

## Summary of the REACH proposal, 13 December 2005

1. The proposed legislation consists of the following stages: **a single pre-registration** phase of 18 months designed to encourage data sharing; **registration** on a central database of all substances manufactured or imported into the EU in quantities greater than 1 tonne per year; **dossier evaluation**, consisting of mandatory review of testing proposals submitted at registration (primarily for substances supplied in quantities greater than 100 tonnes per year) and a voluntary compliance check of the registration dossier by the European Chemicals Agency; **substance evaluation**, consisting of further evaluation of substances where these may pose a risk to human health or the environment; **authorisation** of the use of substances of most concern; and **restrictions** on marketing and use of substances where the risks to human health and the environment are deemed to be unacceptable. The system will be co-ordinated by a **European Chemicals Agency** ("the Agency") established by the legislation with Member States responsible for a degree of the work and enforcement. The Agency will be located in Helsinki, Finland.
2. The legislation places a requirement on industry to **pre-register** phase-in substances (i.e. substances which are already on the market but not designated as "new" under the current regime) by submitting basic information on the substance – such as its name – to the Agency. This is aimed at minimising the duplication of testing and encouraging sharing of animal and other test data. There will be only one pre-registration phase between 12 and 18 months of REACH entering into force.
3. **Registration** of substances involves the submission by industry of a technical dossier of information about the chemical including a testing package. Registration will work along the principles of 'one substance, one registration'. Manufacturers of the same substance are expected to submit a joint package of hazard data but may opt out of this obligation if they can demonstrate that this would be disproportionately costly; cause a breach of commercial confidentiality; or where there is a disagreement between registrants on the interpretation of results. Registrants are also expected to share animal tests and may also need to share non animal data if it is requested by another potential registrant. To avoid breaches of confidentiality, a company can make use of a third party for the joint submission of data and data sharing of new and existing tests.
4. Under REACH, industry will be required to submit a registration for a brand new substances (i.e. non phase in substance) before it can manufacture or market it. Registration of **phase-in substances** will be staggered over 11 years ie; 3, 6 and 11 years depending on tonnage. In addition, all phase-in substances which are;

- classified as CMRs (carcinogens, mutagens and toxic to reproduction) categories 1 or 2 supplied in quantities greater than 1 tonne per year; or

- classified as very toxic to aquatic organisms and causing long-term effects in the environment over 100 tonnes per year, will also have to be registered within the first 3 years.

5. The registration of low volume phase-in substances (those manufactured or imported between 1 and 10 tonnes) will follow a targeted approach. Potential registrants need only submit available data complemented by a basic package of physico-chemical information unless the substance meets criteria identifying it as of potential risk. In these cases, the full information package specified in Annex V of the Regulation will need to be submitted. All non phase-in substances are not subject to the targeted approach and will need a full registration.
6. Registration requirements themselves will be mostly based on production volume; in general, the higher the volume, the more tests will be required. However, there is scope to omit certain information if there is limited exposure to humans or the environment. It will be up to industry to justify any reduced registration requirements.
7. For substances manufactured or imported in quantities over 10 tonnes, the registration package also requires the submission of a **Chemical Safety Report** (CSR). The CSR details a Chemical Safety Assessment (CSA). This is a risk assessment in which the registrant takes into account the risk management measures implemented by himself or recommended to downstream users. The details of how to perform a CSA and CSR are given in Annex I of the proposed Regulation.
8. Certain substances and categories of substances are subject to specific exemptions. **Waste** is exempted from the entire Regulation while exemptions can be considered by the authorities for certain substances in the interest of defence. **Polymers, cellulose pulp, minerals, ores, ore concentrates and cement clinker** are amongst the substances exempted from registration and evaluation. The full list of exemptions is given in Article 2 and Annexes II and III. Registration requirements for isolated and transported (but controlled) **intermediates** are limited (new data only needs to be generated for transported intermediates in quantities greater than 1000 tonnes per year). Non isolated intermediates do not need to be registered.
9. The Regulation places a duty to register any **substance present in a finished product (or article)** if:
  - the total amounts to over 1 tonne per year per producer or importer and

- it is **intended** to be released under normal or reasonably foreseeable conditions of use.

In addition, a limited 'postcard' notification will apply to substances in articles if:

- they are identified as being of very high concern
- the total amounts to over 1 tonne per year per producer or importer and
- the substance is present in those articles above a concentration of 0.1%.

The obligation to notify does not apply if exposure to humans and the environment can be excluded.

The Agency can request a registration for a substance in an article if it considers that it may pose a risk to humans or the environment.

