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

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The committee adopted the report by Guido SACCONI (PES, IT) tabling hundreds of amendments to the REACH proposal under the 1st reading of the codecision procedure. The report was produced by the Environment Committee, as the main committee responsible, in conjunction with two other committees involved under the "enhanced cooperation" provided for under Rule 47 of the EP's Rules of Procedure - the Industry Committee and the Internal Market Committee. It sought to strike a balance between the various concerns of those three committees, i.e. protecting health and the environment and also easing the burden on industry. It also incorporated numerous amendments tabled by the seven other committees asked for opinions. The key amendments focused on the following areas:

- **Duty of care:** the regulation should incorporate the general principle of the "duty of care" of businesses, i.e. the duty to avoid placing on the market products which endanger health or the environment. Producers would be required to "prevent, limit or remedy" any adverse effects and to inform downstream users of risks automatically and free of charge, so that those users can choose less harmful substances. Consumers and workers should also have access to this information. However, the duty to inform and prevent should not burden SMEs with excessive red tape, and, where appropriate, such businesses should be able to receive aid;

- **Registration:** on the controversial aspect of requiring producers to register chemicals and supply information on their properties, the Environment Committee proposed a compromise (not endorsed by the EPP-ED) whereby the requirements concerning the information to be supplied to the future European Chemicals Agency on substances produced in quantities between 1 and 10 tonnes would be eased. However, the Agency would be required to perform checks (on at least 10% of cases) and could withdraw registrations if the rules were evaded. In addition, proper chemical safety assessment reports would still be required where more than 1 tonne was produced. The other two committees tabled a series of amendments on this aspect, which, like the amendments tabled by the Environment Committee, would be put to the vote directly in plenary. The Internal Market Committee, in particular, wished to ease the information requirements where the quantity produced was less than 100 tonnes, rather than 10 tonnes. The Environment Committee also wanted substances contained in articles to be notified to the Agency if their concentration exceeded 1% and when the possibility of a hazard to the environment or health could not be excluded. It suggested that a 'European quality mark' be placed on articles manufactured in accordance with the REACH Regulation. It also added various entries to the list of products exempt from registration, particularly minerals, foods, polymers and substances for use in product and process orientated research and development (PPORD). However, these exemptions should not lead to discrimination between products and substances manufactured in the EU and those which are imported;

- **One substance, one registration (OSOR):** in accordance with the OSOR principle, various amendments adopted by the Environment Committee reinforced the obligation on businesses to exchange non-confidential data among themselves (in order to avoid duplication of applications). Exemptions would be possible for the purpose of protecting confidential information, but these must be granted by the Agency and on no account could the exemptions apply to data concerning tests on animals. The Agency would be required to publish a list of the substances already registered in order to make life easier for businesses and again to avoid duplication;

- Reducing experiments on animals: MEPs said that, where the required data necessitate experiments, they must primarily be carried out 'in vitro'. If alternatives to experiments on animals exist, their use should be compulsory. Businesses would also be required to communicate to the Agency all results of experiments on animals and all information which could make it possible to avoid experiments on animals, on pain of forfeiting their rights to registration. Moreover, the 6th Framework Programme of Research should include encouragement for research into alternative methods and the European Centre for the Validation of Alternative Methods (ECVAM) should be consulted before any experiment is performed;

- The role of the future European Chemicals Agency: to avoid confusion and duplication between the authorities of the Member States, and with the aim of promoting confidence, the Agency should be "in charge of the overall management of the REACH process". Many amendments dealt with the evaluation procedures, the composition and functioning of the Agency and the principle that it is to be independent and its work transparent, as well as laying down appeal procedures;

- Duration of authorisations: on the basis of the precautionary principle and the substitution principle, the Environment Committee wanted to see more stringent provisions, and felt that authorisations should be granted for a maximum of 5 years in order to encourage the development of alternative methods and substances. These authorisations would be open to revision at any time, particularly if new scientific data necessitate urgent measures. Hazardous substances should be authorised only where no alternative exists and on condition that measures are taken to limit the risks of exposure, particularly of those who are vulnerable, and provided that the social and economic benefits outweigh the risks to health and the environment. Tobacco products and sensitisers should be added to the list of the substances most hazardous to health.