

The European Chemicals Agency, keystone of REACH

REACH, the new European legislation on the use and marketing of chemicals, came into effect on 1 June 2007. The rules require industry to register substances manufactured or imported in quantities of one tonne or more a year. Approximately 30 000 chemicals already on the European market will have to be registered before June 2018. A new European agency, based in Helsinki, has been set up to manage the technical, administrative and scientific aspects of REACH. It will be centrally important to the roll-out and success of the reform.

A core aspect of the REACH rules¹ is that the burden of proof is shifted from the competent authorities onto chemicals manufacturers and importers. Under previous EU law, the Member States had a duty to evaluate the health and environmental risks of "priority" substances² before requiring any necessary risk reduction measures to be taken, up to and including restrictions on use or marketing bans³. This system was too slow, inefficient and did not sufficiently encourage innovation in the chemical industry, and was replaced by the REACH reform after a decade or so of difficult discussions at European level.

The burden of proof now lies on industry: firms that manufacture or import chemical substances in quantities of one tonne or more a year must register them to show that they are completely safe to use. The rule is "no data, no market", i.e., any chemical substance covered by REACH that has not been registered will simply be prohibited from the Community market. Additionally, producers of "substances of very high concern"⁴ will have to get authorization before being able to use them or place them on the market. The European Commission will also be able to restrict the manufacture, marketing or use of certain substances that pose unacceptable risks to human health or the environment – and this can if need be go as far as a total ban on any of these activities.

At least fifteen years' work

The REACH regulation, which entered into effect in the 27 Member States on 1 June 2007, also provides for a European Chemicals Agency (ECHA) to be set up. At the December 2003 European Summit presided over by Italy, the Heads of Government finally decided that the European Chemicals Agency would be based in Helsinki (Finland).

The Helsinki Agency's main task is to manage the registration, evaluation, authorization and restriction procedures for chemical substances to ensure that REACH works uniformly across the European

Union (EU). Around 30 000 chemicals currently on the European market will have to be registered with the Agency in an order of priority set on the basis of their characteristics and production volume (see box, next page).

The Agency's first year of operations was expected to be taken up with setting the organization up and recruiting its staff to be ready to start processing (pre) registrations from 1 June 2008. By the end of 2007, the Agency had a hundred staff on its books. This is likely to be gradually increased to nearly 500 to handle the surges expected as the different registration deadlines draw near.

Registration of substances already on the market is due to be finalized eleven years after the regulation entered into force, i.e., by 1 June 2018. But an extra four years will be needed to clear the extra work created by evaluation of dossiers, i.e., checking the information supplied by industry and whether it meets the REACH requirements. This means that the ECHA's busiest period should run from 2007 to 2021. During – and obviously, after – this period, industry will also have to register substances it intends to place on the market for the first time. There is no specific timetable set for this, and they will have to be registered on a rolling basis before they are marketed. If the average number of chemicals introduced onto the market since the early 1980s is anything to go by, at least 300 new substances are likely to be registered each year with the Agency.

What are its duties?

The Agency's main duty is to manage the technical, scientific and administrative aspects of the REACH system's core elements – registration, evaluation, authorization and restriction of chemical substances.

For registrations:

