MEMO/06/488

Brussels, 13th December 2006

Q and A on the new Chemicals policy, REACH

Questions:

1. What are the overall aims of the new chemicals regulation?

The two most important aims are to improve the protection of human health and the environment from the hazards of chemicals and to enhance the competitiveness of the EU chemicals industry.

Under REACH, the burden of proof for demonstrating the safe use of chemicals will be transferred from Member States to industry to ensure that risks to human health and environment are avoided or adequately controlled. Enterprises that manufacture or import more than one tonne of a chemical substance per year will be required to register the chemical in a central database.

2. Why is a new EU chemicals policy needed?

REACH will replace 40 existing legal acts and create a single system for **all** chemical substances. This is different from the current chemical legislation, which distinguishes between so-called "existing" and "new" chemicals, based on the cut-off date of 1981. All chemicals that were put on the market before 1981 were called "**existing**" chemicals. In 1981, they numbered 100 106. Chemicals introduced after 1981 (over 4300) were termed "new" chemicals. While new chemicals had to be tested quite rigorously under the present legislation, there were **no such provisions for the existing substances**. Consequently, there is a general lack of knowledge on properties and uses of “existing” substances and the risk assessment process was slow, cumbersome and resource-intensive. For example, since 1993, only 140 high-volume chemicals (above 1000 tonnes) have been singled out as a priority for risk assessment and final reports are available for about 70 of these substances. These shortcomings have potentially put human health and the environment at risk.

As regards new substances the current system has also hampered research and innovation. New chemicals manufactured in quantities as low as 10 kg were subject to heavy testing requirements, causing the EU chemicals industry to lag behind its counterparts in the US and Japan in this regard.

REACH will replace this legislation and require manufacturers and importers to gather comprehensive information on the properties of all substances produced or imported in quantities higher than 1 ton per year and to submit the necessary information to demonstrate their safe use in a registration dossier to the European Chemicals Agency. Failure to register will mean the substance cannot be manufactured or imported into the EU market. Currently about 30.000 substances are in the EU market in volumes above one tonne. REACH will also provide encouragement to develop new substances as a result of less burdensome requirements for registration of new chemicals and better incentives for research and development.

3. How will REACH work?

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals.

Registration requires producers and importers to obtain relevant information on chemical substances produced in or imported to the EU market in quantities greater than 1 tonne per year. It involves submitting a technical dossier containing information on the substance and information on how to effectively manage the risk entailed by using it . Quantities above 10 tonnes per year additionally require the submission of a Chemical Safety Report (CSR) to document the safety assessment of the substance.

Evaluation allows the regulatory authorities to decide on proposals for further testing and assess whether information provided by industry complies with the requirements (dossier evaluation). For selected substances, for which a risk to health or the environment is suspected, substance evaluation provides a mechanism to require industry to obtain more information. Evaluation may also lead to the conclusion that action should be taken under the restrictions or authorisation procedures.

Authorisation may be required for substances of very high concern (carcinogens, mutagens, substances toxic to the reproductive system, and substances which are persistent, bio-accumulative and toxic, very persistent and very bio-accumulative or of equivalent concern).

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 decided either for the use of a substance in certain products, the use by consumers or even for all uses (complete ban of a substance).

4. What are the industry obligations?

REACH places greater **responsibility on industry to manage the risk of chemicals** and provide appropriate safety information to professional users and, as far as the most hazardous substances are concerned, also to consumers.

Which industries will get obligations?

Manufacturers and **importers** are obliged to register substances they produce or import in quantities over 1 tonne per year. The registration requirement applies to substances on their own, in preparations and in articles under special conditions (intentional release). Failure to register means that the substance cannot be manufactured, imported or used in the EU market.

Downstream users of chemicals must apply the risk management measures for dangerous substances identified on the supplier Safety Data Sheets. They have a right to make their use of a substance known to the manufacturer in order to make it an identified use and have it covered in their supplier's chemical safety assessment. In this case they have to provide sufficient information to allow the supplier to prepare an exposure scenario for the use. Alternatively they can conduct their own chemical safety assessment and report this use to the chemicals agency.