10. There is a requirement for the provision of **information along the supply chain**. Where a substance or preparation is classified as dangerous, the supplier needs to prepare a safety data sheet. The Safety Data Sheet should be consistent with the results of the chemical safety assessment (where this has been carried-out). Where a Safety Data Sheet is not required, a minimal list of information needs to be supplied to the users. Where a producer or importer of articles has notified the Agency in relation to substances of very high concern, this information must be passed down the supply chain.
11. **Downstream users** have the right to make their use known to a manufacturer with the intention of making this an **identified use** and having that use covered in the assessment and Safety Data Sheet (SDS) supplied to them. Downstream users preparing a CSR shall place exposure scenarios covering identified uses in an annex to the SDS. This will be communicated down to **distributors** who will in turn pass on exposure scenarios and information on use up and down the supply chain. The downstream user will also have to provide sufficient information back up the supply chain to allow for the preparation of an appropriate exposure scenario by the supplier.
12. If the use made by the user is outside the exposure scenario communicated in the Safety Data Sheet, the user should prepare a downstream user chemical safety assessment appropriate for that use. This obligation only applies to downstream users using more than 1 tonne of the substance or preparation per year. In addition, the downstream user will have to send a 'postcard' notification to the European Chemicals Agency before commencing its use of the substance. The notification will include, amongst other things, a brief description of the use and proposals for further testing which are

considered necessary by the user to complete their chemical safety assessment.

**13. Dossier evaluation** consists of two parts;

- a mandatory review of testing proposals (primarily applicable to substances supplied in quantities of 100 tonnes and above per year) aimed at reducing unnecessary animal testing and keeping testing costs to a minimum and
- a review of at least 5% of dossiers to check that they comply with the legislation.

These tasks will be the responsibility of the Agency.

**14. Substance evaluation** allows the authorities to evaluate a substance where they have concerns over potential risks to human health or the environment. The Agency will ensure that substances on the single EU-wide rolling plan are evaluated, relying on the Member State competent authorities to perform the evaluation and prepare draft decisions.

**15. Evaluation of on-site intermediates** may be performed according to the following procedure. If the Member State in which the site is located identifies a risk that is equivalent to the level of concern arising from substances subject to authorisation, they may require further information or take appropriate risk reduction measures as required.

**16.** Category 1 & 2 carcinogens, mutagens and substances toxic to the reproductive system (CMRs); substances which are persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB); or of equivalent concern such as endocrine disrupters where there is scientific evidence of probable serious effects will be subject to **authorisation**. Because of their very hazardous properties, these are collectively referred to as “substances of very high concern”.

**17.** The aim of authorisation is to ensure that substances of very high concerns are properly controlled and eventually replaced by suitable substances or technologies with the aim of reducing risks to human health and the environment. Uses of substances that are subject to authorisation will be banned unless industry can justify continued use either through demonstrating:

- that the risks to human health and the environment are adequately controlled or
- that the socio-economic benefits outweigh the risks and that there are no safer suitable substances or technologies available.

18. All applications for an authorisation from industry must be accompanied by an analysis of possible alternatives considering their risks and the technical and economic feasibility of substitution. All authorisations are also subject to a time-limited review. This would enable further consideration of the availability of alternatives at some point in the future. It is also possible to allow an authorisation to be reviewed at any time should a third party supply new information on possible substitutes to the Agency.
19. The legislation allows for **restrictions** on the marketing and use of substances to be agreed at Community level where there is an unacceptable risk to human health and the environment arising from the manufacture, use or placing on the market of that substance. A substance which is subject to restrictions can only be used in compliance with the terms of that restriction.
20. Certain **information** deemed not to be detrimental to a company's commercial interests shall be made available by the Agency on its website. A company can however, under grounds of commercial confidentiality request the study summaries and robust study summaries, the purity of the substance and the total tonnage manufactured or imported not to be placed on the website. The public will be able to make a request for access to any other information held by the Agency or the Member States and the Agency would consider these requests in line with the Aarhus convention.
21. In taking decisions on access to information, the only information which the Agency shall normally deem to undermine the commercial interests of a company would be the composition of a preparation, the precise use of the substance or preparation, the precise tonnage and the links between the manufacturer and his downstream users. The Safety Data Sheet communicated down the supply chain should contain the name of the supplier of the chemical.

### Expected timetable

Common Position in the Council of Ministers of the EU	Spring 2006
European Parliament Second Reading	Autumn 2006
Adoption of REACH and entry into force	Spring 2007
Implementation: registration target	2008 registration of brand new

dates	substances 2010: 1000 tonnes and above, plus CMRs category 1 or 2 and certain substances dangerous to the environment 2013: 100 tonnes and above 2018: 1 tonne and above
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