

# Environmental Policy and Procedures Special Report

# CRONER

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THE PROFESSIONAL'S FIRST CHOICE

## ■ Registration, Evaluation and Authorisation of Chemicals

The Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation is one of the most extensive and complicated pieces of chemical legislation ever attempted by the European Union (EU). Negotiations on the REACH dossier are now in the latter stages. The UK Government, with its Presidency of the EU in the second half of 2005, is trying to conclude political agreement on the dossier within its EU Presidency in November 2005. The European Parliament has nine committees considering the draft proposed regulation and, in September 2005, they passed their first votes on compromise amendments. Over 5000 amendments have been tabled by individual MEPs. It is anticipated that the European Parliament will consider REACH in plenary session in 2005, and if these ambitious timetables are met, the regulation could take effect as early as 2006.

REACH would make manufacturers, importers and suppliers of substances responsible for ensuring that the substances do not adversely affect human health and the environment. The manufacture, importation or downstream use of "substances", which are widely defined, would require registration. REACH also sets out a system of evaluation of substances. Finally, substances or preparations containing substances of concern which are carcinogenic, mutagenic or reprotoxic require a more demanding authorisation of chemicals.

It is important to note that the proposed REACH Regulation imposes obligations not only on manufacturers and importers but on "downstream users". In practice, it is the downstream users who are likely to be least well informed about the new legislation. Restrictions will be placed upon the manufacturing, marketing and use of certain dangerous substances and preparations. REACH will, in addition, revise, overtake and repeal much of the existing EU law in this area. □



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# Registration, Evaluation and Authorisation of Chemicals

## Strengths and weaknesses

Regulators around the world have struggled to find a rational and workable formula for the regulation of chemical manufacture and use. For example, the "Delaney clause" of the US Food, Drug and Cosmetic Act used to require that no substance "found to cause cancer" should be added to the food supply. But this "zero risk goal" was found to be difficult or impossible to apply in practice. It had the effect of banning the setting of tolerance levels for many substances.

In 1996, the US Congress passed the Food Quality Protection Act. This replaced the Delaney clause with a health-based risk assessment for pesticide residues in food, and required the US Environmental Protection Agency to make findings that particular pesticide residues were "safe" before being allowed, and to find that there must be a "reasonable certainty that no harm will result from aggregate exposure to the pesticide". These tests are easier to formulate than to apply. In legislative terms this equated to no more than a one in a million lifetime risk of cancer. The Environmental Protection Agency was even required to make a specific finding that pesticide residues were safe for infants and children.

The 1996 law required the Environmental Protection Agency to reassess 9700 tolerances within 10 years, and given the true scale of the legislative task as stated, it immediately struggled to meet its requirements. It set wide margins for safety that were instantly attacked by pesticides producers as causing unnecessary loss of products critical to farmers and other users, and the Agency was urged to base its tolerances on "sound scientific data".

All systems of regulation which set regulators the near impossible task of assessing vast numbers of substances against extremely difficult legislative criteria without wholly exceptional levels of highly qualified staff and resources risk failure.

The greatest strength of REACH is the fundamental shift of "producer responsibility" that it entails, requiring manufacturers, importers and downstream users of chemicals — substances — to take primary responsibility for assessing the effects on public health and the environment, of that which they place on the market. This simple idea is nevertheless revolutionary in terms of chemicals regulation.

Until now, although new chemical substances have been subject to regulation (Directive 67/548/EC on the Classification, Packaging and Labelling of Dangerous Substances), and the most toxic substances subject to restrictions on marketing and use (Directive 76/769/EEC



Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations), existing EU chemicals legislation is at best cumbersome and at worst ineffective. As many as 30,000 existing chemicals escape fully effective regulation.

One of the objects behind the new EU REACH chemicals regulation is to establish producer responsibility among manufacturers, importers and downstream users for the chemicals which they place on the market. They, and not the regulators, will have to assume primary responsibility for the assessment of what they place on the market.

