Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

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PURPOSE : to establish the European Chemicals Agency, and set rules on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH), and to amend Directive 1999/45/EC on Persistent Organic Chemicals. PROPOSED ACT : Regulation of the European Parliament and of the Council. CONTENT : the present system for general industrial chemicals distinguishes between "existing substances" i.e. all chemicals declared to be on the market in September 1981, and "new substances" i.e. those placed on the market since that date. New substances must be tested and assessed for possible risks to human health and the environment before they are marketed in volumes starting at 10 kg. Only 3000 new substances have been placed on the market. In contrast, existing substances amount to more than 99% of the total volume of all substances on the market, and are not subject to the same testing requirements. This has encouraged the continued use of "existing", untested substances and inhibited research and development and innovation. Other problems with the current regime include: - the risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively; - the allocation of responsibilities is inappropriate because the public authorities are responsible for the assessment instead of the enterprises that produce, import or use the substances; - only the manufacturers and importers of substances must provide information, but there are no similar obligations on downstream users (industrial users and formulators). - current liability regimes are insufficient to remedy the problems. Establishing a causal connection is often virtually impossible for injured parties if cause and effect occur far apart in time and if adequate test data on the effects of substances are not available. This proposal establishes the REACH system and creates a European Chemicals Agency. REACH consists of the following elements: 1) Registration - there is a general obligation to register substances manufactured or imported in quantities starting at 1 tonne. The registration provisions oblige manufacturers and importers of substances to obtain knowledge on the substances they manufacture or import and to use this knowledge to ensure responsible and well-informed management of the risks which the substances may present. Manufacturers and importers must address the risks of any use identified to them by their downstream users. A downstream user has the right not to identify a use, in which case he would have responsibility for performing a chemical safety assessment. Conversely, the manufacturer is not obliged to supply a substance for a use that he feels he cannot support. The Regulation exempts certain substances that are adequately regulated under other legislation or that generally present such low risks as not to require registration. Registration requires submission of a technical dossier containing information on the substance and information on risk management measures, as well as - starting at 10 tonnes -the chemical safety report that documents the choice of these measures. For the registration of substances in articles, a special regime applies: certain substances incorporated into articles have to be registered. This is required when the substance in questionhas hazardous properties, which will be released from the article. For substances that are released incidentally to the use of the article, a simple notification is required, on the basis of which the Agency may request a registration. These requirements for certain substances in articles are necessary because of their potential impact on human health and the environment. It should be noted that no declaration of contents in articles is required from importers. The provisions place the same duties on importers and EU manufacturers of articles. Polymers are exempted from the requirement to register. The Commission may introduce certain polymers into the requirement to register following a report on the risks posed by polymers in comparison with other substances and the need, if any, of registering certain types of polymers. A limited form of registration is required for certain isolated intermediates. The following should also be noted: - a number of rules regarding data sharing are set out in order to reduce testing on vertebrate animals and to reduce costs to industry; - information must be passed both up and down the supply chain, and between all actors in that supply chain; -downstream users must consider the

safety of their uses of substances, based primarily on information from their supplier, and to take appropriate risk management measures. For an identified use, a downstream user may use the risk management measures prepared by the manufacturer or importer but he must satisfy himself that the relevant exposure scenarios are consistent with his use and that he has implemented all the relevant risk management measures. Guidelines will be developed to ensure that this process is manageable, in particular for small and medium enterprises. If a downstream user is using a substance in a way not covered by a manufacturer's or importer's chemical safety assessment (including incorporating it into an article) or if he intends to use different risk management measures, then he must send a short report to the Agency. Downstream users are not required to submit chemical safety assessments to the authorities because the administrative burden on both industry and authorities would be disproportionate. 2) Evaluation - there are two types of evaluation: - dossier evaluation which is twofold again: - one aim is to prevent unnecessary animal testing. Therefore the Regulation requires authorities to examine proposals for testing in order to check the quality before a test is performed and to prevent the same animal test to be performed repeatedly; - the regulation gives authorities the task of checking the compliance of registration dossiers with the requirements of the registration title; - substance evaluation: provides a mechanism for an authority to require industry to obtain and submit more information in case of suspicion of a risk to human health or the environment. To promote a consistent approach, the Agency will develop guidance on prioritisation of substances for evaluation. Member States then prepare rolling plans of the substances that they wish to evaluate. 3) Authorisation - a system for uses of substances and the placing on the market of substances for such uses is established for the substances of very high concern. The substances selectedfor the authorisation system have hazardous properties of such high concern that it is essential to regulate them through a mechanism that ensures that the risks related to their use are assessed, weighed and then decided upon by the Community prior to actual use. In line with the general REACH approach, the requirements for the applicants under the authorisation approach are risk-based, as he has to demonstrate that the risks related to the use of the substance concerned are adequately controlled or that they are outweighed by socio-economic benefits. Substances of very high concern are defined as: substances that are category 1 and 2 carcinogens or mutagens; substances that are toxic to the reproductive system of category 1 and 2; substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative; and substances such as endocrine disrupters which are demonstrated to be of equivalent concern. 4) Restrictions - the provisions enable risk reduction measures to be introduced across the Community where this is shown to be necessary. The restrictions provisions act as a safety net for the whole REACH system as well as for the Community legislation as a whole because any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if a risk needs to be addressed. The Regulation creates the European Chemicals Agency (Agency) to manage the technical, scientific and administrative aspects of the REACH system, and ensuring consistency of decision making, at Community level. 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 Regulation also contains provisions on classification and labeling inventories, enforcement, and competent authorities in the Member States. The direct costs of REACH to the chemicals industry are estimated at a total of some EUR 2.3 billion over an 11-year period. The costs to downstream users of chemicals are estimated at EUR 2.8 to 3.6 billion over a period of 11 and 15 years respectively - if the market reacts as expected with 12 per cent of substances being withdrawn because continued production would not be profitable. Costs could rise to EUR 4.0 to 5.2 billion if industry faced higher supply chain adaptation costs. These estimates include the direct costs passed on from the chemicals sector to downstream users. The total costs for the chemicals industry and the downstream users are thus estimated to EUR 2.3 to 5.2 billion.