

EXPLANATORY NOTE

1. Purpose of this note

This note explains the essential features of a new system to implement the policy set out in the Commission's White Paper of February 2001 on the 'Strategy for a future Chemicals Policy'. The new system, developed jointly by the Enterprise Directorate-General and the Environment Directorate-General, is called REACH – **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals.

2. Duty of Care

A central feature of the new system is a duty on all companies that manufacture, import and use chemicals - regardless of the quantity - to use substances in such a way that human health and the environment are not adversely affected. This is achieved by assessing the risks arising from the manufacture, import or use of those chemicals and taking the necessary measures to manage any risks identified.

3. Registration

Registration requires manufacturers and importers of substances gather information on the substances they manufacture or import, and use the information for responsible and well-informed management of the potential risks of the substance. This is documented in their Chemical Safety Report (Annex I).

All firms manufacturing substances in, or importing substances into, the EU in quantities of 1 tonne or more per manufacturer or importer per year will be required to submit relevant information to the Agency before new substances are first manufactured in or imported into the EU. The information required increases at the tonnage thresholds of 10, 100 and 1000 tonnes respectively (Annexes V to VIII).

Substantial efforts have been made to minimise costs and animal testing by allowing:

- the use of existing sources of information,
- the use of information not based on testing of vertebrate animals where possible (especially below the 10 tonne threshold),
- the reading across of data from analogous substances,

- the sharing of test results,
- the grouping of similar substances, and
- the dispensing with some requirements altogether where the information is not needed because of the properties or use of the chemical, or that more extensive information is already available. For example, testing can be waived in some cases on the grounds of lack of exposure during its intended use.

To ensure greater cost/resource efficiency, companies manufacturing or importing the same substance can form consortia and share information needed for registration. To facilitate this manufacturers and importers of substances that are already on the market will have to 'pre-register' their substance(s). Those manufacturers and importers having pre-registered the same substance will then be participants of a 'substance information exchange forum' (SIEF), where they will exchange available information on tests involving vertebrate animals. This will save time, money and reduce animal testing.

If information required for substances manufactured or imported in quantities of 100 tonnes and more per year (set out in Annexes VII and VIII) is not available, testing proposals to meet these requirements will have to be submitted as part of the registration (for it to be complete). These proposals will be examined by the authorities at the evaluation stage to ensure only the right tests will be performed and to avoid double testing.

As regards research and development, exemptions from REACH requirements will be available for substances subject to product and process orientated research and development, for up to 10 years, i.e. initially 5 years, which can be renewed for a further 5 years.

Special reduced registration requirements have been developed for polymers and intermediates:

- Polymers with certain dangerous properties will be subject to a reduced registration package, other polymers will be exempted from registration altogether. Monomers will follow the general rules. Many polymers subject to registration will only need to be registered after 12 years.

- Non-isolated intermediates, kept in closed systems, are excluded from the REACH system altogether.

For intermediates used on site or transported to up to two other sites under strictly controlled conditions, as the exposure potential is limited, less information needs to be submitted than for other substances.

The information gathered on intrinsic properties of substances will help manufacturers and importers to improve the assessment of their risks and the development of measures to adequately control those risks. Chemical safety assessment will need to cover manufacturers' and importers' own uses of a substance as well as uses by downstream-users they supply with the substance. Registrants will have to assess at least 90 % of these so-called 'intended uses' of their substances. The assessments will be documented in the Chemical safety report.

To 'phase-in' the new system, deadlines will be established for registration of substances that are already being manufactured. This will start with substances in quantities of 1000 tonnes or more, and substances that are carcinogenic, mutagenic or toxic to reproduction (CMR substances) below that tonnage, 3 years after the Regulation comes into force, and end with substances in quantities of 1 tonne or more after 11 years.

As a consequence of introducing a single system for all substances, the current notification requirements for new substances, contained in Directive 67/548/EEC, will be repealed. Substances previously notified under this system will be considered to be registered.

4. Substances in articles

Substances in articles in quantities of 1 tonne or more will also have to be registered if sufficient amounts of the substance are released to pose a risk, to human health and/or the environment, and the substance has not already been registered for that use. For reasons of practicality, this requirement will be phased in shortly after the registration deadlines for substances (at the relevant tonnage level).

5. Downstream users and Information through the supply chain

Under the REACH system, manufacturers and importers of substances will provide downstream users with the information they need to be able to fulfil their duty of care, i.e. in particular information on recommended risk management measures for the 'intended' uses. A downstream user will only have to report his use of a substance to the Agency, if he uses it in a way that was not intended by his supplier or if he disagrees with the recommended risk management measures. This report might under very exceptional circumstances include testing proposals if a downstream user considers them necessary. This reporting requirement will be phased in after the respective registration deadlines for the suppliers. Downstream users of substances in quantities of under 250 kg/year have no reporting obligation.

