**MEMO/07/218**

Brussels, 1st June

# Questions and Answers on the European Chemicals Agency (ECHA) and the REACH Regulation



## 1. ECHA

ECHA is the new European Chemicals Agency based in Helsinki. It will mark its start-up with the launch of its website on 1 June 2007, the day of entry into force of the REACH Regulation, and will become fully operational by 1 June 2008.

### 1.1. What will ECHA do?

ECHA will manage and coordinate the registration, evaluation, authorisation and restriction processes of chemical substances under the REACH Regulation to ensure consistency in the management of chemicals across the European Union. The Agency will provide Member States and EU institutions with scientific and technical advice on chemicals covered by the Regulation. The Agency's website will provide industry with guidance and tools and the public with a range of information on registered chemicals.

### 1.2. What is ECHA's role with regard to other EU bodies?

As a regulatory Agency, ECHA, will be independent from other European Union bodies. It will be managed autonomously and have its own staff with the full legal capacity to act in its own name.

It will be linked to other EU Institutions, through the members of the Management Board. The European Union will exercise financial control over the Agency and EU Staff Regulations will apply.

**1.3. What is the organisational structure of the Agency and the role of its various parts?**

| Body | Role | Starts |
|---|---|---|
| **Executive Director** | The legal representative of the Agency, responsible for the day-to-day management and administration, including responsibility over its finances. The Executive Director will report to the Management Board. | Nomination foreseen in autumn 2007 |
| **Management Board** | Governing body of the Agency responsible for nominations, adopting the financial planning, budget work programme, annual reporting & strategic documents. | First meeting on 27-29 June 2007 |
| **Secretariat consisting of various Directorates** | Supports the Committees and Forum, and undertakes work on registration & evaluation processes as well as preparation of guidance, maintenance of databases, website and helpdesk. | From summer 2007 |
| **Member State Committee** | Resolves potential differences of opinion on draft evaluation decisions proposed by the Agency or Member States and makes proposals for identification of substances of very high concern. | From 2008 |
| **Risk Assessment Committee** | Prepares opinions on applications for authorisation, on proposals for restrictions and on classification and labelling. | From 2008 |
| **Committee for Socio-economic Analysis** | Prepares opinions on applications for authorisation, on proposals for restrictions and on questions relating to the socio-economic impact of possible legislative action. | From 2008 |
| **Forum** | Coordinates a network of Member States' competent authorities responsible for enforcement | From 2008 |
| **Board of Appeal** | Considers appeals against decisions taken by the Agency | When the 1st appeal is submitted |

### 1.4. What next?

During its first year the Agency will be busy recruiting and training staff, while establishing its operational procedures and preparing its committees and the Member State Forum. In addition, it will provide REACH guidance and run a helpdesk, coordinate a network of national helpdesks and further extend its website. ECHA will be fully operational by 1 June 2008

From 1 June to 1 December 2008 the Agency will face its first major challenge. It will have to handle the pre-registration of substances and intermediates. About 180,000 such pre-registration files are expected to be submitted.

### 1.5. How many people will work at the Agency?

The staff of the Agency is expected to grow from about 100 at the end of 2007 to about 200 in 2008. Some 450 staff are expected to be working at the Agency by 2010.

### 1.6. When will the Agency begin recruiting?

The Commission began recruiting for the Agency in February 2007. First, the post for Executive Director was published and then a call for the first staff members. The Management Board of the Agency will appoint an Executive Director some time in autumn 2007. The current recruitment process for the technical staff will be completed this summer and it is expected that about 60 people will start work in early autumn. Further recruitment is foreseen later in 2007 and early 2008.

Forty Commission officials will be seconded to the Agency for 18 months. They will assist in establishing the necessary processes and training which will enable the Agency to become operational as soon as possible. They are due to arrive in Helsinki over the summer.

### 1.7. What is the annual budget of ECHA? Where do the funds come from?

The Agency's budget for 2007 is €15 million. Over the next 15 years the annual budget is expected to be on average €90 million. It will be largely financed from the fees paid by industry. The remaining balance will be covered by the EU budget as approved by the European Parliament and Council.

### 1.8. Will the Agency be responsible for all work related to REACH processes?

No, the Agency will have a co-ordinating role in managing the registration, evaluation, authorisation and restriction processes. Member States will carry out the evaluation work and in most cases will prepare proposals to subject substances to harmonised classification, restriction or authorisation. The decisions on authorising and restricting the use of a chemical are made by the European Commission.

## 2. REACH

The EU's new chemicals legislation **REACH** stands for the Registration, Evaluation, Authorisation and Restriction of Chemicals, and it **enters into force on 1 June 2007**.