What types of obligations will they get?

The first REACH obligation, **pre-registration**, will take place from 1 June 2008 to 30 November 2008. Following pre-registration, **registration** deadlines apply in November 2010, June 2013 and June 2018, depending on the volume band or level of concern of the substance. Registration obligations apply to manufacturers and importers of chemicals who need to gather comprehensive information on the properties of the substance they produced or imported over one tonne per year. This information and evidence demonstrating the safe use of the substance need to be submitted in a registration dossier to the **European Chemicals Agency** (see below). Users of chemicals are advised to communicate proactively with their suppliers to ensure that their uses are covered by registration dossiers of their suppliers.

New substances need to be registered before they are placed on the market. Their registration will start on 1 June 2008

If a substance has been identified for **authorisation,** companies may only manufacture, import or use the substance after the so-called “sunset date” if they have obtained an authorisation for a particular use. Companies can apply for an authorisation until 18 months before the “sunset date”, providing all relevant documentation, including an analysis of substitutes and where safer alternative substances are available, substitution plans, and an indication of relevant Research and Development plans if appropriate.

Companies using substances subject to **restrictions** must respect the conditions of the restrictions.

5. How will authorisation work in practice?

Around **1500 substances of very high concern** may become subject to authorisation, including:

- CMRs (substances that are carcinogenic, mutagenic or toxic to reproduction), category 1 and 2,
- PBTs (substances with persistent, bio-accumulative and toxic properties),
- vPvBs (substances that are very persistent, very bio-accumulative).
- Substances identified from scientific evidence as causing probable serious effects to human health and the environment equivalent to those of the other categories mentioned above, for example certain endocrine disrupting substances (substances disturbing the body’s hormone system). These will be identified on a case by case basis.

The authorisation system is intended to ensure that such substances will be progressively replaced wherever they cause unacceptable risks for human health and the environment or where there are no other reasons that justify carrying on using them.

In particular, there may be applications where exposure to human beings or the environment is very limited and where risks can be adequately controlled. In other cases, the use of such substances can create substantial socio-economic benefits that outweigh the risks associated with the use (e.g. ensuring safety of equipment for cases where there is no suitable alternative). For these uses, special rules for authorisation have been defined.

For certain substances that are carcinogenic, mutagenic or toxic to the reproductive system (CMR substances), an authorisation will be granted if the producer or importer can show that risks from the use in question can be adequately controlled. This means that scientists can agree on a "safe threshold" below which a substance does not create negative effects to the human body or the environment. For other CMR substances and substances with persistent, bio-accumulative or toxic properties (PBT, vPvB substances), where adequate control is not possible, an authorisation will only be granted if no safer alternative exists and if the socio-economic benefits of the use of the substance outweigh the risks.

6. What are the key improvements for environment and health from the agreed package?

Authorisation: The main benefit of the agreement of Council and Parliament relates to a stricter authorisation system. Prior to applying for authorisation all companies will have to analyse alternatives. If they identify a suitable alternative, they will have to submit a *substitution plan*. If no suitable alternatives are identified, they will have to inform on relevant research and development activities, if any.

All persistent and bio-accumulative substances (PBTs and vPvBs) can only be authorised if no suitable substitute is available and if it is demonstrated that the socio-economic benefits from the particular use of the substance outweigh the risks to human health and the environment. The Commission will review whether endocrine disruptors should be subjected to the same strict conditions after 6 years from entry into force of REACH.

The criteria for identifying persistent and bio-accumulative substances (PBTs and vPvBs) will be reviewed and updated by the Commission within 18 months of entry into force of REACH.

Information flow: The agreement of Council and Parliament on this point will make more information available to consumers about the presence of substances of very high concern in articles.

Duty of care: The agreement of Council and Parliament clarifies in two recitals the general responsibility of industry to avoid adverse effects on health and environment when manufacturing, importing, using or placing on the market chemicals.

