

# A brief introduction to the European Commission's regulatory proposal on Registration, Authorisation and Evaluation of Chemicals (REACH)

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This briefing outlines the European regulation on Registration, Evaluation, and Authorization of Chemicals (REACH) as proposed by the European Commission [1] on October 29, 2003 and as amended by the political agreement between the European Union Member State governments of December 13, 2005. It is not a comprehensive guide to REACH; it offers an introduction to some of the main features, and suggests further sources of information. A new legal text, reflecting the political agreement, should be available in the second quarter of 2006; this is known as the ‘Common Position’ and will be the text considered in any future negotiations.

## **Introduction to REACH**

REACH is designed to be an integrated approach to the control of the manufacture, import and use of chemicals in Europe. It intends to create a system which is based on information about chemical substances, and which ensures that useful safety information (i.e. appropriate risk management measures for identified uses) gets to those using them. While the REACH system may be quite complex, it should be borne in mind that it is replacing a more complicated network of 40 or so pieces of legislation.

Crucially, the main responsibility in REACH for chemical safety is clearly placed on industry (and manufacturers and importers of substances in particular), not on public authorities or downstream users (although they do have important duties).

REACH can be thought of as fulfilling two key roles. It describes the phased process to overcome the lack of data on existing chemicals (sometimes referred to as the ‘burden of the past’) – including a series of deadlines, based on tonnage, for registering information on existing chemicals. This should mean that information on all existing substances manufactured in, or imported into, the EU in tonnages of 1 tonne or more per year should be available within 11 years of REACH entering into force. Second, it lays out the regulatory system for the management of chemicals in the EU. For example, information requirements for all ‘new’ substances, the system for the control of substances of very high concern, and the information that should pass both up and down the supply chain.

This briefing provides information on the provisions of REACH, and which chemicals are affected by which provisions. The scope of different parts of the regulation vary – for example, a substance may not need to be registered, but could be subject to restrictions if evidence of a problem emerged.

This briefing splits REACH into the following (based on the structure of the regulation itself):

- Definitions – i.e. what is a substance? Or an intermediate?
- Substances totally exempted from REACH – some substances and/or uses are totally outside REACH
- Registration – The process under which substance manufacturers in the EU and EU-based importers of substances will be obliged to send a registration dossier containing information on the substance to a new central European Chemicals Agency. This applies to substances manufactured in, or imported into, the EU in quantities of one tonne per year or more. This provision includes a phase in period of up to 11 years in order to collect this information for phase-in (‘existing’) chemicals. The exact deadline is largely based on volume with 3, 6 and 11 year deadlines in place.\*

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\* Note: Substances includes substances on their own, in preparations or in articles. REACH requires registrants of the same substance to cooperate to prepare a single dossier of hazard data; ‘one substance one registration’ (OSOR).

- Evaluation – the new European Chemicals Agency (the Agency), with support in some cases from Member State experts, will evaluate Registration dossiers and individual substances. Dossier evaluation will be of all proposals for additional testing on animals and a minimum of 5% of dossiers for compliance with the regulatory requirements. Substances may be evaluated if there is suspicion of a particular risk to human health or the environment. This may lead to requests for further information to clarify risks, or ensure compliance with the requirements, to MS or the Commission making proposals for ‘restrictions’, or no further action.
- Authorisation - substances of very high concern (SVHC) will be subject to authorisation. First, SVHC are identified (more can be added as and when they are identified) and a list of them published by the Agency. Substances on this list will then be selected, on the basis of risk, to be subject to the authorisation process. Industry (manufacturers/importers (M/I) and potentially downstream users (DUs) – those who use chemicals in processes and products) will need to submit an application for each use of the selected substances they wish to continue. SVHC are defined as those that are category 1 or 2 carcinogens, mutagens, and reproductive toxins (CMRs); are persistent, bio-accumulative and toxic (PBTs); very persistent and very bio-accumulative (vPvBs); and of a similar level of concern, i.e. endocrine disrupters.
- Restrictions – where chemicals pose “unacceptable risks” to human health or the environment that need to be managed on an EU-wide basis may have limitations placed on their marketing and use ranging from outright bans for particular substances or uses to classification and labeling requirements.
- Agency – A new European Chemicals Agency will be created in Helsinki, Finland.
- Classification and labeling – REACH creates a new inventory of the classification and labeling of all substances which are registered or placed on the market and meet the criteria for classification as dangerous.
- Information flow – Much, though not all, of the information generated by REACH will be publicly available. Commercially sensitive information will normally be kept confidential.

