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EU CHEMICALS POLICY

New chemicals marketed in the EU have to undergo stringent safety assessments to evaluate their potential health and environmental impacts. The majority of chemicals that have been on the market for some time ("existing chemicals") have not undergone such strict assessments. New proposals (REACH - Registration, Evaluation and Authorisation of CHemicals) currently before the European Parliament are designed to eliminate the differences between existing and new chemicals, and to address concerns over the potential effects of chemical exposure on human health and the environment. This briefing describes the proposals and examines issues such as the likely impact of REACH on competitiveness, world trade and animal welfare.

Background

Assessing new chemicals

Since September 1981, all new substances marketed in the EU at volumes of 10 kg per year or more must first be assessed and tested for potential risks to human health and the environment.[1] Around 3,000 substances have been registered since this date. Over 100,000 existing substances were already on the market in 1981, and these were registered on a closed European Inventory of Existing Commercial Substances (EINECS) (see box 1). Despite the fact that existing substances account for more than 99% of the total volume on the market, they are not currently subject to the same level of testing as new substances, and in some cases little test data on their impacts is available. The new REACH proposals are designed to rectify this situation. The proposals are subject to a co-decision process between the European Parliament and Council, which could take up to two years, with possible implementation of REACH in 2006.

The REACH proposals for existing chemicals

Registration

REACH requires all chemicals manufactured in or imported into the EU in a volume of 1 tonne or more per year to be registered with the competent authority within a new European Chemicals Agency (ECA). The ECA will manage a central, EU-wide database. Companies will have to submit basic information including a brief description of the uses of the substance and any uses that the manufacturer advises against, a technical dossier of test data and future testing proposals. Data requirements vary according to the production volume and suspected toxicity of the substance. Registration will be undertaken in several stages, with deadlines varying with production volumes:

- Substances supplied in excess of 1,000 tonnes a year and some substances of high concern (box 2) will be registered within 3 years of the law coming into force;
- those in excess of 100 tonnes within 6 years;
- those in excess of 1 tonne and 10 tonnes within 11 years (these categories must be registered within the same timeframe but have different data requirements).

Evaluation

Each member state will be responsible for evaluating substances registered with the ECA by companies within its borders. Two types of evaluation are proposed:

Box 1 What chemicals does REACH apply to?

The REACH Proposals potentially apply to all chemicals, including those registered on the EINECS inventory. The EINECS list contains substances such as cement and metals, and REACH will apply to these as well as chemicals. Companies will be required to register all substances produced or imported in volumes of 1 tonne or more per year. However, certain chemicals are exempted from the proposals; these include polymers (e.g. plastics), intermediates in chemical processes that never leave the factory, pharmaceuticals and foods. Each individual use of a chemical has to be registered; if a company wishes to employ a chemical for an unregistered use the registration dossier must be updated to reflect this. Final preparations do not have to be registered under the REACH proposals. Thus the individual components (solvent, dyes, etc.) of a household cleaner may each have to be registered, but not the household cleaner itself.

- Dossier evaluation – all registrations that propose further animal tests will be evaluated to ensure that such tests are strictly necessary. The evaluation process checks if test data for the substance in question are already available, and whether alternative tests could be employed to prevent unnecessary animal testing.
- Substance evaluation – carried out if a competent authority suspects that a substance poses a risk to human health or the environment (for example because of its structural similarity to a known dangerous substance). This involves examining the dossiers of all registrations for a substance to clarify the risks, and may result in the authority requesting further information from those registering the substance.

Authorisation, substitution and restriction
Substances identified through registration and/or evaluation as being of high concern (see box 2) will be subject to **authorisation**. Without authorisation, these substances cannot be used or placed on the market. Authorisation will be granted (one for each use and user) if the risks associated with a substance can be proved by industry to be "adequately controlled". It may also be granted if the socio-economic benefits of continued use are considered to outweigh the risks. This type of decision may take into account whether industry is actively researching to find an alternative **substitute**. Authorisations granted for socio-economic reasons will be time-limited and reviewed on a case-by-case basis. The use of other substances that pose unacceptable risks, but are not classified as of high concern, could be **restricted** if requested by a member state. Restriction may ban use in certain products, by consumers, or even any use at all.