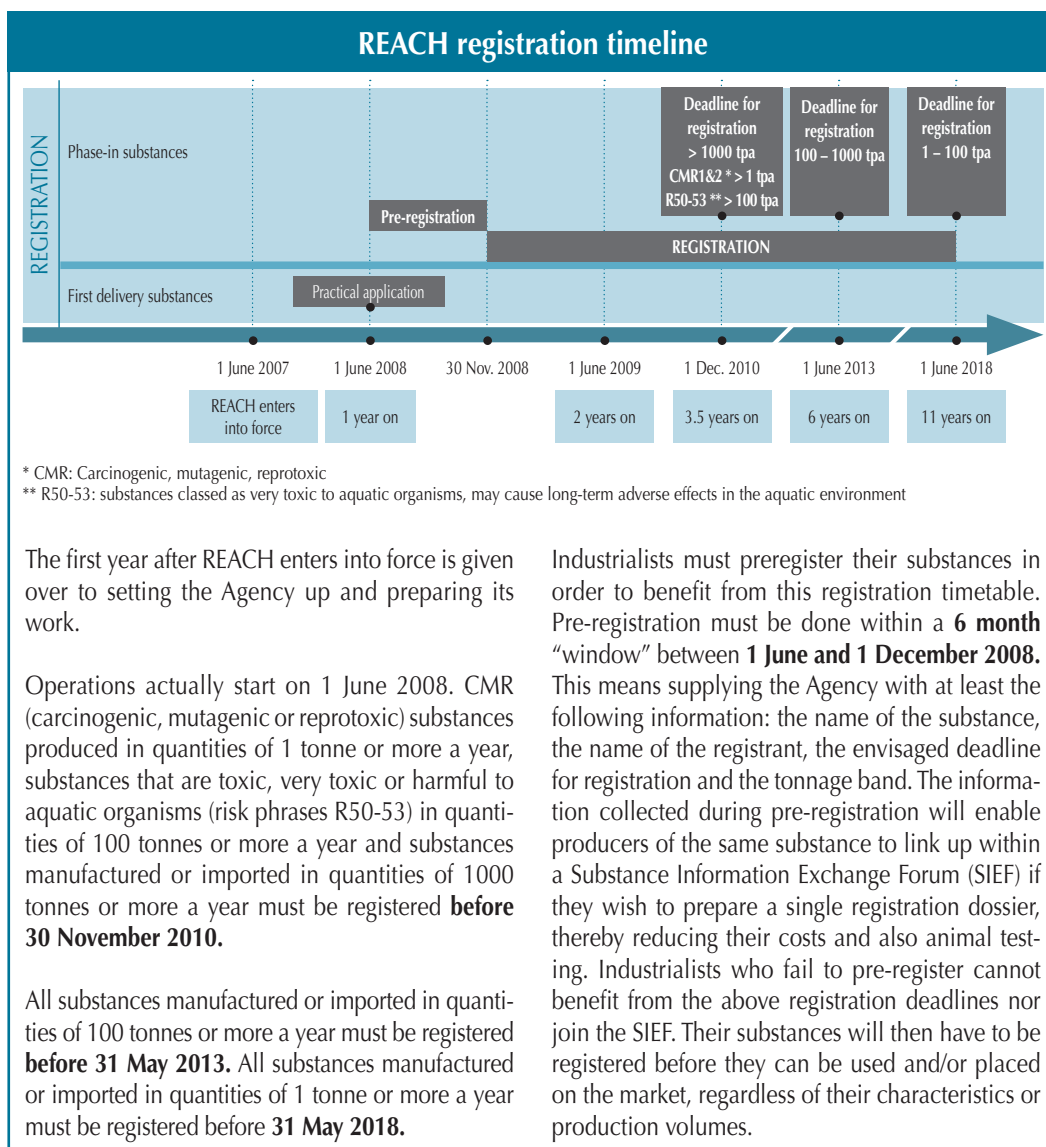
- it will manage the registration procedure;
- it will process applications for exemption of substances used in research;
- it will facilitate sharing of animal testing data

¹ Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation and authorization of chemicals. REACH is an acronym for Registration, Evaluation and Authorization of CHemicals.

² Chemicals placed on the market before September 1981 produced in quantities of more than 1000 tonnes a year which were suspected of having harmful effects for human health or the environment. Only 141 substances have been classed as priority since 1993, and risk assessments have been finalized on for 84 of these.

³ Directive 76/769/EEC of the Council of 27 July 1976 relating to restrictions on the marketing and use of certain dangerous substances and preparations.

⁴ About 1500 substances, including carcinogens, mutagens and reprotoxins (CMRs), as well as those that break up slowly or not at all (persistent), that accumulate in the environment (bioaccumulative) and are toxic (PBTs).



The first year after REACH enters into force is given over to setting the Agency up and preparing its work.