REACH is a major reform of chemicals management legislation in Europe. It is not yet finalized. The major regulatory hurdle was however cleared on 13 December 2005 when the EU Member States reached a political agreement on changes to the original proposal from the European Commission. It is extremely unlikely that major changes will be made at this stage, though minor changes are likely. The REACH proposal is still being discussed by the European Parliament and the EU Member States, it will soon to be subject to a ‘second reading’, with entry into force estimated to be in the first half of 2007 (see [www.chemicalspolicy.org](http://www.chemicalspolicy.org) for recent updates of this political process).

For a much more detailed explanation of how REACH works, with many flowcharts, see the Commission’s process description [2]. The Commission has also published a detailed, question and answers paper on REACH [3]. Both the European Commission’s Environment and Enterprise departments (Directorates General) have REACH web sites: <http://europa.eu.int/comm/environment/chemicals/reach.htm> and <http://europa.eu.int/comm/enterprise/reach/index.htm>. These can be accessed from the Lowell Center Chemical Policy Initiative Website [www.chemicalspolicy.org](http://www.chemicalspolicy.org)

## Definitions

REACH is concerned with the management of the use (including manufacture) of substances, on their own, in preparations and in articles, for the whole of the life cycle of the substance. Some key definitions (largely taken from the text) are:

*Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, [This paper – and much discussion on REACH – often uses the word ‘chemical’ rather than ‘substance’. To complicate matters a substance can also sometimes be a mixture, such as a crude oil fraction.]

*Preparation* means a mixture or solution composed of two or more substances (such as paint).

*Article* means an object which during production is given a specific shape, surface or design which determines its function to a greater degree than its chemical composition (such as a chair or a computer).

*Polymer* means a substance consisting of molecules characterized by the sequence of one or more types of monomer units (such as a plastic)

*Intermediate* means a substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another substance.

*Non-isolated intermediate* means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place.

*On-site isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an) other substance(s) from that intermediate take place on the same site operated by one more legal entities.

*Transported isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

*Phase-in substance* means a substance is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) or was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before entry into force.

*Importer* means any natural or legal person established within the Community who is responsible for import.†

Most of these definitions are very similar to those already in use in the existing European chemicals legislation, though some are new – i.e. *phase-in substance*. It is important to carefully check definitions before acting. For example, substance definition will be crucial as it has implications for registration and the ‘one substance one registration’ (OSOR) requirements in particular.

## Registration

Registration is the main procedure for collecting information on substances manufactured in, or imported into, the EU and identifying how they can be manufactured and used safely by the registrant and downstream users. Article 5 lays out the basic requirement of registration:

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† Note that many of the registration requirements in REACH are based on the tonnes per annum (tpa) of the substance manufactured or imported by the company concerned, not the total or cumulative amount produced or imported.

*“Save where this Regulation provides otherwise, any manufacturer of a substance in quantities of 1 tonne or more per year shall submit a registration to the Agency.*

*Save where this Regulation provides otherwise, any importer of a substance, either on its own or in a preparation, in quantities of 1 tonne or more per year shall submit a registration to the Agency.”*

It is important to note that this requirement to register applies to substances produced in Europe, substances imported into Europe, substances imported into Europe in preparations (mixtures of chemicals), and may apply to substances in articles. The 1 tonne total refers to the total amount manufactured or imported by a single legal entity in one year – i.e. if a chemical is imported in several preparations by one company; REACH applies to the total tonnage of the substance imported by the company.

### **Exemptions from REACH**

The following groups of substances are exempt from REACH: radioactive substances within the scope of Council Directive 96/29/Euratom; substances, on their own, in a preparation or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit; non-isolated intermediates; and waste as defined in Directive 75/442/EEC (as amended).

