The main proposals for improving REACH set out here are the product of detailed discussions held by the European Trade Union Confederation (ETUC) and its members (European industry federations and national trade union confederations) in an ad hoc working group initially tasked by the ETUC Executive Committee with preparing the unified European trade union position on REACH[1].

The ETUC's proposals for improving REACH

The ETUC's March 2005 conference gave over an entire session, chaired by Estefania Blaunt of the Spanish trade union Comisiones Obreras, to the presentation and discussion of trade union proposals for improving REACH[2]. Waldemar Bahr of the European Mine, Chemical and Energy Workers' Federation (EMCEF) presented the ETUC's proposals on the duty of care, Werner Schneider of the German Confederation of Trade Unions (DGB) those on registration, François Laurent of the Confederation of Christian Trade Unions of Belgium (ACV-CSC) those on evaluation, Francisco Blanco of Comisiones Obreras' chemical division those on the authorisation requirements, and Bernd Eisenbach of the European Federation of Building and WoodWorkers (EFBWW) those on downstream users and SMEs. Finally, Henning Wriedt of the German Work and Health consultancy looked at relations between REACH and the legislation to protect workers exposed to chemicals. These proposals follow directly on from the declarations adopted by the ETUC and its members, and aim to optimize the expected cost/benefit ratio of the reform in order to make the REACH system a more effective and paying proposition.

Duty of care

The proposed REACH Regulation adopted by the European Commission on 29 October 2003 seeks to deliver aims wholly congruent with all three pillars of the European Union's sustainable development policy: economic (industrial competitiveness), social (protection of human health and jobs) and environmental. REACH covers approximately 30 000 substances manufactured or imported into Europe in quantities of 1 tonne or more a year. These chemicals are part of our daily lives, being used in the manufacture of cosmetics, clothing, computers and other consumer goods. Chemicals contribute to European economic prosperity in terms of trade and jobs. The European chemical industry had an estimated turnover of 556 billion euros for the EU-25 in 2003, and the chemical sector employs 1.7 million people[3].

There are a hundred thousand different chemicals listed on the Community market, some of which can be harmful to human health or the environment.

Article 1.3 of the REACH proposal says that "this Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle"[4].

Furthermore, the States at the September 2002 Johannesburg World Summit on sustainable development pledged that by 2020, chemicals would be used and produced in such a way as to minimise the harm to human health and the environment.

[1] The declarations adopted by the Executive Committees of 17-18 March and 1 December 2004 are downloadable from www.etui-rehs.org/hesa > Main topics > Chemicals.
[2] Also downloadable from www.etui-rehs/hesa > Main topics > Chemicals.
[3] *Facts and Figures, The European chemical industry in a worldwide perspective*, CEFIC, June 2004, updated in July 2005. See: www.cefic.org/factsandfigures.
[4] The text of the REACH proposal can be downloaded from: http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0644en.html.

ETUC proposals on the duty of care

The European trade unions expect manufacturers, importers and downstream users to comply with article 1.3 and the Johannesburg pledges. But they believe that the text should clarify the responsibility of manufacturers and importers by reintroducing a general duty of care for all chemicals.

This is because manufacturers and importers must be responsible for documenting and communicating in an appropriate way all relevant safety information to downstream users and consumers. This principle would apply to all chemicals regardless of production volume, which means industry not only fulfilling its REACH obligations, but also shouldering the basic social, economic and environmental responsibilities that go with entrepreneurship.

There is a clear need for extra information and training for workers and their representatives on the risks and appropriate use of the substances they handle. That requires better communication on health and environmental protection between workers and their employers, and throughout the supply chain. That communication needs to be organised between trade unions and employers' organisations, and then spread through companies. The chemical industry's Responsible Care programmes are a good benchmark (see article page 36).

Registration

The REACH system requires chemical manufacturers and importers to submit a registration dossier for all substances produced or imported in quantities of 1 tonne or more a year, containing the information necessary for them to be used safely. Without a registration dossier, the 30 000 substances covered by the reform will not be able to be manufactured or imported on Community territory.