### 2.1. What are the objectives and scope of REACH?

The objectives of REACH are to:

- Protect human health and the environment
- Maintain and enhance the competitiveness of the EU chemicals industry
- Prevent the fragmentation of the internal market
- Increase transparency
- Integrate with international efforts
- Promote non-animal testing
- Comply with EU international obligations under the WTO.

By creating an EU-wide system for the management of chemicals REACH will bring together the EU chemicals legislation. REACH will no longer differentiate between so-called "existing" and "new" chemicals.

Previously all chemicals put on the market before 1981 were called "existing" chemicals while chemicals introduced after 1981 were termed "new" chemicals. New chemicals had to be tested quite rigorously under the legislative provisions which are repealed by REACH. There were no such provisions for "existing" substances. As a result knowledge on properties and uses of “existing” substances is rather limited.

Under REACH, the burden of proof for demonstrating the safe use of chemicals will be transferred from Member States to industry.

### 2.2. How does REACH work?

Companies that manufacture or import one tonne or more of a chemical substance annually will be required to register it in a central database at the European Chemicals Agency.

The **registration** procedure involves submitting a technical dossier containing information on the substance and guidance how to handle it safely. For quantities of 10 tonnes and more companies also need to submit a Chemical Safety Report to document a safety assessment of the substance demonstrating safe handling for all identified uses and manufacturing.

**Evaluation** allows regulatory authorities to determine if further testing is needed and to assess whether information provided by industry complies with the requirements (dossier evaluation). Substances suspected to pose a risk to health or the environment will be selected for substance evaluation. This may lead to the actions under the restrictions or authorisation procedures.

Substances of very high concern are subject to an **authorisation** procedure. Companies who apply for authorisation need to show that the risks posed by those substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks. The aim is to give industry the incentive to progressively substitute these substances with safer alternatives when technically and economically feasible.

Substances of very high concern are:

- carcinogens, mutagens or toxic to the reproductive system, categories 1 and 2
- substances which are persistent, bio-accumulative and toxic
- very persistent and very bio-accumulative
- or of equivalent concern

Member States and the Agency, on a request from the Commission, can place substances on a candidate list of substances of very high concern. The first list will be available on the Agency's website from late 2008. Some 1500 substances may fall to be considered.

**Restrictions** are the safety net of the system. Any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if its use poses unacceptable risks to health or the environment. Restrictions can be imposed on the use of a substance in certain circumstances and products, the use by consumers or even on all uses (complete ban of a substance). Restrictions and authorisations can also apply to substances produced or imported in volumes below 1 tonne per year.

### 2.3. What is the timeframe for the registration of chemical substances?

**From 1 June 2008 to 1 December 2008** the **pre-registration** of so-called phase-in substances will take place. Companies are strongly encouraged to pre-register their phase-in substances to benefit from staggered registration timelines. Pre-registration requires companies to send only limited information to the Agency.

Pre-registration will allow companies to get in touch with other companies who are intending to register the same substance and gives them sufficient time to set-up 'Substance Information Exchange Forums' (SIEF). In a SIEF, companies are obliged to share animal testing studies to keep the number of animals used for testing to an absolute minimum. They may also share other data voluntarily.

By **1 December 2010** the following will have to be registered with the European Chemicals Agency: all substances produced or imported in quantities equal to or greater than **1000 tonnes/year**; carcinogens, mutagens and substances toxic to reproduction (**CMR category 1 and 2**) equal to or greater than 1 tonne/year and substances classified as very toxic to aquatic organisms (**R50/53**) at and above 100 tonnes/year;.

On **1 June 2013** all substances produced or imported in quantities equal to or greater than **100 tonnes/year** will need to be registered as are substances produced or imported in quantities equal to or greater than **1 tonne/year** by 1 June 2018.

Manufacturers and importers not having registered substances in time according to the appropriate volume levels will no longer be able to manufacture in or import that substance to the EU market.

**Non-phase-in substances** need to be registered before they are manufactured or imported. Their registration will start on 1 June 2008.

**Substances in articles which are on the "candidate list of substances of very high concern"** will need to be reported to the European Chemicals Agency from 1 June 2011.

### 2.5. Is REACH a testing programme?

No, REACH is not intended to be a testing programme. New testing should only be a last resort if available information is not sufficient. Companies registering the same substance need to share the available data. The data owner will get financial compensation from other companies who use this data.

In addition to data sharing, a combination of factors including the use of alternative methods and exposure-based waiving of testing will prevent unnecessary animal testing.

### 2.6. Are there registration fees?

Yes, there are fees to complete the registration process. The fees will be set in a separate Fee Regulation, which will be published by 1 June 2008.

### 2.7. Will REACH change the rules for classification and labelling?

No, but many REACH provisions refer to and build on classification and labelling like registration, chemical safety assessment, preparation of safety data sheet, authorisation and restriction.