The key step that determines the scope of REACH is the registration procedure (Title II). There are three main levels of exemption from registration. First, a series of cases in which substances are exempted from registration for specific uses. Second, a list of fully exempt substances. Third, a list of substances that are subject to more limited registration requirements.

Article 2 provides that the registration requirements shall not apply to the extent that a substance is used:

- In medicinal products for human or veterinary use within the scope of Regulation (EEC) No 2309/93, Directive 2001/82/EC of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.
- As a food additive in foodstuffs within the scope of Council Directive 89/107/EEC.
- As a flavoring in foodstuffs within the scope of Commission Decision 1999/217/EC.
- As an additive in feeding stuffs within the scope of Council Directive 70/524/EEC.
- In animal nutrition within the scope of Council Directive 82/471/EEC.”
- Registered substances that are exported (out of the EU) by an actor in the same supply chain as the registrant and re-imported by an actor in the same supply chain do not have to be re-registered.
- Polymers are exempt (monomers and additives are normally subject to registration).

Individual and groups of substances listed in annex II (these tend to be food-related chemicals, such as glucose, and also other chemicals considered safe such as water and others considered to be so well understood or ubiquitous that Registration would be of no benefit i.e. cellulose pulp, carbon, nitrogen, argon), and in annex III (chemicals created by chemical reactions within products; certain listed substances occurring in nature if they are not chemically modified i.e. crude oil, natural gas, coal, minerals, ores, ore concentrates and process gases; substances occurring in nature if they are not chemically modified during their manufacturing, unless they meet the criteria for classification as dangerous according to Directive 67/548 – this would be expected to include, for example, common

salt; and basic elemental substances for which hazards and risks are well known) are fully exempt from registration. ‡

### Limited registration

Certain substances are subject to more limited registration: (1) Chemicals already notified under the current new chemicals system (1981) will be considered registered under REACH. When a higher threshold is reached the additional information for that and lower tonnages will be required; (2) Substances being used for product and process oriented research (PPORD) and development (i.e. a chemical being used in the development of a new product) can be exempted from registration for 5 years, extendable by a further 5 (or 10 if used in the development of medicinal products). Companies will need to submit a short notification to the agency, who will decide whether to accept the exemption; (3) Substances used in plant protection or biocidal products will be considered registered, for those uses only, through the relevant vertical legislation; and (4) on-site isolated intermediates and transported isolated intermediates have a more limited registration, based on available information, except in the case of transported isolated intermediates manufactured or imported at 1000 tpa or more, when the registration must include ‘Annex V’ information – i.e. the same information as a 1-10 tpa marketed chemical.

Substances in articles:

- If an unregistered substance is present in articles i.e. imported chairs, the draft regulation makes distinctions between two situations:
  - If it is intended to be released as part of the functionality of the article, is present in the articles at 1 tpa or more per M/I, then it should be registered.
  - A notification (a limited amount of available information) is required if the substance is present in the articles at 1 tpa or more per M/I, the substance has been identified as being a SVHC, and the substance is present in those articles above a concentration of 0.1% weight by weight (w/w). This is not required if exposure to people and the environment can be excluded during normal or reasonably foreseeable conditions of use. The Agency may require a Registration for such notified substances in articles.§

### Registration requirements vary by tonnage

The registration requirements vary by tonnage produced or imported per manufacturer/importer – they are prioritized so that higher volume chemicals require more information (see Table 1). This table also includes an estimate of how many phase-in chemicals fit into each category, from a report from the Commission’s Joint Research Centre [4].

It is important to note that a chemical produced at 100 tpa and above is registered with only available data and a *testing proposal* for new data for annexes VII & VIII. The new information requested in these annexes does not need to be available at this point and the need or otherwise for this information will be established through a Dossier evaluation of the testing proposal.

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‡ Note: some substances are exempt under both Annex II and Annex III. The Commission is committed to reviewing all exemptions from Registration with 12 months of entry into force.

§ The deadlines for Registration of substances in articles are the same as for other substances.