7. Which are the most dangerous substances? How many are there?

Substances of very high concern are:

- carcinogens (category 1 and 2)
- mutagens (category 1 and 2)
- substances which are toxic to reproduction (category 1 and 2)
- persistent, bio-accumulative and toxic substances (PBTs),
- very persistent and very bio-accumulative substances (vPvBs)
- substances identified from scientific evidence as causing equivalent concern to those mentioned above, for example substances which disturb the hormone system (endocrine disruptors)

It is estimated that there are about 900 substances of very high concern at the moment and it is expected that REACH will generate new data which will help to identify another 600 substances of very high concern over the next 11 years. REACH will therefore address about 1500 substances of very high concern.

Substances which are not of *very high concern* can still be *dangerous,* for instance:

- acutely toxic substances
- skin and lung sensitizers
- highly explosive and flammable substances

The share of dangerous substances among the new substances manufactured or marketed since 1981 is about 70%. This includes substances of very high concern and those of lesser concern but which are still dangerous. This means that 70% of new substances have at least one dangerous property.

8. Will the use of hazardous substances be restricted or banned?

The use of certain dangerous chemicals is acceptable as long as appropriate risk management measures are implemented, such as the use of good ventilation or protective clothing. If measures at company level are not sufficient to keep the risks for human health and environment acceptable, REACH foresees limitations or even bans of substances for certain uses (for instance in consumer products).

However, the most dangerous substances (those of very high concern) will be subject to authorisation, thereby putting the burden on the applicant to show that the risks are adequately controlled or that the socio-economic benefits from the use outweigh the risks.

Both the restriction and the authorisation processes can also be applied to substances produced or imported in volumes below 1 tonne per year. This would for instance allow addressing risks from particles on a nano-scale. However, substances of very high concern produced or imported in high volumes will normally be subjected to authorisation as a matter of priority.

9. Will articles that contain chemicals be labelled and will consumers have access to the information on chemicals registered in the database?

All articles contain chemicals and most articles are safe. However, industry will have to show that the use of their chemicals in articles is safe and this may involve labelling and instructions for safe use. Much of the key safety information will be available free of charge on the website of the European Chemicals Agency and more will be available on request. In particular, consumers may request information about the presence of substances of very high concern in articles.

10. What is the timeline for the implementation of REACH?

June 2007: Entry into force of REACH.

June 2008: European Chemicals Agency becomes operational.

June 2008 to November 2008: Pre-registration of so-called phase-in substances.

November 2010: Registration deadline for substances in quantities of 1000 tonnes and above as well as carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) above 1 tonne/year and substances classified as very toxic to aquatic organisms (R50/53) above 100 tonnes.

June 2013: Registration deadline for substances in quantities of 100 tonnes and more and substances toxic for the aquatic environment.

June 2018: Registration deadline for substances in quantities of 1 tonne and more.

Voluntary registration prior to the deadline is of course possible. Registration dossiers can be submitted as of 1 June 2008.

New substances need to be registered before they are placed on the market. Their registration will start on 1 June 2008.

11. What will the European Chemicals Agency do?

The Agency will manage and in some cases carry out the technical, scientific and administrative aspects of REACH and ensure consistency at Community level in relation to these aspects. The Agency shall provide the Member States and the Institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals covered by the Regulation.

The new European Chemicals Agency will be established in Helsinki, Finland, in 2007. It will be headed by an Executive Director and it will have a secretariat which is planned to grow in a year from around 80 to 220, and then gradually to the planned full staff of about 450.

The Commission is preparing the recruitment of the Executive Director and other staff shortly after the regulation has been adopted. The available posts are expected to be advertised in early 2007 on the DG Enterprise REACH website in the job opportunities section at:

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

12. When will the guidance and tools be available?

New guidance documents and IT tools are currently developed under REACH Implementation Projects to make the transition to the new system as easy as possible. These instruments comprise easily understandable guidance for SMEs, more detailed information for specialists in chemical companies and IT tools for on-line registrations to the future European Chemicals Agency (ECHA).