Operations actually start on 1 June 2008. CMR (carcinogenic, mutagenic or reprotoxic) substances produced in quantities of 1 tonne or more a year, substances that are toxic, very toxic or harmful to aquatic organisms (risk phrases R50-53) in quantities of 100 tonnes or more a year and substances manufactured or imported in quantities of 1000 tonnes or more a year must be registered **before 30 November 2010**.

All substances manufactured or imported in quantities of 100 tonnes or more a year must be registered **before 31 May 2013**. All substances manufactured or imported in quantities of 1 tonne or more a year must be registered before **31 May 2018**.

Industrialists must preregister their substances in order to benefit from this registration timetable. Pre-registration must be done within a **6 month "window" between 1 June and 1 December 2008**. This means supplying the Agency with at least the following information: the name of the substance, the name of the registrant, the envisaged deadline for registration and the tonnage band. The information collected during pre-registration will enable producers of the same substance to link up within a Substance Information Exchange Forum (SIEF) if they wish to prepare a single registration dossier, thereby reducing their costs and also animal testing. Industrialists who fail to pre-register cannot benefit from the above registration deadlines nor join the SIEF. Their substances will then have to be registered before they can be used and/or placed on the market, regardless of their characteristics or production volumes.

between manufacturers of the same substance to enable them to submit a single registration dossier by setting up a Substance Information Exchange Forum (see box).

For evaluations:

- it will evaluate dossiers (to check whether they are complete and contain sufficient information on substances);
- it will coordinate evaluation of substances, which will be mainly done by Member States' experts;
- normally, it will take the decisions required by evaluations⁵. If the Member States' representatives cannot agree, the final decision will lie not with the Agency but the European Commission.

For authorizations/restrictions, it will provide the European Commission with expertise on both kinds of procedure.

The Agency has also a general duty to provide the Member States and Community institutions with the best possible technical and scientific advice on questions relating to chemicals that fall under REACH.

The European Commission's departments have drawn up guidance in collaboration with the different interested parties to help industrialists and competent authorities fulfil their REACH obligations⁶. Computer tools (REACH IT) have also been purpose-developed to make it easier to register chemicals. The IT based guidance documents, databases and computer tools will be managed and updated by the Helsinki Agency.

Another big task for the Agency will be to support the national helpdesks, set up to answer queries from local industrialists about their obligations under the regulation in the language of the EU country concerned. All the national helpdesks will work in close cooperation with the Agency's helpdesks to provide identical answers to the same questions.

Finally, the Agency will make all non-confidential information on chemicals collected during the different phases of REACH publicly-available on its website⁷. This reflects one of the big aims of the reform, which is to provide extra information on chemicals that will contribute to their safe use.

⁵ E.g., requests to manufacturers or importers for additional information on the properties of substances.

⁶ See REACH Implementation Projects (RIPs), <http://ecb.jrc.it>.

⁷ <http://echa.europa.eu>.

How is the Agency organized?

The European Chemicals Agency is made up of different bodies. It is headed by an Executive Director and a Management Board as effective corporate governance bodies (see box). The Management Board is composed of 35 members: one representative from each Member State appointed by the Council (27 members in all), three members representing the European Commission, two independent members appointed by the European Parliament and three representatives of interested parties appointed by the European Commission. The three interested parties are the European chemical industry, represented by the European Chemical Industry Council (CEFIC), environmental NGOs, represented by the Institute for European Environmental Policy (IEEP) and the European Trade Union Confederation. Although full members of the Management Board, the three interested parties' representatives do not have the right to vote. The Management Board takes its decisions by two-thirds majority of all members with the right to vote.

The Management Board has fairly wide powers. It draws up the Agency's budget and oversees its implementation. It elects the Agency's Executive Director, the members of the Risk Assessment Committee and the Socio-Economic Analysis Committee, and the chairman, members and alternates of the Board of Appeal.

The Management Board's remit also includes adopting the annual report, the Agency's annual and multiannual work programme, and the final annual budget. It draws up its own operating rules and procedures, and those of the three commit-

tees and the forum (see box). It also lays down the rules for accessing documents held by the Agency, the Agency's financial rules and its staff regulations. The Management Board also adopts the rules of procedure that govern relations with the Luxembourg Advisory Committee for Safety and Health at Work in regard to substances that fall both under REACH and worker protection legislation.