The greatest potential weakness of REACH is the width of its scope. The EU regularly enacts subject-specific directives with a narrow scope, which are negotiated by one or two technical experts from each Member State and applied without much difficulty once enacted. It is far less successful when it seeks to apply common tests and common standards across the board to an extremely wide range of materials.

Large numbers of industries become involved, all pointing out how the proposal does not work for them, what its consequences will be, and arguing for changes. Officials negotiating the text within the Council of Ministers either knock corners off the Commission's original proposals, or become stubborn and defiant about their consequences to particular industries in their determination to "finish the job". Members of the European Parliament, which since the Amsterdam Treaty have powers of "co-decision" with the Council of Ministers on most environmental measures in the EU, are subject to similar countervailing pressures.

Consider the scope of the REACH Regulation. It encompasses both the 3000 "new" and the 30,000 "existing" substances. It applies to organic chemicals, as originally envisaged. But it also covers inorganic materials such as ores, concentrates, metals, minerals, coal, crude oil, petroleum gas, cement — most of the industrial feedstocks and raw materials of the majority of industries within the EU. It includes, at least as drafted by the European Commission text at 29 October 2003, bread, olive oil, and public water supplies containing chemicals — or if it does not do so, then specific amendments to ensure that result will be required. Just how likely is it that a sound system of regulation can be

devised and applied in one regulatory instrument to such a variety of substances, preparations, articles, products and industries without all manner of unexpected outcomes, uneven costs, market distortions, industrial impacts and regulatory surprises?

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## Background

REACH had its origins in the February 2001 European Commission (EC) White Paper, entitled *Strategy for a Future Chemicals Policy*. This set out the aims of the reform of current EU chemicals legislation as being:

- protection of human health and the environment
- maintenance and enhancement of the competitiveness of the EU chemical industry
- prevention of fragmentation of the internal market
- increased transparency
- promotion of non-animal testing
- conformity with EU obligations under the World Trade Organization.

If further argument was required for the need for an overhaul of existing EU chemical legislation, it could be found in Directive 76/769/EC (Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations), which REACH will re-enact and repeal. It is difficult to apply and has numerous amendments and adaptations which are difficult to compile, let alone to keep track of and understand.

The EC's White Paper was followed in May 2003 by an Internet consultation process. This attracted more than 6000 contributors from a vast variety of fields with different points to make. The text of the regulation was substantially amended, and the draft

REACH Regulation presently under discussion was formally adopted by the European Commission on 29 October 2003. It is this text which is the subject of negotiations in the Council of Ministers and hectic activity before the European Parliament.

## Scope

As presently drafted, REACH goes far wider than a simple and straightforward application to the organic chemical industries, and catches within its scope large numbers of inorganic materials and substances and preparations, thereby affecting many industries that had little or no understanding that they were to be within the scope of what is still seen as a “chemicals” regulation.

A “substance” is defined in REACH (Article 3) as:

*“A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity derived from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.”*

A “preparation” is defined in REACH (Article 3) as:

*“A mixture or solution composed of two or more substances”.*

For example, in practice this means that, metallic alloys are regarded as “preparations”, regulated under the Dangerous Preparations Directive (99/45/EC) if one of the component parts is a “substance” which itself contains carcinogenic, mutagenic or reprotoxic (CMR) characteristics.

There are 30,000 types of alloys which are of great importance to a large number of EU industries. Many alloys contain CMRs if taken on their own, but producers and users of alloys insist that the substances are bonded in alloys in such a way as to constitute minimal risk of adverse effects on public health and the environment. Many metallic alloy products in every day use will be affected if the text is not amended.

This problem was in part recognised in the preamble to the Dangerous Preparations Directive itself, and the EC began the work of re-considering the appropriate classification of alloys. But the work was seen as too complex, and abandoned,

apparently on the assumption that it would all be “sorted out” by REACH itself. That has not yet happened. In a process which combines policy with inertia, the REACH Regulation is absorbing some very difficult interpretational issues that have been left unresolved in the EU chemicals regulation that preceded it. REACH is not in all respects a “clean sheet” and it does not resolve all the difficulties of its legislative predecessors.