The timetable for registration is phased over 11 years. Substances produced or imported in quantities of 1 000 tonnes or more a year (tpa), and CMR substances (carcinogens, mutagens and toxic for reproduction) from 1 tpa, will have to be registered the first, i.e., during the first three years after REACH comes into force. Substances between 100 and 1 000 tpa will have six years in which to be registered, and those between 10 and 100 and 1 and 10 tpa up to 11 years after the rules come into force.

The ETUC supports the volume-based approach

The ETUC strongly supports the volume-based prioritisation system proposed in the Commission's October 2003 text. It is a clear, objectively measurable criterion that gives firms the legal certainty it needs to easily programme their REACH obligations.

The approach has also been fine-tuned, as the legislation proposes that CMR substances – classified as extremely dangerous – be included in the first wave of registrations.

European trade unions believe that introducing risk-based prioritisation criteria into the registration phase, as the industry and some Member States[5] want, would doom the reform to failure because it requires risk and exposure data that are currently lacking for too great a number of substances, but which the REACH system itself is meant to generate. The upshot would be to perpetuate the failings of the current legislation, and allow substances to continue circulating on the market with no idea of their impacts on human health or the environment, and keeping the burden of proof on the public authorities instead of shifting it to producers as the REACH reform plans to do.

The ETUC supports the OSOR proposal

Approximately 30 000 substances will have to be registered under REACH. Some of these are manufactured or imported by more than one company, so there could potentially be more than one registration dossier per substance.

The ad hoc working group on REACH set up by the Council of the European Union is currently examining the Anglo-Hungarian OSOR (One Substance – One Registration)

[5] See the European Chemical Industry Council's (CEFIC) proposals: www.cefic.org. The governments of Malta and Slovenia recently put forward a joint proposal for to prioritize registration for substances between 1 and 10 tpa.

proposal. This would require manufacturers of the same substance to share all the data they hold and work out an arrangement for sharing the cost so as to submit a single registration dossier.

The ETUC supports this proposal as aiming to cut the costs to industry and the national authorities of implementing REACH. But the ETUC will maintain its support for OSOR when the practical details are known only if the legal liability of manufacturers, importers and downstream users remains intact. That would ensure that the responsibility of individual manufacturers is not diluted when submitting a joint dossier.

The ETUC proposes that a chemical safety report be required for all substances registered

An application to register a substance must always be accompanied by a technical dossier which includes information on the identity, properties or classification of the substance. But it does not require a chemical safety report, which is only required for substances from 10 tpa upwards.

That means that there will be no chemical safety report for 20 000 of the 30 000 substances registered under REACH (see table).

Obligation to produce registration dossiers

		Registration dossiers	
Volumes (tpa)	Number of substances	Technical dossier	Chemical safety report
1 – 10	20 000	yes	no
10 – 100	4 600	yes	yes
100 – 1 000	2 800	yes	yes
> 1 000	2 600	yes	yes

The good thing about the chemical safety report is that it has to include exposure scenarios for substances that are classified as dangerous, PBT or vPvB[6]. The exposure scenario describes the risk management measures necessary for safe use in each identified use of the substance, and must be annexed to the safety data sheet supplied to all downstream users of the substance.

The ETUC thinks the obligation to produce a chemical safety report should be extended to the 20 000 substances between 1 and 10 tpa.

There are three reasons why:

- It would improve the safety data sheets of a much greater number of substances by adding relevant risk management information to them;
- The extra costs of the measure would add only marginally to the total costs of registration[7]. Given the likely additional health and safety benefits to workers and consumers, this measure is definitely a paying proposition;
- It would help increase coherency and the synergies between REACH and existing worker protection legislation, because Chemicals Directive 98/24/EC requires employers to assess the risks to their workers of all dangerous substances present in the workplace regardless of the volume used.

It makes good sense, therefore, for the REACH chemical safety report to apply to all substances covered by the reform, not just those above 10 tpa. Especially so since, far from being a duplication of work, the REACH chemical safety report and the Directive 98/24/EC risk assessment have different scopes but can dovetail with and inform one another[8].

