REACH begins to see the light of day

Michael Warhurst, Senior EU Toxics Programme Officer at the WWF European Policy Office in Brussels, describes "REACH"—the most important legislation on chemistry to be introduced in the European Union

Introduction

On the 7th May 2003 the European Commission published a draft text of the new **R**EACH (**R**egistration, **E**valuation and **A**uthorisation of **CH**emicals) chemicals regulation. The text, amounting to around 1200 pages, was published on the internet for an 8-week consultation on workability, which ends on the 10th July: http://europa.eu.int/comm/environment/chemicals/whitepaper.htm

This consultation is the next stage of the European Union's (EU) long journey towards reforming the way chemicals are regulated in Europe. In the words of the Commission: *'The aims of the proposed new Regulation, which will replace 40 different pieces of current legislation, are to increase the protection of human health and the environment from exposure to chemicals while at the same time to maintain and enhance the competitiveness and innovative capability of the EU chemicals industry.'*

Most of the 1200 pages of the draft regulation are annexes, particularly a large annex on test methods and a smaller annex ensuring that substances that are already subject to marketing and use restrictions continue to be subject to the same restrictions—both of these annexes are very similar to current legislation. The heart of the new proposal is the Regulation itself, which is 66 pages long, with 117 articles. The intention is that the REACH regulation will lead to the repeal of a large amount of current legislation—the Regulation itself repeals 39 Directives and 2 Regulations!

The EU passes two types of law—directives and regulations. A Directive is not directly binding in the Member States, so Member State governments must write their own legislation to implement it. In contrast, a Regulation is binding in all Member States—it's proposed that the REACH legislation will be a regulation, therefore it will be binding on all 25 Member States of the enlarged European Union.

The Commission will gather the comments from the consultation, assess and agree any changes, then publish the regulation as a legislative proposal—it is predicted this publication could occur during October 2003. Once the legislative proposal is published, it will pass to Member State governments and the elected European Parliament, who will jointly finalise the legislation over a period of around 2 years, including two parliamentary readings. Parliament and Governments will have equal power over the final result, which will probably have to be finalised using a procedure called conciliation, a time-limited process that forces compromise.

The key elements of REACH

REACH is designed to be an integrated approach to the control of the production, import and use of chemicals in Europe. It intends to create a system which is based on information about chemicals, rather than ignorance, and which ensures that useful safety information flows down to those using chemicals. As mentioned in my earlier article,[1] the current regulatory system does not adequately fulfil these or many other requirements.

REACH can be thought of as fulfilling two key elements:

- it lays out the regulatory system that will be in place when it is fully implemented, when all chemicals on the market produced or imported at >1 tonne per annum are registered with safety data, and there is no longer a backlog of chemicals for which there is insufficient safety information.
- it describes the phased process to overcome the backlog of a lack of safety data on chemicals—including an 11-year period for registering safety information on chemicals.

REACH is complex, so this is only a brief description—the Commission has produced an explanatory note on the system which provides more details.[2]

Registration

One of the primary aims of the REACH system is to ensure there is sufficient information available on chemicals to enable their adequate control. The current regulatory system has required the notification of safety data on chemicals put on the market since 1981, as soon as more than 10 kg/y (per manufacturer—all tonnage thresholds are per importer or manufacturer, rather than cumulative totals for the substance) are produced. At the same time, those chemicals on the market since prior to 1981 (around 30,000 marketed at over 1 tonne per annum) have not had to have mandatory safety data. REACH proposes to change this:

- The threshold for registering new chemicals is increased from 10 kg to 1 tonne, with no animal testing required until 10 tonnes per annum are produced. This is a considerable deregulation over the current system.
- Substances used in process orientated research and development can be exempt from registration for 5 years, extendable for another 5 years in exceptional circumstances—this is a considerable deregulation from the current system.
- The existing—or 'phase in'—substances will have to be registered over an 11-year period following the entering into force of the regulation. If the regulation enters force in 2005 (2006 may be more likely), then this will lead a deadline of 2008 for chemicals produced or imported at over 1000 tonnes per annum per producer, whilst those produced or imported at 1–10 tonnes per annum would not need to be registered until 2016 (by which time these chemicals will have been on the market for more than 35 years). The exception to the later deadlines are lower tonnage chemicals