Overview
Of the 100,000 existing chemicals on the EINECS database, the European Commission estimates that around 30,000 are used in sufficiently high volume (1 tonne or more per year) to require registration. Most of these (20,000 or so) are used in volumes of 1 to 10 tonnes per year, and the data requirement for these will be lower than that for higher volumes. Overall, the Commission suggests that around 1 in 5 of the substances registered will need to be evaluated (around 6,000) and that some 1,500 of these may require authorisation.

Issues

The registration process

Prioritisation
Prioritisation of substances for registration is a contentious issue. Some regard the proposed system, where production volume is used as an approximation for exposure, and therefore risk, as the most simple route available. Industry would prefer a risk-based approach, where the intrinsic hazard of the substance and levels of exposure to humans and the environment are taken into account. The Chemical Industries Association (CIA) suggests that substances with exposure levels and hazards of low concern should be exempt from registration.

Box 2 Substances of high concern
Substances identified as being of high concern include:
- Cancer-causing chemicals (carcinogens)
- Chemicals that cause mutations (mutagens)
- Those that harm reproduction (reprotoxins)
- Persistent, bioaccumulative and toxic substances (PBT)
- Very persistent, very bioaccumulative substances (vPvB)
- Substances which cause serious and irreversible effects to humans or the environment of equivalent concern to those mentioned above. This class may include substances found to have endocrine disrupting properties. This class will be assessed on a case-by-case basis.

Environmental NGOs such as WWF do not agree with a risk-based approach, citing the potential for unforeseen risks. Such groups suggest that a risk-based system may not be robust (because existing data on many substances are sparse), may be more labour intensive for the regulatory authorities, and open to challenge if apparently similar chemicals were prioritised differently. They argue that while a volume-based approach is far from ideal, it is less open to confusion and may at least be considered to approximate the highest exposure risk.

The House of Commons Science and Technology Select Committee has suggested introducing a pre-registration process for highly toxic, low-production volume chemicals, to allow such substances to be dealt with quickly.[2] However, industry is concerned that products prioritised on the basis of limited data and subsequently "cleared" by further testing may be permanently affected by the negative publicity.

Data sharing and consortia
The proposals encourage (but do not compel) companies that manufacture or import the same substance to form a consortium for registration of that substance. The commission sees the advantages of consortia as being:
- minimising animal testing
- reducing costs by sharing between several companies
- maximising sharing of existing data
- reducing the workload for industry and the authorities
- Increasing the speed of decisions
- creating a level playing field

However, sharing data within consortia may have implications for intellectual property rights. For instance, companies may be reluctant to join consortia if it means revealing proprietary details of, for example, a manufacturing process that has not been patented.

Volume-based registration may discourage smaller producers from joining consortia involving larger-scale producers, as the presence of the latter would bring forward the deadline for registration. Smaller companies may prefer to wait "on the sidelines" until their registration deadline, leading to unnecessary duplication of some test data. There is also concern within industry over cost sharing within consortia and the issue of "free riders" – those joining a consortium after test data have been collected and submitted at the others' expense.

The UK government is currently promoting the idea of "one substance-one registration". This approach is

designed to reduce the duplication of testing and share the costs of registration between all companies that produce or import the same substance. Industry and environmental NGOs such as WWF both support this idea in principle. However, while WWF support mandatory consortium formation, the CIA and the British Association of Chemical Specialities (BACS) disagree. The government proposes the creation of one databank per substance registered, with mandatory sharing of core data, but not of information on the use of a substance. Industry regards the details of what data will be shared as an important factor in the feasibility of the proposals.

Evaluation

As member states are responsible for carrying out evaluations, there is concern that there will be inconsistencies in the evaluation process from one member state to another. It has been suggested that all member states should be required to carry out a minimum number of evaluations at each stage of the process to ensure a harmonised approach across the EU.