The guidance and IT tools to support registrants and users of chemicals will be made available free of charge through the Agency website that will be launched in mid 2007. The website will consist of an IT based guidance Navigator-tool and detailed guidance documents. The Navigator will help the users to find out their obligations and direct them to relevant parts of the guidance, tools and formats available on the website. The detailed documents provide information on the methods and procedures required to comply with REACH. The IT tool for submitting registrations will be IUCLID5. It will be rolled out to the industry in Spring 2007.

Further information on IUCLID5 is available at: http://ecb.jrc.it/iuclid5/

13. What are the main benefits of REACH?

The main benefit of REACH is that the hazards and risks of chemicals are more systematically identified, which allows for appropriate risk management measures by industry or, if necessary, further regulatory action by the public authorities.

This will contribute to the prevention of health problems caused by exposure to chemicals, leading to a lower occurrence of diseases and preventable deaths, and, with that, lower costs for the national health systems. The benefits will come gradually as more and more substances are phased into REACH. The anticipated overall benefits to environment and human health are generally expected to be significant although a quantitative assessment is difficult. The Commission's Impact Assessment in 2003 developed an illustrative scenario which put the health benefits alone in the order of magnitude of €50 billion over a 30 year period.

The European chemicals industry will benefit from a single EU regulatory system, a decision-making system with clear deadlines, and more consumer confidence in their products. Downstream users of chemicals will get relevant information on the safe use of the chemical substances they use in their production process which will help them to ensure better protection of their workers. The chemicals industry's products will be safer for consumers and the environment and it will be easier to put corporate social responsibility into practice.

14. How much will REACH cost?

Testing and registration costs for producers and importers of chemicals: The Commission's Impact Assessment in 2003 estimated the direct costs of REACH to the chemicals industry at a total of some €2.3 billion over an 11 year period. The changes in the proposal since then have further reduced the administrative and cost burden for companies, in particular for the substances supplied in lower volumes and for SMEs. However, the cost of the Agency increased significantly because the Council and Parliament have added substantial new responsibilities, in particular that of ensuring a harmonised approach to the evaluation of registration dossiers. However, these additional Agency costs should be seen in the context of from tasks being shifted from the competent authorities of the Member States to the Agency.

Costs to downstream users: The costs to downstream users of chemicals were estimated in the Commission's Impact Assessment of 2003 at €0.5 to 1.3 billion, under the assumption that 1 to 2 % of the substances would be withdrawn because continued production would no longer be profitable. Costs could rise to €1.7 – 2.9 billion when industry would face higher substitution costs in the downstream supply chains.

Total costs: Consequently, the overall costs of the Commission's proposal of 2003 to the chemicals industry and its downstream users were estimated to be in the range of €2.8 - 5.2 billion. From a macroeconomic perspective, the overall impact in terms of a reduction in the EU's Gross Domestic Product (GDP) was predicted to be very limited. The changes introduced in REACH by the Parliament and the Council in the co-decision process have not changed this overall picture significantly. The cost-efficiency of the proposal has been further increased as the registration requirements for low volume substances with no hazard indication have been reduced, whereas the requirements for authorisation have been strengthened. This will contribute to a marked improvement in health and environment protection while safeguarding the competitiveness of industry.

15. What is the difference between REACH and the present system of chemicals management?

The present legislation requires public authorities to identify and address possible safety issues for the chemicals on the market. REACH aims to change this balance by requiring industry to take responsibility for assessing the risks of chemicals and for ensuring their safe use. At the same time, the efficiency of the system is improved in as far as there are better incentives for developing safer chemicals, which will help promoting the competitiveness of the EU chemical industry.