REACH is not a testing program; new test data will often not be required. Available data should be used as long as it can be justified as being technically and scientifically rigorous. Existing studies can be used, wherever in the world they are generated, computer modeling approaches may be applicable ((Q)SARs – (Quantitative) Structure Activity Relationships), and the use of analogues is possible (i.e. the OECD HPV Programme category approach). New testing, in particular on animals, is very much a last resort and, as mentioned above, should be subject to evaluation by the Agency before it is undertaken as part of a Registration Dossier. Industry is also able to argue that some information is unnecessary, for example because of the exposure pattern of the chemical (‘exposure based waiving’). Annex IV outlines the information required for all Registrations, Annexes V-VIII set-out the information requirements for different tonnages (including conditions for waiving particular information requirements), and Annex IX explains how the information requirements may be met (there is considerable flexibility that should be carefully considered when preparing a Registration).

Annex 1 explains how industry should take the information they have gathered, and relate to their knowledge about the uses of the chemical, in order to perform a Chemical Safety Assessment (CSA – a type of risk assessment) and recorded in a Chemical Safety Report (CSR). Only if a substance “meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB” does the registrant have to assess exposure and do a risk characterization (see [5] for an amended version of Directive 67/548/EEC for these definitions). In these cases, the chemical safety report must include a description of risk management measures that should be taken to ensure that the risks for each use are “adequately

**Table 1: Registration requirements in the REACH system, and estimated number of substances [4]**

1-10 tpa	<b>Generally in vitro safety information</b> (described in Annex V) (no chemical safety report) [17,500 substances], plus all available data
10-100 tpa	<b>Chemical Safety Report</b> (analysis of hazards, exposures and safe uses) and the safety information listed in <b>Annex V + VI</b> . [4977 substances]
100-1000 tpa	<b>Chemical Safety Report, Annex V+VI, existing information</b> they have for <b>Annex VII</b> and a <b>testing proposal</b> for the provision of <b>new information in Annex VII</b> . [2641 substances]  This testing proposal will be reviewed by the authorities <b>in a dossier evaluation</b> , and can include i.e. justifications as to why testing is not needed.
1000 tpa and above	<b>Chemical Safety Report, Annex V+VI, existing information</b> they have for <b>Annex VII and VIII</b> and a <b>testing proposal</b> for the provision of <b>new information in Annex VII and VIII</b> . [2704 substances]  This testing proposal will be reviewed by the authorities <b>in a dossier evaluation</b> , and can include i.e. justifications as to why testing is not needed.
On site isolated intermediate at 1 tpa and above	<b>Available data</b>
Transported isolated intermediate at 1 tpa and above	<b>Available data, and if produced at 1000 tpa and above, annex V (as in 1-10 tpa registration of traded chemical)</b> . [1,700 substances at 1000 tpa and above]

controlled”. The use and appropriate risk management measures (RMM) are communicated to downstream users in the form of an “exposure scenario” which is passed down the supply chain as an Annex to the (material) safety data sheet (SDS). If a chemical is not classified as dangerous, the exposure assessment and risk characterization are not required.\*\*

### **Registration Requirements for 1 – 10 tpa per M/I**

Special rules apply to the registration requirements for ‘phase-in’ substances in the 1-10 tonne band. Broadly speaking, the full Annex V data-set is only required if the substance is identified as being of high risk. This will benefit around 70% of substances (i.e. those not considered to be of high risk) in this tonnage band (it is anticipated that this will benefit SMEs in particular as they are responsible for a disproportionate number of substances in the 1-10 tonne bracket). Low risk substances have to submit, as a minimum, basic physiochemical data and available data. Substances identified as high risk (i.e. they do not meet the criteria as being of low concern) and new (non phase-in) substances would have to apply the full Annex V information requirements. The criteria to identify the high risk substances are straightforward and risk-based: those predicted to be category 1 or 2 CMRs or PBT/vPvBs; or with disperse or diffuse uses and are likely to meet the criteria for classification as dangerous for any human health or environmental end-points. For chemicals produced at below 10 tonnes per annum a chemical safety assessment is not required. However, existing worker protection, environmental, transport and consumer legislation, and other elements of REACH will still apply ensuring a minimum level of protection for people and the environment.