DOI: 10.1039/b307627j

that have carcinogenic, mutagenic or reproductive toxin classifications 1 or 2, which should all be registered by 2008.
• The registration information required varies with the tonnage, with chemicals produced at 1–10 tonnes per annum requiring information that can be produced by non-animal testing ('annex V')—this is predicted to cover 20,000 of the 30,000 existing chemicals.
• Traded intermediates are treated in the same way as other chemicals, whilst non-isolated intermediates are exempt, and isolated intermediates and isolated intermediates transported to one or two other sites (*e.g.* contract production) need to be registered, but only with available data, except in the case of those transported at >1000 tonnes per annum which require annex V. The situation regarding registration of polymers is too complex to describe in this article.
• The legislation incorporates mechanisms to assist (and in some cases force) data sharing and consortium formation, in order to avoid duplication of animal testing. In addition, there is an annex which lists the justifications that companies can use to avoid new testing, for example by claiming that the chemical they are registering is similar to another for which data exists.
• The registration package must include a chemicals safety report, in which the producer/importer should describe how 'adequate control' of risks can be achieved for those uses (or exposure scenarios) that the producer is supporting—which should cover 90% of uses of the substance.
• A number of groups of substances are exempt from registration including pharmaceuticals, vetinary medicines and food additives. Pesticides and biocides will be considered as having been registered for these uses if they have gone through the relevant EU system.

The registration itself will be sent, probably electronically, to a new chemicals agency. The registration will then be subjected to a basic, automated completeness check, to ensure that all parts are filled in. This completeness check won't look at the dossier in more detail (this is left to the optional Evaluation stage). The quality of the Agency's registration database will depend on the quality of the industry dossiers—but there will be market mechanisms to encourage quality as, for example, companies will have to send the chemicals safety report to their downstream customers—they also have an overarching Duty of Care.

Evaluation

Evaluation is carried out by Member States Competent Authorities—the authorities that operate chemicals policy in individual countries. In the UK this is Department for Environment, Food and Rural Affairs in association with the Environment Agency and the Health and Safety Executive.

There are two forms of evaluation proposed:

Normal evaluation. Companies registering chemicals produced at over 100 tonnes per year will also have to submit test plans to outline their justification for doing—or not doing—the extra tests required for these chemicals. Every test plan must be evaluated by a Competent Authority through normal evaluation.

Priority evaluation. Priority evaluation gives competent authorities the chance to review registration dossiers, to check them for accuracy, to look at cumulative releases and a range of other options. Such evaluations are voluntary for the Competent Authorities—the number of registration dossiers that are checked in this way will depend on how much resources individual Member States decide to put into priority evaluation.

Authorisation

Authorisation is a new regulatory mechanism, designed to deal with the chemicals of very high concern. It has two components—the identification of such chemicals, and the process by which authorisations are given to carry on using them. The intention of authorisation is to phase out the use of the worst chemicals—or at least to make it more expensive to carry on using them, as there will be a charge for an application for authorisation.

Criteria. Chemicals of very high concern are defined as:
• Chemicals that are classified as carcinogenic, mutagenic or reproductive toxins, categories 1 or 2.
• Chemicals that are persistent, bioaccumulative and toxic (PBT), defined with clear criteria, for example half life in fresh water greater than 40 days, bioconcentration factor over 2000 and long-term no-observed effect concentration for marine and freshwater organisations is less than 0.01 mg/l. There is a provision for other evidence to be used to identify chemicals as PBT.
• Chemicals that are very persistent and very bioaccumulative (vPvB), defined with clear criteria, for example half life in fresh water greater than 60 days and bioconcentration factor of over 5000. There is a provision for other evidence to be used to identify chemicals as vPvB.
• Chemicals, such as those having endocrine disrupting properties, which are shown to give rise to an equivalent level of concern as other substances subject to authorisation.

Identification of chemicals subject to authorisation will be the responsibility of the Agency and Competent Authorities, who will also prioritise which should be dealt with first.

Process. Once a chemical has been prioritised for authorisation, a date will be set beyond which no unauthorised use of the chemical will be permitted, along with a date at least 18 months earlier when companies must have applied for an authorisation for any use they wish to continue. There is also a provision for the exemption of uses or categories of use from authorisation.