The EU's chemical legislation has for a long time required industry to classify and label dangerous substances and preparations according to standard criteria.

The current EU classification and labelling legislation will be replaced in the coming years. The European Commission is currently finalising a proposal for a new Regulation which is based on the UN Globally Harmonised System for the Classification and Labelling of substances (GHS). Relevant REACH provisions will be updated accordingly.

### 2.8. Which chemicals are exempted from REACH?

Low-risk substances such as water, oxygen, noble gases and cellulose pulp are excluded from registration. Other substances naturally occurring in nature such as minerals, ores and ore concentrates, and cement clinker do not need to be registered as long as they are not chemically modified. These substances as well as other exempted substances are listed in annexes IV and V of the REACH Regulation.

### 2.9. What is not covered by REACH?

Several uses are exempted from all or some parts of REACH. This includes substances in food and medicinal products as they are covered by other specific legislation.

Waste is also exempted from REACH. Member States may exempt substances used for defence purposes.

### 2.10. Do polymers need to be registered?

Polymers are exempted from registration and evaluation, but its basic ingredients, monomers and other components, must be registered.

The Commission may propose legislation for the registration of polymers once a practicable and cost-effective way of managing polymers on the basis of sound technical and valid scientific criteria can be established.

### 2.11. Do intermediates need to be registered?

Chemical substances used to manufacture other chemical substances are called intermediates. If manufactured and used inside a closed system they are fully exempt from REACH (non-isolated intermediates). Intermediates that are separated during the production process (isolated intermediates: on-site & transported) will need to be registered. Simplified information requirements apply in this case since they pose lower risks for human health and the environment.

### 2.12. What manufactured products are covered by REACH?

Products such as construction material, electronic components, toys or vehicles are covered by REACH if they contain substances intentionally released. These substances need to be registered.

Products with substances on the candidate list of substances of very high concern will need to be notified to the Agency. A first candidate list with these substances is likely to be published by the Agency in autumn 2008.

### 2.13. What are the main benefits of the new REACH Regulation?

The main benefit of REACH is that it more systematically identifies hazards and risks of chemicals. This allows companies to identify and communicate appropriate risk management measures through the supply chain.

Better knowledge on chemicals and more efficient communication on risk management measures will contribute to the prevention of health problems caused by exposure to chemicals. This is expected to lead to a lower occurrence of occupational diseases and preventable deaths, thus lowering costs to national health systems. The benefits will come gradually as more and more substances are assessed under REACH.

The European chemicals industry will also benefit from a single EU regulation covering all chemicals. REACH provides clear deadlines for decision-making and may enhance consumer confidence in chemical products.

Downstream users of chemicals will get relevant information on the safe use of the chemicals substances they use thus helping them to better protect their workers. Everyday products are expected to become safer for consumers and the environment, facilitating the implementation of companies' corporate and social responsibility policies.

## 3. Help for companies and further information

### 3.1. Will industry receive help to comply with its obligations?

The European Commission, in close cooperation with industry, Member States and NGOs, has developed a number of technical guidance documents, and IT tools for industry and national authorities to facilitate the implementation of REACH. All necessary information can be obtained via the website of the European Chemicals Agency in Helsinki. A navigator tool on this website will help companies to identify their obligations under REACH. The IT tool for entering and storing information on chemicals and preparing and submitting registration dossiers to ECHA will be IUCLID 5.

REACH requires EU Member States to set-up helpdesks to provide companies with the necessary information to fulfil their obligations under the new chemicals legislation.

### 3.2. What should companies do to prepare for REACH?

To prepare for the implementation of REACH companies should carry out the following three steps:

**STEP 1. Nominate a REACH manager**

- Identify a person within the company who will be accountable for preparatory activities and compliance
- Ensure appropriate skill-set and management support

**STEP 2. Be aware of information sources**

- Regulation (1907/2006/EC)
- Guidance documents (will be available for all main topics on the ECHA website)
- The ECHA website is a single point of entry for information on REACH helpdesks in Member States

**STEP 3. Identify the company's obligations under REACH**

- Create an inventory of substances (on their own, in preparations and those intentionally released from products)
- Consider exemptions for substances and uses in the inventory
- Compile data based on volumes (≥ 1 tonne ≥ 10 tonnes, ≥100 tonnes & ≥ 1000 tonnes
- Understand the sources of the substances (EU or non-EU supplier)
- Determine the obligation with regard to each substance (manufacturer, importer or downstream user)

### 3.3. Is there more information available?

Further information can be found on the following websites:

**European Chemicals Agency:** http://echa.europa.eu

**European Commission:**

http://ec.europa.eu/enterprise/reach/index_en.htm

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

http://ecb.jrc.it/REACH/