6. Evaluation

There are two types of evaluation under REACH:

1. Standard evaluation: Testing Proposals submitted by industry for substance-tailored testing involving animals, for substances above the 100 tonne threshold, will be subject to evaluation by a Member State Competent Authority (CA) to avoid unnecessary animal testing and to ensure high quality. Testing must then be performed and information submitted following the CA decision on the testing proposal.

Generally, the CA of the Member State responsible for the registration will also evaluate the testing proposals. It is proposed, however, that 'phase-in' substances should be allocated to Member States' CAs on the basis of their populations.

2. Priority evaluation: CAs may also perform a more in-depth evaluation of any substance. Such an evaluation is voluntary. For that purpose, the CA of a Member State may check the quality of information submitted in the registration and may ask for additional information if the quality of information submitted was not sufficient or if there is a reason for concern. A substance shall only be evaluated by one Member State at a time and any evaluation must be based on previous work.

To ensure consistency, decisions by individual CAs on further testing will be agreed through a Community-wide procedure. The Agency also has a key role in identifying any inconsistent application of the process. Disagreement between CAs can ultimately result in a Commission decision being required.

7. Authorisation

All uses of substances with intrinsic properties of very high concern will have to be authorised, once such a substance is identified in Annex XIII.

Such substances of very high concern are:

- category 1 and 2 CMRs;
- substances which are persistent, bioaccumulative and toxic (PBT);
- substances which are very persistent and very bioaccumulative (vPvB), and
- other substances, such as endocrine disruptors, that present an equivalent level of concern.

Substances to be authorised will be identified in Annex XIII along with a deadline for applications, and the date by which applications must be processed by the authorities. First priority will be given to substances where regulatory action will have the greatest impact on the protection of human health and the environment.

Prior to inclusion in Annex XIII, some PBTs and vPvBs, and certain other substances giving rise to similar levels of concern will have to be identified on a case-by-case basis. A Member State initiating the procedure to subject such substances to the authorisation system, has to demonstrate that PBT or vPvB properties or equivalent properties of very high concern are present. This is subject to an agreement procedure, which may result in a Commission Decision in the event of disagreement between the Competent Authorities.

To obtain an authorisation, a manufacturer, importer, or downstream user will have to demonstrate that the risk from the use of a substance can be adequately controlled or that the socio-economic benefits outweigh the risk. Authorisation decisions for uses for which the risks cannot adequately be controlled, should take account of available information on alternative substances and processes that may replace the

use. To focus efforts on aspects of highest concern, authorisations will only consider risks from the properties that led a substance to be subjected to authorisation (if a carcinogen is also an irritant, the irritancy will not be considered).

Community wide authorisations will be granted by the Commission after considering a recommendation of the Agency in all cases where the applicant places, or intends to place, the substance on the market.

To simplify and lighten the system, an authorisation will be valid for enterprises further down the supply chain as long as they abide by the conditions of the authorisation for the intended use and inform the Agency.

Grouping of applications for authorisation is also possible, subject to justification by the applicant. Groups can be: manufacturers, importers and downstream users; substances; uses; or any combination of these groups. This is to enable costs to be minimised and to enable the system to process applications rapidly.

8. Restrictions

The restrictions process acts as a general 'safety net' for the whole REACH system. Any substance may be subject to restrictions (e.g. banning, or allowing particular uses under specified conditions), regardless of whether they are subject to registration or not. The restrictions process enables risk reduction measures to be introduced across the Community where they are shown to be necessary. Member States may suggest restrictions to be proposed by the Commission by sending a structured dossier to the Agency. The Agency will deliver an opinion to the Commission on the risks identified and the socio-economic impacts, taking into account alternative substances and processes. Restrictions will be adopted by a Commission Decision in a comitology procedure.

The Commission can also make use of the restrictions process to, for example, add new category 1 and 2 CMRs to the existing ban for consumer use or to implement relevant aspects of international agreements on persistent organic pollutants (POPs).

9. Agency

A newly created, independent Agency will be at the centre of the REACH system. It will play a key role in supporting the Commission, Member States and other actors with technical expertise and by establishing and running the IT infrastructure.

Through its expert Committees, it will advise the Commission:

- on priorities to set up the authorisation procedure,
- on applications for authorisations for the uses of substances of very high concern,
- on risk reduction measures for dangerous substances.

Furthermore, the Agency will help ensure a common approach between Member States, in particular in the evaluation stage and in enforcement issues. For the latter purpose, it will establish a forum of Member States to co-ordinate a network of enforcement authorities to promote a common approach to implementation of the measures.

The Agency will be established with an Executive Director appointed by the Management Board on the proposal of the Commission and responsible to the Board consisting of 15 representatives, including 6 nominated by the Commission. All Member States will be invited to make nominations for appointment to the Agency's Committees; the Management Board will appoint members on the basis of established competence. The aim will be to have nationals from all Member States, which make suitable nominations, present on the committees.

Most of the costs of the Agency will be met by fees fixed by the Agency and levied on enterprises for registration and authorisation, the remaining costs will be met by funding from the Commission.