There are two routes by which authorisation may be obtained:
• If the company can show that the risk to human health or the environment is adequately controlled. There is currently no provision for the regulator (generally the Agency and Commission) to refuse such an authorisation request if adequate control is justified. It is not currently clear what adequate control means for vPvB and PBT chemicals, nor for no-threshhold effects such as carcinogenicity and potentially endocrine disruption.
• If the company cannot show adequate control, then they must also submit a socio-economic analysis of the use, and the regulator may also consider the existence of safer alternatives, though 'the existence of alternatives is in itself insufficient grounds to refuse an authorisation'.

Authorisations may be time-limited, and may be reviewed if circumstances have changed.

Restrictions

The draft regulation includes a restrictions process, which is basically a modification of the current marketing and use restrictions process, redesigned to make it more rapid (hopefully). It also introduces the new option of restricting the manufacturing of a chemicals, rather than just its marketing and use—this provision will be used for the control of UNEP POPs for example.

The restrictions process is designed to deal with all unacceptable risks to human health and the environment from the manufacture, marketing or use of a substance. It complements authorisation,

providing a method of dealing with problems that authorisation doesn't address, for example neurotoxic effects or sensitisers.

Chemicals Agency, decision making and the public database

The draft regulation proposes the setting up of a new chemicals agency, which will have the role of administering the whole system. The Agency will also host a number of committees of representatives from Member States, which will create a decision making process, for example for authorisation. In most cases though the decisions will have to be enacted by the Commission, as only it has the legal competence, and REACH will have to be enforced by the Member States, as only they have competence in this area.

One of the Agency's roles will be the creation of a database of information on all registered substances, incorporating a short profile of hazardous properties, labelling requirements and any authorisations or restrictions—all non-confidential information from this database will be available over the internet to anyone in the world. It is clearly intended that most of the information transfer in the new system will be electronic, so it will be vital that an effective IT solution is constructed—fortunately work has already started on developing the 'REACH IT' system.

The relevance of REACH to green chemistry

REACH has the potential to change the landscape for the development of green chemistry, as long as the eventual legislation retains its current nature (and, in the view of the environmental NGOs, is slightly extended). For example:

- The authorisation system will have clear criteria for identification of the worst chemicals, signalling that they should be moved away from. Once chemicals enter authorisation itself, it will become more difficult to continue using them, therefore providing pressure to develop and adopt alternatives (though the environmental NGOs would like to see a stronger push for substitution within authorisation).
- The development of new chemicals is encouraged by a deregulation of the thresholds for registration, and research and development exemptions are extended.
- There will be a substantial expansion in both the information available about chemicals on the market—through the requirement to register—and in the accessibility of this information, through the creation of the internet registration database. There is also an obligation for chemical safety reports to pass down the supply chain, to ensure that downstream users know what they are using. These improvements in information will make it clearer where problems are, and encourage innovation to solve those problems. The current text will, however, leave one part of the supply chain in the dark—those companies that buy articles (*e.g.* fabric, components) will not receive any additional information about the chemical composition of the articles.

Next steps

The draft regulation is proving to be very controversial, with many and varied claims of costs and benefits being made.[3] It is clear that there is a huge debate ahead. After the consultation finishes (July 10th), the Commission will debate the results, and may revise its proposals. It is currently predicted that the Commission will then publish a legislative proposal in around October 2003, and then it will be up to Member State governments and the European Parliament to debate and finalise the legislation—a process that could take at least 2 years.

REACH has a real potential to substantially increase the drivers towards green chemistry. However, much remains in the balance and will depend on the outcome of the political debate over the next couple of years.

For further information contact: A. M. Warhurst, WWF European Policy Office, 36 Avenue de Tervuren, Box 12, 1040 Brussels, Belgium. Tel: +32 2 740 0926; Fax: +32 2 743 8819; e-mail: MWarhurst@wwfepo.org; http://www.panda.org/epo/toxics

References

1 A. M. Warhurst, *Green Chem.*, 2002, **4**(2), G20–G24.
2 European Commission, Explanatory note on the REACH system. 2003: Brussels, Belgium. European Commission, http://europa.eu.int/comm/enterprise/chemicals/chempol/reach/explanatory_note.pdf.
3 WWF and EEB, *A new chemicals policy in Europe—New opportunities for industry*, 2003, Brussels, Belgium. http://www.panda.org/downloads/europe/wwfeebreachnewopforindustry.pdf.