Comparison between the present system and REACH

Present system	REACH
There are gaps in our knowledge about many of the chemicals on the European market.	REACH will close the knowledge gaps by providing information on hazards and risks of chemicals produced or imported in volumes higher than 1 tonne/year per manufacturer/importer.
The 'burden of proof' is on the authorities: they need to prove that the risk from the use of a chemical substance is unsafe before they may impose restrictions.	The 'burden of proof' will be on industry. It needs to demonstrate that the risk from the use of a chemical can be adequately controlled, and recommend appropriate measures. All actors in the supply chain will be obliged to ensure the safety of the chemical substances they handle.
Notification requirements for '*new* substances' start at a production level of 10 kg. Already at this level, one animal test is needed. At 1 tonne, a series of tests including other animal tests have to be undertaken.	Registration will be required for both old and new substances when the production or import reaches 1 tonne. As far as possible, animal testing will be minimised.
It is relatively costly to introduce a new substance on the market. This encourages the continued use of "existing", untested chemicals and inhibits innovation.	Innovation of safer substances will be encouraged under REACH through: more exemptions for research and development; lower registration costs for new substances; and the need to consider substitute substances when applying for authorisations.
Public authorities are obliged to perform comprehensive risk assessments that are slow and cumbersome.	Industry will be responsible for assessing the safety of identified uses, prior to production and marketing. Authorities will be able to focus on issues of serious concern.

16. How will REACH promote innovation and development of safer substitutes?

To enhance industry's competitiveness, one of the objectives of REACH is to promote R&D and innovation. For example:

- Uses of substances in product- or process-oriented R&D do not need to be registered for up to 5 years, renewable for a further maximum of 5 years in the case of a substance being exclusively used in the development of medicinal products or, under certain conditions, for a further maximum of ten years if the substance is not placed on the market.
- The REACH threshold for registration (1 tonne/year) is much higher than the current threshold of 10 kg for new substances.
- The costs of registering a new substance will be significantly lower than the current cost of notification.
- Registration will be quicker than the current notification, thus reducing the time to market.

- The authorisation requirement for substances of very high concern will encourage companies to increase their research into safer substitutes.

- The discrimination of new substances versus existing substances will come to an end.

17. Will REACH result in more animal testing?

The aim of REACH is to ensure that health and environment (including animals) are protected from adverse effects due to dangerous chemical substances. Acquiring the necessary knowledge on the properties of substances will entail some animal testing.

However, REACH has been designed to reduce animal testing to the absolute minimum. Unnecessary tests are avoided due to the obligation to share all data generated through testing on vertebrate animals, and by the provision that for large volume substances testing proposals must be approved by the Agency before new test on animals will be performed. This will ensure that the endpoints studied are relevant, that the scientific validity of the research is sufficiently high, and that the testing programme does not duplicate other studies.

The second reading agreement has further improved the situation, by introducing a public consultation period of 45 days before certain tests can be carried out, to verify whether the data is already available and consequently the tests are unnecessary.

An increase of 3% of animal testing in comparison to the current level of animal tests in the EU is only expected for the first eleven years after adoption of REACH. After these 11 years, the burden of the past concerning a lack of knowledge about 30.000 substances in use today should be adequately addressed and the numbers should then go down again steeply because only a few new substances per year will have to be tested.

18. Will REACH become the world standard for chemicals legislation? Which other countries may orient their system according to REACH?

REACH is currently the most ambitious chemicals legislation in the world. However, several third countries have carefully followed the discussions in the EU over the last few years and have shown a keen interest to learn from REACH. These include Switzerland, Norway, Canada, Japan, Korea New-Zealand and certain developing countries such as China. In the United States, discussions in Congress have begun about whether the current US legislation is sufficient to protect health and environment and REACH is regularly mentioned in that context. Several states including Massachusetts and California are increasing their capacity to monitor bio-accumulative chemicals and to ban or phase out dangerous substances.

The Commission is in contact with a large number of other third countries and will endeavour to help them with training and technical assistance to deal with the new legislation. The EU has indeed taken a constructive international leadership role on chemicals safety and REACH has the potential to inspire new standards worldwide.

19. Which international activities concerning chemicals exist?

As chemicals are traded internationally, chemical safety is a global concern and inspired a number of international initiatives. The European Union is playing a leadership role in all of them and cooperates closely with third countries.