### **Timetable for registration**

Chemicals that are new to the European market will continue to be subject to pre-market registration, as in the current system (in place since 1981), however the registration threshold has been increased from 10 kg/year to 1 tonne/year. Substances being manufactured in the EU for the first time will also need to be registered prior to manufacture. Under the current system a notifier must wait 60 days before putting a new substance on the market, whilst in REACH they only need to wait 21 days. A major challenge for REACH is the phasing in of registrations for the backlog of existing chemicals that have not been systematically considered to date. This, so called, ‘burden of the past’ is estimated to be around 30,000 chemicals, all of which have been on the EU market since before 1981. The registration of these “phase-in” chemicals will be gradual, with 3 deadlines, prioritized on the basis of tonnage produced and with accelerated registration for carcinogens, mutagens and reproductive toxins (CMRs) and PBT/vPvBs – see Table 2.

It is important to note that in order to benefit from this phase-in period a registrant must normally pre-register with some basic information by a deadline of 18 months after entry into force (EIF) of REACH. Companies that have only just started, after the pre-registration deadline, manufacturing or importing a phase-in substance may also benefit from the phase-in deadlines. The principle aim of pre-registration is to facilitate data sharing and ‘one substance one registration’ (OSOR).

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\*\* It is worth noting that the registration dossiers will be submitted to the Agency which will only do a basic completeness check— there will be no detailed analysis of the information in the dossiers unless the dossier is selected for evaluation. It is only in evaluation that any industry data and justifications as part of a Registration will be examined by the regulator.

**Table 2: Phase in dates for registration of existing chemicals**

3 years after the entry into force (EIF) of REACH	Those chemicals produced and imported at 1000 tpa or more, those chemicals produced or imported at 1 tpa or more and which are classified as CMR category 1 and 2, and those classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) at 100 tpa or more.
6 years after EIF	Those chemicals produced and imported at 100-1000 tpa.
11 years after EIF (2018 assuming 2007 EOF):	Those chemicals produced and imported at 1-100 tpa.

### **Data sharing and consortia**

The single pre-registration procedure (with a deadline 18 months after REACH enter into force) will identify each potential manufacturer and importer of a phase-in substance. These companies will then become members of a Substance Information Exchange Forum (SIEF). All registrants of a substance within a SIEF must cooperate to prepare a hazard data set. They should share available data with the costs being shared proportionately. Registrants of the same substance do not have to do a joint registration of a CSA but may do so if they wish. Flexibility has been introduced by allowing companies to opt out of submitting a joint information package where they can demonstrate it would: be at disproportionate cost; cause a breach of confidentiality; or where there is a disagreement between registrants on an end-point. Sharing of animal test data remains mandatory. To simplify the system, the sharing of non-animal data has been made mandatory if requested by a potential registrant.

### **Evaluation**

The dossiers submitted in the registration process will only be checked by the Agency for completeness; their accuracy and compliance with the regulatory requirements will not be checked at all unless they enter the ‘evaluation’ process.††

Evaluation is carried out by the Agency with support for substance evaluation from Member State authorities and national sources of expertise. All decisions (i.e. requests for more data) must be approved through a European process, in which all Member States must agree with the proposal, or if unanimity can’t be reached, the Commission takes the decision. This makes it impossible for any Member State to operate in isolation.

Evaluation is a process by which registration dossiers can be examined. It may result in a request for further information on substances from the registrant. There are two types of evaluation with different aims. *Dossier evaluation* (i.e. per individual registration) involves checking testing proposals to prevent unnecessary animal testing, (repeating existing tests, tests of poor quality, or unnecessary tests.) The Agency will be responsible for checking all proposals for testing on animals submitted as part of the registrations before the tests are performed. In a *Compliance check*, the

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†† On-site isolated intermediates are exempt from normal evaluation but can be subject to checking by the relevant national authority.

Agency will check the compliance of a minimum of 5% of all registration dossiers with the registration requirements. National enforcement action is possible as a result.

Under substance evaluation, the Agency, in conjunction with Member State Authorities, may clarify suspicions of risks to human health or the environment by requesting further information from industry on particular substances. Any costs incurred should be shared among registrants of the substance. Substance evaluation will be prioritized on the basis of risk following guidance to be developed by the Agency.