How geared-up is the Agency?

REACH entered into effect in the 27 Member States on 1 June 2007, but will enter properly into operation on 1 June 2008 when the pre-registration period begins (see box). The Agency was also created on 1 June 2007, and so was given 12 months to ready itself to manage the REACH system. With operational D-Day rapidly approaching, how ready is the Agency? An idea can be gleaned from the minutes of Management Board meetings posted on its website.

The Management Board met six times between June 2007 and March 2008, and has already taken a series of decisions. In October 2007, it elected the Belgian Geert Dancet as Executive Director. He is in post for five years, and can be re-elected once.

The work programmes for 2007 and 2008 have also been adopted, with budgets of 15.3 and 66.4 million euros, respectively. The entire 2007 budget and more than 90% of the 2008 budget are Community-funded. Ultimately, the Agency should achieve financial independence through the registration and authorization fees paid by industrialists, which should cover its entire operating costs. The Board has also appointed the members of the Risk Assess-

How the European Chemicals Agency is organized

The **Management Board** is responsible for adopting the annual budget, work programme and report. It appoints the Executive Director.

The **Executive Director** is the Agency's legal representative, and is responsible for the day to day management and administration of the Agency, including responsibility over its finances. The Executive Director reports and is accountable to the Management Board.

The **Secretariat** provides support to the three committees and forum, and carries out work on the procedures for registration and evaluation, preparation of guidance, maintenance of databases and provision of information.

The **Member State Committee** resolves differences of opinion on draft decisions proposed by the Agency or Member States and makes proposals for identification of substances of very high concern.

The **Risk Assessment Committee** prepares opinions on evaluation, on applications for authorisation, on proposals for restrictions and on classification and labelling.

The **Socio-Economic Analysis Committee** prepares opinions on applications for authorisation, on proposals for restrictions and on questions relating to the socio-economic impact of proposed legislative action.

The **Forum** on enforcement matters coordinates a network of Member States' competent authorities responsible for enforcement.

The **Board of Appeal** decide on appeals against decisions taken by the Agency. Appeals lie only against decisions taken as part of the Agency's duties on registration of dossiers, evaluation of dossiers, exemptions from registration for substances used in research and development, and the sharing of data between industrialists.

ment Committee and the Socio-Economic Analysis Committee. The members of the Member State Committee and Forum have been appointed by the Member States. The Management Board has also specified the profile of members of the Board of Appeal to be recruited before June 2008 following a public call for expressions of interest. The Agency is hiring staff as it goes along, also through public advertisements. Guidance documents to help industrialists fulfil their REACH obligations are already available on the Agency's website, and other guidance documents will be progressively posted for downloading. The REACH national helpdesks have already been set up in all Member States⁸.

The only area where the Agency's preparations are trailing badly is the computer software to be used for submitting and processing the industry-supplied data. But the system is meant to be up and running by 1 June 2008.

Workload and independence: two big challenges

During the negotiations on REACH, the Agency's role was substantially strengthened over the Commission's original proposal. A consensus emerged between the European Parliament and Council on having REACH managed by a strong and independent central agency. The Agency's management duties were therefore extended, but unfortunately without a matching increase in its initial operating budget. Its early years – when REACH is starting up – will be beset by challenges, therefore.

One of the biggest will be the Agency's ability to cope with a very heavy workload. This in turn will depend directly on the quality and number of experts that the Agency manages to hire and how efficient the computer-aided management tools they use are. While recruitment seems to be posing no particular problems, the timely delivery and performance of the dedicated computer software is causing concern in some quarters.

Another big challenge for the Agency is its independence from industry, the Member States and also the European Commission. Unprecedented industry lobbying went on all throughout the negotiations on the regulation. And there is likely to be no let-up in that pressure on the central agency tasked with regulating trade in chemicals which accounts for around 480 billion euros annual turnover in Europe⁹.

The Agency will also have to assert its independence from the Member States who are responsible for enforcing and policing the regulation at national level. The Member States will be closely involved in the Agency's work through the Member State Committee in particular, and may be tempted to push national interests at the expense of the Community interest.