Strategic Approach to International Chemicals Management

In 2006 the Commission played a pivotal role in the launch of the Strategic Approach to International Chemicals Management (SAICM). SAICM was developed and negotiated with the participation of a wide range of stakeholders from more than 140 countries and was finally adopted by the UNEP Governing Council in February 2006 in Dubai. SAICM aims to ensure that chemicals management all over the world is done in a manner that will help to reach the target set at the 2002 World Summit on Sustainable Development "to achieve, by 2020, that chemicals are used and produced in ways that lead to a minimisation of significant adverse effects on human health and the environment." The EU has been a keen supporter of SAICM and will also be very active in the implementation of the SAICM Global Plan of Action which sets out nearly three hundred different activities that will help countries to reach this goal. In particular, REACH will help the EU to fulfil the objectives of SAICM.

OECD Programme on high volume substances

The OECD has initiated a co-operative action programme for testing and assessing High Production Volume (HPV) chemicals in a systematic way. When important data gaps are identified or concerns are raised, further investigation, in-depth assessment or risk assessment measures are recommended. The EU participates actively in this programme and there will be mutual reinforcement between the OECD programme and REACH.

Stockholm convention on POPs

The Stockholm Convention on Persistent Organic Pollutants (POPs) sets out to control the production, use, import, export, disposal and release of twelve POPs. The convention bans deliberate production and use of POPs and the development of new POPs, and aims at minimising releases of unintentionally produced POPs. The convention has so far been ratified by the European Community, 18 Member States and the 2 accession countries. The European Community has recently proposed that 5 additional substances should fall under the Convention.

Global Harmonised System (GHS)

The Commission has taken an active part in the UN negotiations on a Global Harmonised System (GHS) for the classification and labelling of chemicals. A draft proposal for a Regulation to implement the GHS into Community law is currently under preparation after a public stakeholder consultation was successfully concluded in the autumn of 2006. The new legislation will replace, after a transitional period of several years, the current provisions on classification and labelling of chemicals, as set out in Council Directive 67/548/EEC and Directive 1999/45/EC.

Rotterdam convention on the trade of dangerous chemicals

The Rotterdam Convention on Prior Informed Consent (PIC) aims at reducing the risk connected with chemicals when they are internationally traded. The Convention sets up a system regulating trade in certain dangerous substances. It entered into force in early 2004. The European Community, 23 of its Member States and the 2 accession countries are parties to the convention. Regulation (EC) 304/2003 of the European Parliament and of the Council implements the Convention and goes significantly beyond its requirements.

20. How will nanoparticles be treated under REACH?

Substances in the nano-scale fall under the scope of REACH and their health and environment properties must therefore be assessed following the provisions of this Regulation. However, methodologies for identifying hazards and evaluating risks of substances at the nano-scale need to be further refined over the next few years. The European Commission is funding research projects to assess the health and environment impacts of nano particles under the 7th Research Framework Programme. It will also be necessary to carefully monitor over the next few years whether the 1t threshold for registration and the information requirements under REACH are adequate to address potential risks from particles on a nano-scale.

21. Which chemicals will be excluded from REACH?

Substances of low risks such as water, oxygen, noble gases and cellulose pulp are excluded from registration. Other substances occurring in nature such as minerals, ores and or concentrates as well as cement clinker are also not required to be registered as long as they are not chemically modified. There are also exemptions from large parts of REACH for substances in food and medicinal products because those are regulated in specific legislation. Waste is exempted from REACH and Member States may exempt substances used in the interests of defence.

If chemical substances used to manufacture other chemical substances are never separated from the mixture of other chemicals inside a closed system, they are fully exempt from REACH (non-isolated intermediates). Intermediates that are separated out during the production process (isolated intermediates) will have to be registered, but with simplified information requirements commensurate with their lower risk.

Polymers are for the time being also exempted from registration and evaluation. (However, its basic constituents, monomers, must be registered; the Commission may also introduce requirements for the registration of polymers once a practicable and cost-effective way of identifying dangerous polymers on the basis of sound technical and valid scientific criteria has been established).

22. How are overlaps between REACH and other legislation avoided?

When the Commission drafted its proposal in 2003, it carefully considered the existing legislation relevant to chemicals and whether there were any overlaps, for instance between REACH and the specific legislation about medical devices, food, medicines, batteries and cosmetics. If a specific piece of legislation already had similar requirements to one of the elements of REACH, then an exemption was given for that element. For example, substances used in medicines are exempted from registration as well as authorisation under REACH, because the existing medicines legislation already requires the submission of data and provides for authorisation of the use of these substances in medicines.