The ETUC wants an extra information requirement for substances between 1 and 10 tpa

The technical dossier for substances between 1 and 10 tpa must fulfil the requirements of Annex V of the Commission proposal. This means supplying data on 14 physico-chemical properties of the substance, and five basic toxicological tests[9].

The ETUC suggests that the information required by Annex V be expanded to include an acute toxicity test and a biodegradability test.

[6] PBT: persistent, bioaccumulative and toxic substances; vPvB: very persistent very bioaccumulative substances, i.e., toxic substances that may accumulate irreversibly in the body or the environment.

[7] Ackerman, F. and Massey, R., *The true costs of REACH*, TemaNord 2004:557, Nordic Council of Ministers, Copenhagen, 2004. See: www.norden.org/pub/miljo/miljo/sk/TN2004557.pdf.

[8] See the article on the relations between REACH and worker protection legislation, page 15.

[9] Skin and eye irritation, skin sensitization, bacterial mutation and short-term toxicity on Daphnia (crustaceans).

An acute toxicity test is a basic toxicological test which indicates the lethal concentration of the substance when accidentally swallowed or inhaled. This information is essential to ensure the proper classification and labelling of the 20 000 substances concerned, and so improve protection for the workers who use them.

The biodegradability test is a basic ecotoxicological test which more clearly identifies aquatic environmental hazards.

These extra tests, which would be made Annex V requirements, should not place an undue cost burden on industry because this information is already supposed to exist for very many substances. The chemical industry, in fact, has already committed to carrying out toxicological tests through voluntary agreements entered into under the Responsible Care programmes[10].

Evaluation

The evaluation procedure allows the competent authorities in each Member State to scrutinize the registration dossiers drawn up by manufacturers or importers.

Two types of evaluation are proposed: substance evaluation and dossier evaluation.

- **Substance evaluation: the authorities can require the industry to provide more information in order to clarify suspected risks that certain substances may present to human health and the environment. A system is provided whereby the competent authorities of Member States can split the work by distributing the substances for evaluation. The agency will develop risk-based criteria to determine in which order these substances will be evaluated. Substance evaluation can result in measures under the authorisation or restriction procedure.**
- **Dossier evaluation: the purpose of this is to check the quality of registration dossiers. There is a difference between the examination of testing proposals (article 39) and the compliance checking of registration dossiers (article 40).**

Under article 39, the competent authority has to give a decision on testing proposals made by the manufacturer or importer so as to avoid purposeless animal tests.

Article 40 allows but does not oblige the competent authorities to check whether a registration complies with the requirements of the regulation and its annexes.

The ETUC wants mandatory compliance checking for a minimum number of randomly selected dossiers

The ETUC makes the case that if article 40 is left optional, the aim of quality checking dossiers will not be fully delivered. A Member State could very well not take up the option for many reasons (understaffing, other priorities, etc), so that dossiers could go through without meeting all the regulation requirements or with poor quality information.

Looking at what is workable given the workload involved in checking, the ETUC suggests that the competent authorities in each Member State should have an obligation to spot check a minimum number (e.g., 5%) of dossiers.

This would mean that all registration dossiers were open to compliance checking, without adding too much red tape. This would be an incentive to all manufacturers and importers to submit good quality, compliant dossiers that contained the information needed to ensure a high level of protection of human health and the environment.

[10] For the voluntary agreements contracted by the chemical industry under Responsible Care programmes: www.responsiblecare.org.

Authorisation

Each use and placing on the market of substances of very high concern (CMR, PBT, vPvB, etc.) must be authorized by the Commission whatever their production volume. To get an authorisation, the applicant must show that the risks related to the use of the substance "are adequately controlled". But even if he cannot, an authorisation may still be granted if the applicant can show that the risks are outweighed by socio-economic benefits and there are no suitable alternative substances or technologies. An authorisation granted on socio-economic grounds will be limited in time.

The substance as such, or as used in a preparation or an article, may also be subject to a Community-wide restriction if it is shown that the risks are unacceptable to human health or the environment.

The ETUC wants to strengthen the application of the substitution principle in the authorisation phase

The ETUC argues that the authorization procedure should aim to promote substitution of the most dangerous chemicals, as required by European carcinogens legislation (Directive 2004/37/EC).