Authorisation, substitution and restriction

Authorisation and restriction

Terms such as "adequate control" and "socio-economic benefit" that the proposals use to determine whether an authorisation will be granted are hard to define. This could result in disagreements, particularly when two similar substances undergo evaluation with different outcomes. Restriction further complicates the issue, with confusion over which process is most appropriate.

Mandatory substitution

WWF supports mandatory substitution, where authorisation will not be granted if an alternative, less harmful substance is available. It believes that this approach has the potential to be a driving force for innovation in the development of new chemicals. The CIA believes that substitution should not be mandatory, as it is a complicated process (see box 3) and market forces drive voluntarily substitution where available. This suggestion is contested by WWF.

Box 3 Potential effects of substitution

Many commercial products such as printing inks contain a mixture of substances, possibly up to 60 individual chemicals in one formulation. Preparation of these chemicals may involve the use of several hundred other substances in upstream processes. If one of these substances is withdrawn as a result of REACH, the potential costs of reformulation are high. For example, the British Coatings Federation estimates that the withdrawal of a substance that necessitated reformulation of the resin that binds an aircraft topcoat to a coat of primer would result in:

- ~4 person years work on reformulation and testing for the coatings manufacturer;
- ~1.2 person years on assessment and production for the aircraft component manufacturer;
- ~2.5 person years on assessment and monitoring for the aircraft constructor;
- ~1.2 person years on assessment and retraining for airlines in repainting.

This totals almost 9 person years of work to compensate for a single application of the withdrawn substance.[3]

Economic withdrawals

An area of concern for downstream user (DSU) groups is the prospect of substances being withdrawn from the market for economic rather than safety reasons. If a producer considers the costs of REACH to outweigh the profit from manufacture of a substance, production may cease. This type of withdrawal has been noted after the introduction of the Biocidal Products Directive, with around 60% of these products coming off the market.

Substances in articles

Some of the chemicals contained in an "article" (a product) may be harmful to the environment or health. If such a substance is intentionally released as part of the function of an article, such as ink in a printer cartridge, it may have to be registered. If release is unintended, but occurs anyway, the Agency must be notified and will decide whether registration is required. Enforcement of this area of REACH is viewed as potentially difficult. For instance, the number of articles imported into the EU and the chemicals they contain are unknown. It has been suggested that initial enforcement efforts concentrate on articles that contain substances of high concern.

Box 4 The cost of REACH

The Commission estimates the direct costs of testing and registration under REACH as € 2.3 billion over 11 years, which represents less than 0.1% of the annual turnover of the EU chemicals industry. A report by the Institute for Environment and Health (IEH) suggests that the costs may be closer to € 8.7 billion.[4] Costs to downstream users, from increased prices of chemicals and substitution costs, are estimated by the Commission as between € 2.8 – 5.2 billion. Whereas the likely direct costs can be calculated from data requirements and fees payable, it is difficult to estimate the costs to downstream users.

As the figures below illustrate, REACH testing costs are lower for small volumes, but place a disproportionate burden on small producers in terms of cost per tonne.

Approximate cost of REACH per chemical over 10 years:[4]

Volume (tonnes)	Test costs	Cost / tonne (over 10 yrs)
1	£20,000	£2,000
<10	£20,000	≥ £200
<100	£80,000	≥ £80
<1000	£100,000	≥ £10
>1000	£150,000	< £15

Economic impact of REACH

Competitiveness

As outlined earlier, industry is particularly concerned that information submitted does not compromise confidential data. Another factor is the potential increased cost of chemicals, which it suggests could threaten the competitiveness both of the EU chemical industry (see box 4) and of the manufacturing industry as downstream users.

Speciality chemicals

The European Chemical Industry Council (CEFIC) estimates that 20% of the chemical industry will carry 80% of the costs of REACH, mainly companies (often SMEs) working on fine (high quality) and speciality chemicals at relatively low production volumes. These companies employ around 430,000 people across the EU, with ~16% of the sector located in the UK.