Evaluation may lead to the conclusion that action needs to be taken under the restrictions or authorisation procedures, or that information needs to be passed on to other authorities responsible for other relevant legislation.

The Agency's role is to perform all dossier evaluations and ensure that substance evaluations are carried out efficiently and consistently across the EU. It is recognized that the requisite expertise rests primarily with the Member States hence the core scientific work on substance evaluation being carried out by them. The Agency has responsibility for ensuring that substances on the single EU-wide rolling plan (for substance evaluation) are evaluated, relying on the Member State competent authorities to perform the evaluation

### **Authorisation**

Authorisation is a procedure for controlling the use of substances of very high concern, defined as Category 1 & 2 Carcinogens, Mutagens and Reproductive toxicants (CMRs), persistent, bioaccumulative and toxic (PBT) substances, based on scientific criteria, very Persistent and very Bioaccumulative (vPvB) substances, based on scientific criteria, or those that give rise to an 'equivalent level of concern' to those mentioned above where there is scientific evidence of probable serious effects to humans or the environment (such as endocrine disruptors) which will be identified on a case-by-case basis. The criteria for PBT and vPvBs are set-out in Annex XII of the REACH proposal.

These substances are considered to have hazardous properties of such high concern that it is necessary to regulate them centrally through a mechanism that ensures that the risks related to their actual uses are assessed, considered and then decided upon on an EU-wide basis. The justification is that the effects on humans and the environment of these substances are very serious and normally irreversible. Substances that fall into these categories will be fed into the authorisation system as resources allow. Their uses will not be banned by default.

The biggest difference between authorisation and restrictions is that in authorisation all uses of a chemical are banned except those that are specifically authorized following an application by industry, while in restrictions authorities provide the justifications for limitations on the marketing and/or use of particular substances, preparations or articles. Therefore, in restrictions, the regulator must find out which uses exist, and which should be restricted, while considering whether safer alternatives are available in the case of important uses. In authorisation, it is industry that applies for authorisation of the uses it wants to continue.

Not all chemicals of very high concern will enter authorisation immediately, as there will first be a prioritization process involving the Agency to identify those chemicals of most concern. Once

chemicals have been selected through this prioritization process (with a consultation), they will then enter the full authorisation process. It has been suggested that in the first years of operation of REACH the authorisation process will only process tens of chemicals per year, but numbers will increase as the REACH procedures become more established. Once a substance has been selected for authorisation a deadline will be set when use of the chemical must cease, except when industry has successfully applied to continue use (an authorized use).

Authorisation can be based solely on ‘adequate control’ having been demonstrated. However, adequate control cannot apply to PBTs, vPvBs and non-threshold CMRs as it is not possible to determine a threshold in accordance with Annex I, section 6.4. All applications for an authorisation must be accompanied by an analysis of possible alternatives considering their risks and the technical and economic feasibility of substitution.

“Adequate control” refers to an exposure below a Derived No-Effect Level (DNEL) for humans or below a Predicted No-Effect Concentration (PNEC) for the relevant environmental compartment for the use in question. All authorisations will be subject to a time-limited review. This would enable further consideration of the availability of alternatives at some point in the future. There is a specific requirement to allow an authorisation to be reviewed at any time should a third party supply new information on possible substitutes to the Agency.

### **Exemptions from the authorisation system**

Exemptions from the authorisation system are the same as those from registration (above), but also include:

- Uses as plant protection products or as biocides
- Uses as on-site isolated intermediate or transported isolated intermediate
- Uses in scientific research or PPORD
- If the authorisation relates to a human health problem, then uses in cosmetics or food contact materials are exempt, based on the assumption that the specific vertical pieces of legislation should cover human health concerns
- Substances present at specified low concentrations in preparations.

### **Restrictions process**

The Restrictions procedure is designed as a safety net to enable conditions (up to and including prohibition) to be placed on the manufacture, placing on the market or use of substances, on their own, in a preparation or in an article. Restrictions apply on an EU-wide basis if it can be demonstrated that the risk posed by the substance or use are not adequately controlled. All uses/activities of a restricted substance which are not specifically restricted are allowed unless the substance is included in the authorisation system.