As the Commission proposal stands, an authorisation can be granted provided it is shown that the risks are adequately controlled, even where a safer alternative is available. This does not work in favour of eliminating the most dangerous substances.

The ETUC proposes that an authorisation should be granted only:
- if it can be shown that adequate alternative substances do not exist;
- if the socio-economic benefits outweigh the risks to human health or the environment;
- if the use of the substance is adequately controlled.

The ETUC wants all authorisations to be time-limited

There is at present no time-limit on the authorisations that can be granted under REACH where the risks are adequately controlled. Only authorisations issued on socio-economic grounds can be reviewed. The ETUC wants all authorisations to be time-limited in order to promote the development of substitution plans.

The ETUC wants to extend the list of substances subject to authorisation

Not just CMR, PBT and vPvB substances, but also those with similar properties, like endocrine disruptors, can require authorisation. The ETUC wants the list extended to include substances with highly sensitising properties that can also cause serious and irreversible effects in humans or the environment.

Downstream users and SMEs

REACH defines downstream users as, "Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities".

Distributors (who store chemical substances or preparations before placing them on the market) and consumers are not regarded as downstream users. Downstream users of chemicals, therefore, would be such things as formulators or industrial users of chemicals found across a wide range of sectors of industry, like construction, carmaking, textiles, etc.

The REACH system requires downstream users to assess the safety of their uses of chemicals in light of the information communicated by their suppliers, and to take appropriate risk management measures. Specifically, they must satisfy themselves that the safety data sheet accompanying the substance supplied covers their intended uses of it.

If it does, they must implement all the relevant risk management measures set out in the safety data sheet. If not (i.e., if the intended use of the substance is not covered by the manufacturer or importer's safety data sheet), the downstream user can either:

- **inform his supplier of his intended use of the substance. The supplier will then be able to undertake a chemical safety assessment and add appropriate risk management measures covering the "identified" use to the safety data sheet;**
- **keep the use of the substance confidential. In that case, he must himself prepare the chemical safety report and implement the measures resulting from it.**

The ETUC wants steps taken to inform SMEs of their obligations before REACH comes into force

There is great confusion surrounding the real obligations of the different actors in the REACH system. These obligations differ widely according to where the company stands in the supply chain. Downstream users, for example, have no obligation to register the substances they use (see above). Substances only have to be registered by their manufacturers or importers. The confusion stems from the fact that many manufacturers and importers, as well as by far most downstream users, are SMEs, and their REACH obligations are lumped together with the costs of it.

The ETUC therefore calls for a targeted information campaign to be run by the Member States and the Commission to inform SMEs of their real obligations. The early setting-up of help and information services on REACH in each Member State would be welcome.

The ETUC wants help for SMEs in fulfilling their REACH obligations

SMEs have more limited human and financial resources than large companies, and so will probably have more difficulties in implementing the reform. The ETUC calls on the Commission to take account of the specific characteristics of SMEs when drawing up the technical guidelines intended to help the different actors in the supply chain to fulfil their REACH obligations (see the different RIPs projects). It also calls on the different European industry associations to prepare their members before the reform takes effect, in particular by looking at an industry cost-sharing arrangement.

Links between REACH and worker protection legislation

There are two distinct bodies of European chemicals legislation: one covering the marketing of chemicals, and one protecting the workers who use them. REACH is concerned with the first of these. When it comes into force, it will bring changes to existing legislation on trade in chemicals. But REACH will also have positive spin-offs for worker protection legislation, which will continue to apply alongside the commercial legislation (see article page 15).

The ETUC's proposals

Particular attention should be paid to ensuring that the obligations laid down in the REACH system are consistent with those of the occupational safety and health directives.

A dialogue should be held on this issue between the social partners. This could be held in the tripartite Luxembourg Advisory Committee on Safety and Health at Work. The outcomes of the London workshop staged in June 2004 by the British, German, Dutch and Swedish governments would be a good starting point. Similarly, this should be the subject of social dialogue at sectoral level.

To avoid inconsistencies and increase synergies between both pieces of legislation, worker representatives should be consulted on framing practical guidelines to help industries comply with the REACH regulation. ■