Lube-Tech

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REACH

The EU regulatory framework for the Registration, Evaluation and Authorisation of CHemicals

Background

After three years of negotiations the Council of the European Union at its 2773rd meeting unanimously adopted the REACH Regulation (registration, evaluation, authorization and restriction of chemicals), the cornerstone of the new European chemicals policy which replaces around 40 legislative instruments currently in force. In the framework of the codecision procedure, negotiations between the Council and the European Parliament took place over the last three months in order to reach an agreement in second reading so that this important piece of legislation could enter into force on 1 June 2007. The compromise package was agreed upon in the informal trilogue on 30 November 2006 and was adopted by the Plenary of the European Parliament on 13 December 2006.

Objectives of the new EU chemicals legislation

The Community chemicals policy aims at avoiding chemical contamination of air, water, soil and the human environment in order to preserve biodiversity and to safeguard workers' and citizens' health and safety. This policy seeks to balance health and environmental benefits with the need to sustain a competitive, innovative and job-creating European industry and the proper functioning of the internal market. In this context, the main objectives of the new REACH system are:

- To establish a coherent registration system designed to provide basic hazard and risk information on new and existing chemical substances manufactured in or imported into the EU;
- To reverse the burden of proof, moving it away from Member States' authorities to producing and importing companies, who will be responsible for demonstrating that substances can be used safely;
- To introduce responsibility for downstream users to provide information on uses and associated risk management measures relating to substances;
- To maintain the existing restriction system and to introduce an authorisation procedure for the most hazardous substances as a new instrument;
- To ensure greater transparency and openness for the public by providing easier access to relevant information on chemicals;
- To establish a European central entity (the Agency) to facilitate the administration of REACH and ensure that the system is applied in a harmonised way across the EU.

Main features of REACH

REACH will apply to all substances and for substances manufactured or imported in quantities over 1 tonne per year. Special registration and evaluation requirements will be introduced. This Regulation is expected to be applied to approximately 30,000 substances. The REACH system is based on the following:

- a initial phase of pre-registration which will take around 18 months and during which the Agency will inform companies of REACH new provisions.
- the registration of phase-in substances ("existing substances) will start three and a half years from the entry into force of REACH and in this first phase substances of high concern or substances manufactured or imported over 1000 tonnes. Registration of phase-in substances manufactured or imported between 10-100 tonnes will take place six years after the entry into force of this new Regulation. A period of 11 years is foreseen before starting the registration of low-volume substances (1-10 tonnes).
- the regulation also includes rules on the role of distributors and downstream users in the supply chain, especially as regards how manufacturers, importers or downstream users should react to information on identified uses provided by distributors and/or downstream users. The text also clarifies that downstream users can participate in a Substance Information Forum and the cases in which downstream users should conduct a Chemical Safety Assessment and prepare a Chemical Safety Report.
- the Agency, placed in Helsinki, will play a central coordinating role in the evaluation of substances carried out by Member States' authorities which have the required expertise in this field.
- the aim of the authorisation scheme is assuring that substances of high concern are properly controlled and to replace progressively such substances by less dangerous substances. Authorisations will be granted where an applicant can demonstrate that a substance can be adequately controlled or if this is not the case if the applicant is able to show that the socio-economic benefits outweigh the risks to human health or the environment arising from the use of substances.

Main key features of the EP-Council agreement in second reading

The negotiations between the Council and the European Parliament have been mainly focussed on the following topics: duty of care, communication of information, animal welfare, comitology, registration/data-sharing, the Agency and the authorisation including substitution.

- On **registration**, the compromise provides that seven years after the entry into force of REACH, the Commission shall review whether or not carcinogenic, mutagenic or toxic for reproduction substances (CMR substances) in the 1-10 tonnes band should be covered by a Chemical Safety Assessment; as far as testing methods for reproductive toxicity are concerned, the text in the common position was retained but the Commission will review these testing requirements twelve years after the entry into force of REACH.
- On the **Agency** the agreement reached stipulates on one hand that the European Parliament will appoint two representatives in the Managing Board. On the other hand, the selected candidate will be invited to make a statement before the European Parliament prior to his appointment as Executive Director.
- On **authorisation/substitution**, the compromise includes the following modifications of the Council's common position:
- persistent, bioaccumulative and toxic properties (PBT) or very persistent and very bioaccumulative properties (vPvB) substances identified under Article 56(f) have been excluded from the "adequate control route". Six years after the entry into force of REACH, the Commission will review whether or not to extend this to substances with endocrine disrupting properties;