## Structure

### Registration

Each manufacturer or importer of more than one tonne of a “substance” in the EU will have to register that substance and to provide detailed information on its risks and hazards, and uses and end-of-life characteristics.

Failure to register a substance will result in exclusion from the market, and this is therefore an obligation which cannot be ignored. Registration applications, under the text of the European Commission Regulation as presently tabled, will be made to the newly established European Chemicals Agency as the central receiving authority in the European Community.

Producers and importers of articles will also have to register substances which are contained in them if the substances as classified as dangerous, if they are intended to be released during normal and reasonably foreseeable conditions of use, and if they are present in quantities of one tonne or more per year.

### Evaluation

Each Member State of the EU will have to establish evaluation plans and authorities to consider dossiers of information on substances which will be submitted by applicants, and to be able to decide whether the information submitted is adequate or if the substance has characteristics for which further action is required.

### Authorisation

Substances of high concern, particularly those which are Category 1 and Category 2 carcinogens, will require authorisation for each use. Authorisation



is a major undertaking. It will only be granted where the registrant provides socio-economic data to show that the use is essential and that no satisfactory alternative exists. A review and/or a phase-out date will then be specified for the use of that substance. In some circumstances, Member States will be able to impose other restrictions on use.

The European Commission's aim with authorisation is to ensure that substances of very high concern are used in a way where the risks are adequately controlled, or that they are replaced by suitable alternative substances or technologies (a concept known as "substitution").

## The European Chemicals Agency

The European Chemicals Agency, based in Finland, will have a key role in the management of the REACH Regulation. The UK proposal has introduced changes to ensure that it is managed and run effectively. The UK proposes that the Agency management board allows one representative per Member State and sets the framework for the language regime of the Agency.

## Negotiating process and timetable

REACH is under very active negotiation at both the Council of Ministers and the European Parliament, with both institutions aiming to achieve political agreement as early as November 2005.

The European Parliament began its formal consideration of REACH at a public hearing on 19 January 2005. A number of committees of the European Parliament have been reviewing the regulation in detail. These include the committees on the environment, public health and food safety; on industry, research and energy; and on internal market and consumer protection. Rapporteurs from those committees have already produced separate reports, and several thousand amendments have been tabled.

The main three committees have now voted on compromise amendments covering several hundred of those originally tabled, and intensive work is being undertaken in assessing the effects of different

amendments and preparing for the plenary session of the Parliament. In addition, opinions will be given by the European Parliament committees on budget, economic and monetary affairs, employment and social affairs, women's rights and gender equality and international trade.

Many countries around the world, particularly those involved with primary production of raw materials and the export of ores concentrates metals and minerals have been extremely active in making representations to the EU institutions about the way in which the REACH regulation will affect their economies and markets.

In addition to papers and studies from major industrial countries such as the USA and Japan, primary materials producers in Latin America and Southern Africa have been among those making vigorous representations about the impact of REACH on primary materials production and therefore on their economies. For better or worse, the impacts of REACH are truly international.

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Shortly after launching its revised proposal for a regulation, the EC began to undertake a series of REACH implementation projects. The aim of these has been to develop guidance, methodology, and tools for industry and regulatory authorities. They have covered issues such as the guidance on chemical safety reports, guidance on information requirements and the information technology necessary to support the operation of REACH.

The Commission has also launched a Strategic Partnership on REACH Testing (SPORT). This project aimed to carry out a thorough test of the workability of the REACH proposal in practice, and brought in as observers or participants non-governmental organisations (NGOs), trades unions, large and small businesses and regulatory authorities.

In November 2004, a selection of companies started to simulate the registration and dossier evaluation

stages of REACH. A manufacturing or importing company led the work on each substance, and participants included Member State competent authorities and downstream users, with the EC simulating the work of the central Chemicals Agency. The European Chemicals Industry Council has claimed that, based on the findings of the SPORT report, REACH in its present form will not be workable unless significant adjustments are made.