On the other hand, the specific legislation on medical devices only covers risks to patients' health, not risks to workers producing these devices or risks to the environment. Therefore, substances used in medical devices still need to be partially subjected to the registration element of REACH, to ensure that companies address the risks of the substances to workers and the environment.

The final agreement includes also a review clause which requires the Commission to re examine the situation as regards possible overlaps with other relevant legislation after 5 years and to make proposals if appropriate.

23. What does "review" mean, what topics will be reviewed and by when?

REACH foresees that over the next twelve years after entry into force, the Commission will carry out a number of reviews of parts of the regulation to take into account any new experience gathered during a set time period and, where appropriate, present a legislative or quasi-legislative proposal to amend the law to ensure a high level of protection for human health and the environment.

The term "review" in this legislative context should not be confused with the "reviews" the Commission will do in order to amend or withdraw time-limited authorisations granted to industry for a particular use of a substance of very high concern. The following information relates only to the reviews in the legislative context:

Within 12 months of entry into force of REACH the Commission will review Annex I (rules for chemical safety reports) Annex IV (substances exempted from registration where sufficient information is known and the risk is minimal) and Annex V (substances exempted from registration under the current legislation).

Within 18 months the Commission will review Annex XIII (criteria for identification of persistent, bio-accumulative and toxic or very persistent and very bio-accumulative substances (PBTs and vPvBs).

After 5 years, the Commission will review the scope of this Regulation to avoid overlaps with other relevant Community provisions and the rules concerning the European Chemicals Agency.

After 6 years, the Commission will review whether or not substances that have endocrine disrupting properties should still be authorised if a suitable safer alternative exists.

After 7 years the Commission will review whether or not to extend the obligation to submit a Chemical Safety Report (CSR) to CMR substances below 10 tonnes and after twelve years a similar review will consider all substances below 10 tonnes.

Furthermore, the Commission will carry out a review on whether or not to extend the duty to inform consumers about substances in articles to other substances which are not of very high concern but which could still be dangerous or unpleasant (e.g. allergens). The requirement for a reproductive toxicity test for volumes between 10 and 100 t per year (laid down in Annex VIII) will be also reviewed after 12 years.

24. Where can the agreement be found?

The Common Position of the Council can be found at:

http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf

The agreement between Parliament and Council can be found at:

http://www.europarl.europa.eu/sce/server/internet/amend_motions_texts/sce_amend_motions_texts_main_02.jsp?ref=A6-0352/2006

The agreement is contained in amendment 191 which appears in the left column of that website. It has five parts (191a until 191e) but the crucial part concerning the main text and the main annexes are contained in parts **191a and 191b**. The parts 191c, d and e contain the very long Annex XVII about restrictions which has been copied over from existing legislation and updated to accommodate changes in the existing legislation since the 2003 Commission proposal was adopted).

25. Further background information

Further information is available at:

http://ecb.jrc.it/REACH/ (specific information on guidance)

http://ec.europa.eu/enterprise/reach/index_en.htm (general information on REACH)

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm (general information on REACH)

Glossary and abbreviations

Agency: The European Chemicals Agency will be in charge of the day-to-day management of REACH.

Animal testing: Testing carried out on research animals, mainly mice and rats, in order to predict the potential negative effects of a substance in humans or animals.

Article: Manufactured object with a special shape, surface or design which determines its function to a greater degree than its chemical composition.

Authorisation: Use-specific permission to use a substance of very high concern.

CMR: Abbreviation for several groups of substance of very high concern, namely those which are carcinogenic (cause cancer), mutagenic (cause damage to genes) or reproductively-toxic (cause either a decrease in fertility or problems with development of the foetus). CMRs are classified in three categories according to the weight of scientific evidence of damages to human health. Only category 1 and 2 substances for which there is a high level of evidence of health damage to humans are subject to authorisation under REACH.

