REACH - worldwide model to control chemicals
European Parliament ENVI Committee visit to ECHA in Helsinki

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The REACH Regulation is the most ambitious and comprehensive chemicals legislation in the world. It aims to fill information gaps on the properties and risks of the majority of chemical substances on the EU market, and introduces a more rigorous system to minimise the risks to human health and the environment posed by hazardous substances.

On 8/9 April 2010, the ENVI Committee of the European Parliament visited the European Chemicals Agency (ECHA) in Helsinki to inform itself on-the-spot with the latest developments in the implementation of REACH. ECHA is at the heart of the new regulatory system for chemicals in the European Union. Its mission is to manage all REACH tasks by carrying out and coordinating the necessary activities to ensure a consistent implementation at Union level and to provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals.

ECHA got off to a good start in 2007 prior to its official opening in June 2008. The Commission spent significant resources in the 4 years leading up to REACH's entry into force. Draft guidance documents and IT tools were developed and staff were provided - 38 Commission officials were sent to Helsinki during the first year of operation to set up the agency. These preparatory activities are unprecedented in the establishment of comparable agencies.

Since then, the ECHA has successfully managed its first challenges. Ultimately, pre-registration numbers in 2008 vastly exceeded previous estimates with more than 2.7 million pre-registrations received from 65.000 pre-registrants, covering over 140.000 substances. Now, the ECHA faces its second crucial deadline on 30 November 2010. By that date, industry has to submit registration dossiers for all high volume substances and for certain categories of substances of concern. The expected number of registrations of existing (phase-in) substances and new (non-phase-in) substances is approximately 25.000, which is close to the original Commission estimate. ECHA also expects to receive approximately 1500 inquiries prior to registration, 300 notifications for substances undergoing product and process orientated research and development and to make 500 data-sharing decisions.

The EP delegation to the ECHA remains concerned that the number of pre-registrants during the pre-registration phase has delayed the creation of substance information exchange fora (SIEFs) and is also making communication between SIEF participants more difficult than expected. Consequently, by mid-2009, industry had only been able to provide limited information about the number of SIEFs and SIEF participants who intended to submit registrations by the 2010 deadline. Parliament will closely follow the future development of SIEFs and examine whether its objective, namely the exchange of information to avoid duplication of studies, can be met.

Shortly after the first registration deadline, ECHA faces its third deadline on 3

January 2011, as companies have by that date to submit notifications for their substances, irrespective of their volume of production or sale, in order to permit ECHA to set up a classification and labelling inventory under the CLP Regulation. 2 million CLP notifications are expected by January 2011.

It will be a huge challenge for ECHA to handle these registrations and notifications as well as the steady increase of scientific dossiers concurrently submitted by authorities: restriction proposals, proposals for the identification of substances of very high concern and proposals for harmonised classification and labelling. ECHA will also have to perform timely updates of the candidate list which it will recommend for inclusion on the authorisation list. The ENVI Committee has expressed time and again its concerns about the very limited number of substances on the candidate list of substances of very high concern. Almost 3 years after the entry into force of REACH, the consumer`s right to know about substances of very high concern in articles continues to be almost non-existent due to the very limited candidate list. To date, only 29 substances are on that candidate list, even though there are around 500 non-intermediate substances that meet in Parliament's view the criteria of a substance of very high concern. It is a step in the right direction that both Commissioners Tajani and Potocnik recently agreed on a road-map for the inclusion of 106 priority substances by 2012. Dangerous substances clearly need to be regulated earlier.

ECHA will also have to build up capacity for upcoming or accelerating operational tasks in view of assessments of applications for authorisations and the science-based evaluation of the large volume of registration dossiers for chemical substances that will have been received by the 2010 deadline. This will mean the handling of hundreds of test proposals and compliance checks with strict legal deadlines. ECHA will also take on responsibility for scientific support for the assessment of active substances and for aspects of products approval under the new biocides regulation which is currently being negotiated between the institutions at EU Level.

ECHA has now 378 staff and is expected to grow to over 500 within the next year. It is of crucial importance that sufficient human and financial resources are provided so that ECHA can master its Herculean tasks. Smooth implementation is key to the credibility of the world`s most ambitious and comprehensive chemicals legislation.