But the Agency also has to stand independent from the European Commission, which originated it and has seconded a large contingent of officials to Helsinki. The Commission will also retain considerable oversight over a series of decisions to be taken in the event of disagreement over the evaluation of substances, the granting of authorizations, or when restrictions are considered. It should be easier for the Agency to preserve this essential autonomy from the Commission when it becomes financially independent through the registration fees paid by industry, and when its budget is therefore no longer tied to Community funds. That should be achieved by 2010.

The Agency's independence must be ensured by its Executive Director who, according to article 83 of REACH, "shall perform his duties in the interests of the Community and independently of any specific interests". Since the final appointee is a former Commission official, there is no doubt that his actions will come under the closest scrutiny. The Management Board will play an expectedly central role here. The oversight it exercises over the Executive Director, the appointments it makes to the committees and Board of Appeal, and the decisions it takes on the rules of procedure will all be decisive for the efficiency and real independence of the ECHA. That independence is crucial – the image and credibility of the Agency, as well as the REACH system as a whole, not just in the eyes of industry but also and especially those of European citizens, depend on it.

What role do the interested parties play in the Management Board?

The 35-member Management Board includes three members representing interested parties. These are the three interest groups that were among the most involved and active while the reform was in the works: the chemical industry, environmental NGOs and European trade unions. They also have the biggest stake in seeing the two main aims of REACH delivered: ensuring a high level of protection for human health and the environment, and enhancing the competitiveness and innovative capacity of European industry. Like all members of the Management Board, they are committed to perform their duties in "the best interests of the Agency". By definition, however, they also represent their organization's interests, and this is presumably why they have no right to vote in Management Board decisions.

The ETUC representative's remit is therefore to argue the common interest of the millions of European workers who are exposed to chemicals in the Agency's work, and hence in REACH implementation. His main focus at the early board meetings, which dealt with getting the Agency set up and laying down its rules of procedure, were the Agency's independence and transparency of its work. When the Committees' rules of procedure were being

⁸ http://echa.europa.eu/reach/helpdesk/nationalhelp_contact_en.html.

⁹ www.cefic.be/factsandfigures.

framed, the ETUC representative argued for and won the other Board members' support for the principle that candidates employed by a business enterprise or industry association should not be eligible for the Risk Assessment Committee or Socio-Economic Analysis Committee¹⁰. He was also instrumental in getting observers, especially trade union ones, into these committees as well as in the Member State Committee and Forum.

His future input should also be valuable in arguing the case for workers when the Management Board comes to decide what form of co-operation and synergies should be set up between the Agency and the Luxembourg Advisory Committee¹¹ on worker protection issues, or when the Executive Director has to seek the Management Board's opinion where the Commission and Member State Committee are at odds over the legal interpretation of the REACH obligations.

Conclusions

It would be mistaken to believe that the long years of taxing negotiations which resulted in the adoption and entry into force of REACH had laid the debate on the management of chemical substances in

Europe to rest. The real challenges are yet to come. The obligations laid down in REACH will have to be applied by industry from this June. This will be the first big test of how the reform works. Shifting the burden of proof onto manufacturers will require a radical change of attitude by industry but also by the national authorities that will be involved in managing REACH.

There is likely to be a fair amount of confusion at first, no immediate benefits for human health and the environment, or for European chemical industry competitiveness, and a great temptation to simplify the rules. The new Helsinki-based European Chemicals Agency will have a key role to play throughout the timetable for REACH implementation, but especially so in the early years. Its ability to manage the teething troubles will determine whether all the obligations laid down for industry are kept in place and ultimately, whether or not the reform succeeds. By adopting REACH, Europe scored over the rest of the world in moving towards a more socially responsible management of chemical substances. What it now has to do is to convert the try. ■

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¹⁰ Some Member States had put forward industry experts to sit on these committees.

¹¹ The Advisory Committee on Safety and Health at Work, based in Luxembourg, assists the Commission in the preparation, implementation and evaluation of all measures concerning safety and health at work. It comprises representatives of the governments, trade union confederations and employers' associations of the EU Member States.