Competent Authorities: The authority or authorities or bodies established by the Member States to carry out their obligations arising from the REACH system.

Computer modelling: Using a computer to predict effects of chemicals. Normally the model is based on data collected on actual occurrences. This helps to avoid animal testing.

Downstream user: Companies that use substances professionally or industrially (on their own or in preparations). Example: a manufacturer who mixes different chemicals to make ink, or uses the ink to print leaflets.

Endocrine disrupters: Substances of very high concern that mimic or inhibit the effects of hormones. They will be identified on a case-by-case basis and may become subject to authorisation. Many of these substances are also CMRs.

Existing chemicals: Chemicals that were reported to be on the market in 1981, when the requirement to notify new chemicals entered into force. There are about 100,000 existing chemicals. According to estimations, some 30,000 of them will be subject to registration in REACH.

Exposure: To come into contact with a substance. The amount of a substance someone comes into contact with is often modelled on a computer.

GHS: Globally Harmonised System for classification and labelling of chemicals, agreed under the auspices of the United Nations.

HPV: High production volume (substances produced or imported annually in volumes of more than 1,000 tonnes per producer or importer).

Identified use: Any particular use of a substance that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.

Intermediates: Chemicals that are used up in the process of making other chemicals.

In vitro testing: Studies done with cell or tissue cultures (as opposed to in vivo testing, where live animals are used).

New chemicals: Chemicals that have been placed on the market since 1981. These have to be notified to the Competent Authorities under the current EU chemical legislation. There are around 4000 ‘new’ chemicals currently on the market.

OECD: Organisation for Economic Co-operation and Development.

PBTs: Substances of very high concern that are persistent (difficult to break down in the environment, e.g. by exposure to sunlight or micro-organisms in the soil), bio-accumulative (accumulate in our bodies and in animals' bodies, e.g. in polar bears) and toxic. Those substances may become subject to authorisation as a priority.

Phase-in substances: substances listed in the EINECS list (European Inventory of Existing Commercial Chemical Substances) or those that have been manufactured in the Community but not placed on the Community market in the last 15 years or the so-called 'no-longer' polymers' of Directive 67/548EEC.

PIC: The Rotterdam Convention on Prior Informed Consent sets up a system to control international trade in certain hazardous substances.

Polymers: Large molecules consisting of repeated chemical units (monomers) joined together. Examples of polymers: plastic materials, two-component glue.

POPs: Persistent (difficult to break down) organic pollutants, banned under UNEP's Stockholm Convention.

Preparation: Mixture or solution composed of two or more substances.

Product and process orientated research and development (PPORD): Substances used in PPORD will have time limited exemptions from testing requirements.

R & D: Research and development.

Registrant: The manufacturer or the importer submitting a registration.

Registration: The first administrative step of REACH. The manufacturers and importers submit information in a standardised format, to demonstrate that they know about the most important properties of their chemicals and that they are managing their risks adequately.

Risk: The risk posed by a substance depends on hazard (the intrinsic properties of the substance) and exposure.

SMEs: Small and medium sized enterprises. A definition of SME is contained in Commission Recommendation 2003/361/EC: "The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million."

Substances in articles: Hazardous substances that are released from articles as part of their function will generally have to be registered. If the release is not intentional, only substances of very high concern have to be notified.

Substitution: Avoiding the use of a hazardous substance by replacing it with another substance (a substitute) or by changing production methods.

Sustainable development: Development that meets the needs of the present without jeopardising the needs of future generations. Sustainable development includes striking the right balance between environmental, social and economic concerns.

Tonnage threshold: Volume-based criteria for different requirements under REACH, formulated as "X tonnes per year and per manufacturer/importer". The tonnage thresholds are used to define registration deadlines.

Toxicity: Property of chemical causing adverse effects on humans, animals or plants (e.g. causes cancer or death).

UNEP: United Nations Environment Programme.

vPvB: Substances of very high concern that are very persistent (very difficult to break down), very bio-accumulative (very liable to accumulate in our bodies or in animals' bodies). Those substances are subject to Authorisation.