SPORT carried out an assessment on the workability of the Commission proposal. This concluded that there were a number of points where further clarification in the legal text was needed. The *UK Presidency Compromise Text* claims to have addressed these issues. The UK 2005 compromise text will form the basis for the remaining negotiations within the Council of Ministers, at least up to the key meetings aiming to conclude those negotiations in November 2005.

Meanwhile and, in parallel, work continues within the key committees of the European Parliament towards the plenary votes of the European Parliament on the several thousand amendments tabled to the REACH text.

In addition to these implementation studies, publication of the European Commission's formal revised proposal in October 2003 was followed by something of a "battle of the impact assessments". As is not wholly unusual, these ranged from dire predictions of extensive economic damage and runaway costs in some industry sponsored studies, to the rose-tinted rival studies commissioned by environmental NGOs such as the WWF Detox campaign and announced under the headline "REACH costs too small to cause harm".

This disparity was part of the background to an extended impact assessment carried out by KPMG (an audit, tax, financial and risk advisory), commissioned by an industry consortium covering both the chemical and inorganic materials and products manufacturers, car manufacturers, flexible packaging manufacturers and USA and Japanese electronics manufacturers.

This study examined impacts on two car manufacturers, four inorganic producers, two converters and two printed circuit board assemblers. Publication of the study in April 2005 led to more

claims from all sides that it supported their arguments, but was taken by the European Commission as providing no "knock-down" arguments to their proceeding with the REACH dossier as originally envisaged.

The KPMG study is probably more useful to individual industry sectors than as a basis for assessment of the overall costs of implementing REACH, where estimates still vary widely. What is certain is that small-to-medium sized enterprises (SMEs) in particular, especially those unable to pass on increased regulatory costs to their customers, will find the procedural requirements of REACH and the time taken to navigate through it a genuinely heavy burden. This has been recognised to some extent in some of the amendments tabled in the European Parliament Committees.

It is also safe to assume that some of the major impacts of REACH, eg in exerting pressure on product substitution, or causing diversion of raw materials to other markets with less rigorous regulatory requirements, have not been fully assessed and will only become apparent in time.

## UK Presidency compromise on REACH text issued

The UK, as President of the EU, has been conducting negotiations within the Council of Ministers at a hectic pace during the second half of 2005 with a view to meeting the UK's objective of concluding political agreement on the REACH dossier by November 2005. With this in mind, the UK issued a paper, known as the *UK Initial Thoughts* document, and rapidly after it has tabled for discussion a full revision of the REACH text in September 2005 known as the *UK Presidency Compromise Text*, which purports to summarise and give effect to the intense debates carried on to date within the Council of Ministers.

### Scope

REACH applies to all substances manufactured and imported over one tonne. Some amendments have been made to seek to clarify exemptions to this scope. Exemptions have been proposed for waste and certain recycled materials. An exemption from registration has also been included for ores and ore



concentrates. At present, however, the UK text would still leave these materials subject to authorisation under REACH.

## Registration

Before the UK assumed the presidency of the EU, the UK and Hungary wanted to bring forward a simplified approach to the registration system in REACH known as “one substance, one registration” (OSOR). OSOR has now been included in the *UK Presidency Compromise Text* and will entail a proposal to require companies supplying the same substance to share and agree on parts of the registration dossier.

Registrants will be required to share animal and non-animal data on the tests carried out on their substances. It is intended that this will spread the costs of registration and minimise unnecessary animal testing. Provisions have been made to protect commercial confidentiality in particular cases.

Efforts have been made to reduce the impact of REACH on SMEs by reducing information requirements for low volume substances manufactured or imported in the 1–10 tonnes range.

The UK claims that the risk-based approach to REACH has been strengthened by proposals requiring that substances identified as potentially persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) based on existing classification criteria, should be registered in the first phase along with high tonnage substances and substances toxic to human health.

The UK states that this is limited to substances manufactured and imported over 100 tonnes, and would apply to about 100 to 200 substances in the first phase of registration.