Innovation
REACH is envisaged by the Commission as a means of stimulating innovation in the chemical industry, through the development of alternative substances as substitutes. Industry believes that the opposite may happen, with increased use of high production volume chemicals, which have lower relative costs due to REACH (box 4). It is concerned that innovation may focus on new uses of existing chemicals instead of developing new substances.

Migration of manufacture and international trade
For any substance or article manufactured within the EU, all chemicals involved in the production process must have gone through REACH. The same item imported from outside the EU will only require the final product to be included in the REACH process, reducing the overall cost of the process for the imported product. This may lead to the migration of manufacturing to countries outside the EU. It is also important that any legislation introduced does not conflict with WTO obligations. .

Availability of information
How, and to what extent, the information gathered by REACH is made available to the public is a matter of debate. Extra labelling on products is one option. Retailers believe that consumers do not generally want to take decisions based on the potential hazards of a product, but would rather rely on the retailer to work in their best interests. Data may be made available on the internet, where they can be accessed by anyone. REACH classifies most information in one of two categories: non-confidential or confidential. While WWF argues for access to as much information as possible, BACS is concerned that the information classified as non-confidential should be restricted to essential items.

Health and environment
The Commission estimates the potential health benefits of REACH could amount to € 50 billion over 30 years, assuming a 10% reduction in diseases caused by chemicals, equivalent to avoiding 4,500 premature deaths a year. Another estimate is that a reduction of18-37 work-related deaths a year would balance out the cost of implementing REACH in the UK.[5] The environmental benefits of REACH are difficult to quantify but the process has the potential to identify substances that may be hazardous to the environment and to limit their use.

Animal Testing
Animal testing can be expensive and time-consuming. Estimates of the number of animals needed to cover the testing requirements of REACH vary widely. A worst-case EU-wide estimate by the IEH is 12.8 million, if all substances have to go through the full testing procedure.[6] This may over-estimate the number of animals, since testing requirements for low production volume substances have subsequently been reduced. The Commission supports the idea of alternative testing methods, but development and validation of these methods can be a slow process, and many are unlikely to be in place in time for the implementation of REACH.

The role of the European Chemicals Agency (ECA)
The Commission has proposed that a new organization, the ECA, is created to manage REACH at Community level, funded by income from REACH fees. Its main responsibilities will be:
- managing the registration process
- co-ordinating evaluation
- guiding Member State "Competent Authorities"
- providing recommendations for the authorisation and restriction procedures

Some groups suggest that the ECA should have greater responsibility and accountability, acting in a stronger role than currently suggested. The CIA believes that the ECA should play a major role in ensuring harmonised enforcement of REACH across the EU, by "sub-contracting" work to Member State Competent Authorities.

UK Competent Authority
Existing responsibility for chemicals legislation is mainly held by Defra and the HSE, as current chemicals policy is, to some extent, directed towards chemicals in the workplace. REACH focuses more on environmental and general health aspects, so a shift of responsibility may occur. Options for the UK may include: **shared responsibility** between authorities currently involved in chemicals regulation, for example the EA and the HSE; **one authority as a host**, outsourcing duties to other organisations; or, establishing **an entirely new organisation** (such an authority would have a greatly reduced workload after the initial implementation phase). The role of any competent authority will depend on the final definition of member state responsibilities.

Overview
The REACH proposals are widely accepted in principle, but there are many details still to be negotiated. Key areas of concern include: **prioritisation** – whether this should be volume or risk-based, or some mixture of the two; **consortia formation and data sharing**; and the potential **economic** and **animal welfare** impacts.

Endnotes
1 Directive EC 67/548
2 Commons Science and Technology Committee *Within REACH: the EU's new chemicals strategy* Sixth Report, Session 2003-04
3 www.coatings.org.uk
4 Figures from UK Partial Regulatory Impact Assessment, (page A22) prepared by ERM for DEFRA, March 2004
5 *UK Consultation Paper on the New EU Chemicals Strategy,* DEFRA, April 2004
6 *Testing Requirements for Proposals under the EC White Paper 'Strategy for a Future Chemicals Policy'* (Web Report W6), IEH, Leicester, UK, July 2001, (www.le.ac.uk/ieh/webpub/webpub.html)

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