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REACH is finally passed into EU law

On 12 December, years of wrangling finally came to an end when the European Parliament voted to approve the final version of the REACH regulations following their second reading in a plenary session with 529 votes in favour, 98 against and 24 abstentions.

This was approved by the European Council on 18 December and the legislation will come into force by mid-2007, with implementation taking place in stages across all 25 EU member states in the years to 2018.

Final approval brought to an end the most protracted debate on legislation ever seen in the EU. The European Council, representing member state governments, Parliament and its Environment Committees, the EC, individual states, industry bodies, NGOs and countries in other regions of the world all had their say many times and over and reacted to the final version in many different ways.

The final changes to the proposals were made less than two weeks before the second reading. A 'trialogue' between Council, Parliament and Commission had concluded an agreed a set of proposals that sought to balance health and environmental issues with the need to reduce cost and make the legislation workable.

As a result, about 17,000 low priority chemicals out of the original 30,000 or so will now be excluded from onerous testing requirements, according to the UK MEP, Chris Davies, who took part in the negotiations to establish a compromise. This, he said, was in keeping with the aim to avoid unnecessary animal testing and reduce the bureaucratic burden on the industry.

In addition, companies will not have to elaborate a Chemical Safety Report when registering substances consumed in volumes of <10 tonnes/year. In addition, IP rights have been somewhat strengthened, with data protection for the registration of products extended from three to six years.

Thus, chemicals of high concern will normally be authorised for use if their effects can be 'adequately controlled'. However, manufacturers of about 1,500 high concern chemicals will have to submit a substitution plan when they apply for authorisation, if safer alternatives are available at an economic cost.

Hormone disruptors, persistent, bioaccumulative and toxic (PBT) substances and very persistent, very bioaccumulative (vPvB) chemicals will not be authorised for use if suitable and safer alternatives exist. Moreover, whereas authorities formerly had to justify concerns about specific chemicals, the onus will now be on manufacturers to show that they are safe.

In the end, endocrine disrupters were excluded from these substitution requirements, though this will be reviewed after six years in the light of the latest scientific evidence. The scope of REACH will also reviewed after five years to determine whether any substances should be excluded from

its provisions.

Reactions were inevitably mixed, though it appears that those most satisfied with what emerged were the larger companies, followed by smaller companies and NGOs and the EU's trading partners most hostile.

CEFIC, the European Chemical Industry Council, called the vote "a decisive step in the finalisation of a long process towards the biggest regulatory framework ever for the chemical industry and its downstream users in Europe", though it regretted that certain late additions would make it less workable.

"The European chemical industry will see REACH as an opportunity to demonstrate that companies have a solid knowledge of chemicals and strong product management practices to ensure chemical safety. The industry wants to make REACH work; CEFIC will play an active role in helping companies to comply with the regulation," said director general Alain Perroy.

Meanwhile, Europe's largest chemicals firm, BASF, said that it was "well prepared" for REACH. The company estimated that the costs of implementation would be about €550 million over 10 years and said that it was continuing to develop alternative products.

In the UK, Steve Elliott, chief executive of the Chemical Industries Association (CIA) said that the new package "represents the best chance for REACH to deliver on its original objective - ensuring improvements in human health and the environment whilst fostering innovation and competitiveness". The industry was committed to ensuring that it is implemented and enforced as effectively as possible.

However, the Chemical Business Association (CBA), which has taken up the cause of SMEs in the chemical supply chain who account for 95% of the industry, argued that the final changes meant that REACH was not fit for purpose.

Melvyn Whyte, chairman of the CBA's REACH Task Force, said that REACH was voted for as "the 'least worst' solution … a compromise deal which serves the needs of politics, rather than the sustainable future of one of Europe's most successful industries".

Whyte added that the CBA is committed to working with the relevant organisations to make REACH workable and will continue to press for improvements in the implementation process. However, he said, there are many enduring workability issues.

"If REACH was a product manufactured by the European Parliament, it would fail most basic quality tests, face rejection because it was not user-friendly, and it would not be bought by consumers because it was too expensive," he concluded.

All three associations have already set up bodies that will help member companies comply with REACH. In this they were joined by the SOCMA in the US, which announced an extension of its chemical consortium management services to cover the new rules imposed by REACH. 'ChemSortia' will be open to other companies as well as SOCMA members.

Greenpeace, meanwhile, said that the vote left REACH "alive but in a critical condition". It approved the need to provide safety data for large volume chemicals, the mechanism to substitute PBTs if safer alternatives exist and the ability of the public to request information about the presence of a limited number of hazardous chemicals in products that was not available before.

However, the organisation, which produced strategically timed reports in the run-up to the vote, was critical of some “major loopholes”, notably the removal of the need to produce any meaningful data on the 60% of chemicals consumed at volumes of <10 tonnes/year, and was scathing about the concept of ‘adequate control’.

“REACH and the new European Chemicals Agency will therefore require ‘intensive care’ from policymakers over the coming years to ensure that they protect the public from highly hazardous chemicals,” Greenpeace concluded.

From within the industry, there have been claims that REACH could impact the development of key drugs. Whilst APIs are mostly exempt, the solvents and intermediates used in their formulation are not necessarily so and changing supplier is no easy matter in pharma. This would particularly affect those using mutagenic, carcinogenic and other hazardous chemicals.

It has been reported that some suppliers have told AstraZeneca that they could not guarantee the supply of key intermediates for two new drugs, one of them an oncology treatment. Glaxo SmithKline, however, said that it had not come up against any such problems as yet, while Pfizer merely said that it was in discussions with suppliers and would not comment further.

Other critics came from developing countries who expect their exports to the EU to be impacted, the metals sector and animal rights activists who – like industry - foresee a huge increase in testing of animals. Some of the strongest criticism, however, came from the US.

Jack N. Gerard, president and CEO of the American Chemistry Council (ACC) said in a statement that the vote had not produced workable legislation or addressed the concerns raised by the EU’s trading partners and the industry.

“A more focused and flexible approach to registration, and a truly risk-based approach to authorisation, could have brought our economies and regulatory systems closer together. Strong and effective chemical regulation should not have to come at the expense of global trade and competitiveness,” he said.

In particular, Gerard described the requirement for a substitution plan for all substances where an alternative might exist as “a poor use of time, energy and resources - particularly given the reality that viable substitutes are not readily available for every use”. This could lead to “unintended and potentially adverse consequences,” he warned.

On the far extremes of politics, the right-wing Institute for Trade, Standards & Sustainable Development (ITSSD) said the regulation was attempt to impose European legislation and cultural preferences on non-EU firms that was based on the discredited precautionary principle and was illegal under WTO law.

REACH, it claimed, should be seen as “a carefully crafted legal instrument specially designed to facilitate the 21st century United Nations-based global governance of every nation's industries, particularly those located and/or based in the United States”. It called on the US and other governments to attack the legislation via the WTO.