing the burden of proof from the competent authorities onto producers for substances covered by the reform. In future, industrialists will have to demonstrate that their substances can be manufactured and used safely before they can put them on the market.

The ETUC also welcomes the adoption of the OSOR system, which should help cut the costs of registration for small and medium-sized firms that manufacture or import chemicals.

However, the ETUC regrets the new concessions granted by Parliament and Council to the chemical industry. Waste, for example, no longer comes within the reform, and a large number of chemicals produced in quantities of more than one but under ten tonnes a year will fall outside the original testing safety net.

But the potential benefits of REACH to workers are closely tied to the information that the system will generate on the hazards of chemicals as well as how to manage the risks related to their uses, a conclusion borne out by the recent study done for the ETUC by the University of Sheffield on the number of work-related diseases that REACH could help to avoid[4].

The ETUC has consistently called for an ambitious REACH regulation, arguing that a lack of reliable data would prevent the project from delivering its health at work aims. The ETUC and its members will therefore continue to press second reading proposals to achieve the best possible ratio between the costs of the reform and the expected benefits for human health, the environment and innovation in European industry (see box).

The ETUC strongly supports the mandatory substitution principle in the authorisation phase as proposed by the European Parliament, partly because it is already found in the EU legislation on the protection of workers exposed to carcinogens[5], and it is synergies rather than inconsistencies that are needed between interlocking legislation, but also because unless they are placed under the cosh, few producers are likely to commit to finding new ways of replacing the production of the most dangerous substances with safer alternatives.

The Commission believes that the co-decision procedure between the European Parliament and Council could be concluded by the end of 2006, so that the REACH system would come into effect in 2007. The regulation would be fully implemented 11 years after that, when the 30 000 substances covered by the reform have been registered with the European Chemicals Agency. ■

Tony Musu, researcher, ETUI-REHS
tmusu@etui-rehs.org

4 Simon Pickvance *et al.*, *The impact of REACH on occupational health with a focus on skin and respiratory diseases*, ETUI-REHS, 2005. The report can be ordered from http://hesa.etui-rehs.org > Publications.

5 Directive 2004/37/EC.