## Substances in articles

One of the key issues that has to be addressed within REACH is how to tackle and regulate substances in articles. There will be little point in regulating the manufacture and import of substances on their own or in preparations, and disregarding manufactured articles made outside the EU which are then imported into the EU containing the same substances.

The UK’s compromise proposal claims only to require the registration of substances intended to be released from articles. Rather than additionally requiring the notification of substances likely to be released, which was considered unenforceable, a requirement has been introduced focusing on substances of very high concern.

EU producers and importers of articles would need to notify the authorities only if the article contains a substance of very high concern above a minimum concentration (regardless of whether or not it is intended to be released). A decision would then be made about whether a full registration needed to be submitted.

## Information in the supply chain

The UK 2001 White Paper states that in order to ensure that substances are used and handled safely, information on their hazards and risks needs to be passed up and down the supply chain. A new requirement has been introduced in the UK Presidency compromise of September 2005 for safety data sheets to be provided for substances that are PBT or vPvB. This, it is claimed, closes a potential loophole for providing information in the supply chain for these substances of very high concern.

## Evaluation

In the UK, compromise text proposals have been included to give the new European Chemicals Agency a more central role in the evaluation phase of REACH (under which registration dossiers will be examined and substances of potential concern identified for further examination).

The UK also recognises that the core scientific work on evaluation of substances would be carried out by Member States. However, responsibility for dossier evaluation has been transferred to the Agency. The UK proposes that a minimum number of compliance checks must be performed to maintain the credibility of the system. Priority for compliance checks will be given to dossiers where registrants cannot agree on a joint data package; where substances at 1–10 tonnes have been registered as low risk but the availability toxicity data is insufficient; or where there has been no other form of verification of the quality of the information contained in the registration dossier.

The UK envisages that substance evaluation will be carried out by Member State competent authorities based on a single EU-wide rolling plan for substance evaluation prepared by the Agency with input from Member States.

## Authorisation

REACH requires any proposed use of substances of very high concern to be subject to an authorisation process over time. These include CMRs, PBTs and vPvBs. The UK proposed compromise of September 2005 does not propose changes to the scope of the authorisation obligations. However, some changes have been proposed to Article 54 which aims to provide a catchall for substances of equivalent concern. This would allow substances on a case by case basis to come within the scope of registration where there is scientific evidence of probable serious effects to humans and the environment giving rise to an equivalent level of concern.

It is proposed that all authorisations be subject to a review. It is also proposed to allow authorisations to be reviewed at any time should a third party supply new information on possible substitutes to the Agency. These provisions will cause considerable practical problems for industry in achieving regulatory certainty and in knowing for how long they are able to rely on the authorisation once granted. In addition, the UK proposal touches on the issue of substitution.

The principle of substitution is relatively straightforward — it entails regulatory pressure to achieve the substitution over time of substances of concern by alternatives. The practice of substitution is in some cases much more difficult, eg where substitutes are not readily available, or where the

need for “institutionalised” substitution is disputed (where the substances are contained in preparations such as alloys in such a form as to constitute little or no practical risk to the public or the environment). Inevitably, this has been and continues to be one of the main hotly debated areas of the REACH proposal.

The UK proposes that the European Chemicals Agency will be funded primarily by fees and Community contributions, and the UK has introduced a new title to the REACH Regulation to clarify where and how fees may be charged by the Agency.

## Conclusions

At least one Member of the European Parliament has tabled an amendment proposing that REACH should be withdrawn. However, with both the Council of Ministers and the key European Parliament Committees now working towards some form of political agreement in 2005, it is more likely that the REACH Regulation will be enacted in something resembling its current form, although it may be amended in the closing stages of its negotiation.

If so, it will change the regulatory landscape for many companies going well beyond the organic chemicals sector, and including manufacturers, importers and downstream users in the inorganic sector and many other areas as well.

Not all of these have a clear idea of what is coming their way, and given the very wide impacts on many aspects of these businesses, more needs to be done to raise their awareness of this critically important legislation. □

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