Proposals for restrictions will be prepared by Member State competent authorities, or by the Agency on behalf of the Commission, in the form of a structured Dossier (set-out in Annex XIV). This Dossier is required to demonstrate that there is a risk to human health or the environment that needs to be addressed at EU-wide level and that the most appropriate set of risk management measures have been identified. Deadlines for the procedure to result in a Commission decision are set out in

detail in REACH to ensure rapid decisions are taken. Interested parties will have an opportunity to comment on proposed restrictions and the Agency will provide opinions on any proposed restriction.

The existing restrictions set out in the Marketing and Use Directive (76/769/EEC - such as the ban on asbestos and restrictions on the uses of certain azo-dyes) will be carried over in a consolidated version into Annex XVI.

Chemicals do not have to be registered in order to be restricted. The restrictions process can deal with chemicals that are exempt from the registration process, and can also lead to action being taken on a 'phase-in' chemical that has not yet been registered. Because of the 'safety net' nature of the restrictions process, there are few exemptions, mainly just those concerning waste, and human health risks from cosmetics (to be dealt with by the Cosmetics Directive).

### **The Agency**

REACH sets up a new European Chemicals Agency to administer the REACH regulatory system. It has already been decided by the European Council of Ministers that this Agency will be based in Helsinki. As explained in the REACH explanatory memorandum [1]:

*“The Agency manages the registration process, plays a key role in ensuring consistency of evaluation, provides criteria to guide Member States’ selection of substances for evaluation and takes decisions requiring further information on substances under evaluation. It also provides opinions and recommendations in the authorisation and restriction procedures and has duties with regard to confidentiality.”*

The Agency will have a Management Board, and a number of committees, including a committee on risk assessment and one on socioeconomic assessment (for establishing recommendations in the authorisation and restrictions procedures), a Member State committee (for decision-making involving the Member States), a forum for exchanging information on enforcement (with Member State representatives), and a Board of Appeal. It is legally impossible for the Agency to enforce REACH, due to restrictions in the EU treaty (and Constitution) – enforcement must happen at Member State level.

### **Classification and labeling**

Companies who market substances and preparations must currently classify and label their products. Under REACH this classification and labeling information will be entered into an inventory which will be published on the Agency’s web site. Substances covered by the inventory will be as follows:

- All substances that have been registered in the first 3 years of REACH, with the information taken by the Agency from the registration dossier.
- Within 3 years of REACH coming into force, industry self-classifications of any substances which are *placed on the market*, and are either:
  - Subject to registration more than 3 years after REACH comes into force, or;
  - Meet the criteria for a dangerous substance or preparation.

If classifications differ for the same substance, the registrants and notifiers should “make every effort” to agree a joint classification; if they fail the database will list all the classifications submitted for that substance. Under the current system, regulators can harmonize classification and labeling of substances. Under REACH, this harmonization is restricted to CMR properties and respiratory sensitizers – all other harmonization will be the responsibility of industry.

## **Information flow and access to information**

The Agency will manage a database of all the information submitted under REACH. Some of this information will always be publicly available via the internet whilst some will only be available to the authorities as it is commercially confidential. There is a further type of information that is not publicly available but may be made available on request in line with the EU's rules on access to information.

The text has been amended to clearly state what information will be published on the Agency website (see Article 116). Companies can however, under grounds of commercial confidentiality, request the study summaries and robust study summaries (from tests), the purity of the substance, and the tonnage band to be excluded from the website. The public will still however be able to request information under the EU's access to information provisions and the Agency would consider these requests in line with the Aarhus Convention (on public transparency of data). The only information which the Agency would normally consider to be prejudicial to the commercial interests of a company would be the composition of a preparation, the precise use of substance/preparation, the precise tonnage and the links between manufacture and his downstream user(s). The Safety Data Sheet (SDS) would still contain the company name which would be communicated down the supply chain to their customer(s).

*For more information on REACH, the current regulatory system for chemicals in the EU and other aspects of chemicals policy, see the Lowell Center for Sustainable Production's Chemicals Policy Initiative web site: [www.chemicalspolicy.org](http://www.chemicalspolicy.org)*

## **1. References**

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