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;

- When suitable alternatives are available taking into account the risk posed by the uses of the substance, a substitution plan shall be a mandatory part of an application for both the "adequate control route" and for the "socio-economic route".

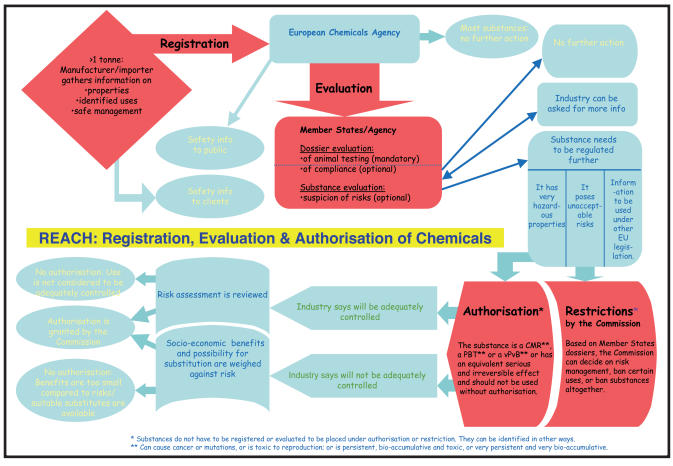
Next steps and entry into force of REACH

The President of the Council and the President of the European Parliament signed the Official Document on 18 December 2006. It will be published in the Official Journal and will enter into force on 1 June 2007.

REACH aims to improve the protection of human health and the environment through the better and earlier identification of the properties of chemical substances. The Commission believe that at the same time, innovative capability and competitiveness of the EU chemicals industry will be enhanced. The benefits of the REACH system will come gradually, as more and more substances are phased into REACH. Initially chemical polymers are not subject to REACH.

The REACH Regulation gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers will be required to gather information on the properties of their substances, which will help them manage them safely, and to register the information in a central database. The Chemicals Agency, based in Helsinki, Finland, will act as the central point in the REACH system: it will run the databases necessary to operate the system, co-ordinate the in-depth evaluation of suspicious chemicals and run a public database in which consumers and professionals can find hazard information.

The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified. But, if a socio-economic case can be made where no alternatives are readily available, we have been told that some specific chemicals may still be authorized for use.



As far as the **EU lubricants blenders** are concerned - the REACH process requires blenders to pass information on **product use** back up the supply chain, so that these uses can be include in the Registration process. End-users will need to be contacted to obtain this vital information and companies will need to check that suppliers have included these uses in their Registration application. It is <u>all important</u> to log all the specific uses in the Registration Process - otherwise your customers (users) will be precluded from using your products for these purposes. At a later date, Blenders will have to issue comprehensive safety information to product users, essentially the info' gathered by the REACH process from their raw material suppliers. This info' will almost certainly be provided, in the yet to be finalised Global Harmonization of Hazard Classification and Labelling System (GHS) format. Those companies that export to the EU or those that import into the EU will also have to comply with REACH.

All chemical and some lubricant companies involved in the EU lubricants sector who wish to continue to supply their products into the EU market, including US and overseas companies - whose activity includes reacting lubricant components (substances), such as additive manufacturers, grease makers and some other lubricants manufacturers, will all have to adopt the <u>full</u> REACH procedures. There is scope for groups of manufacturers producing the same substances (distinct molecules) to form a Group, such as grease-makers, and combine their REACH compliance application. This would allow the cost of compliance per member of the Group to be reduced by spreading these compliance costs over a number of manufacturing companies.

That's the basics of REACH, but we expect more details to emerge through the issue of the REACH Guidance documents, which are provided for new EU Legislation.

The next step: Strategic Partnerships

Strategic Partnerships are being set up to assist the development of procedures and identification of actions that can improve the workability of REACH. By involving stakeholders their understanding of REACH will also be improved. Strategic partnerships are voluntary and have no formal legal consequences, yet all partners can draw mutual advantages from participating in the project. So far two Strategic Partnerships have been advanced:

SPORT – the Strategic Partnership On REACH Testing.

SPORT was created to simulate the registration as well as the dossier evaluation steps of REACH. 29 chemical companies, the authorities from nine Member States, the European Chemicals Bureau and 25 companies using chemicals (downstream users) were involved in the project which started in November 2004. The work was carried out in eight sub-projects and covered about 50 substances. The SPORT Report, with the initial recommendations, was published in July 2005. For further information visit the SPORT website.

PRODUCE - A Strategic Partnership: Piloting REACH On Downstream Use and Communication in Europe

The main objectives of PRODUCE is, like SPORT, to try out the pre-registration, registration and evaluation steps in REACH based on case studies but with a stronger focus on downstream user's obligations, communication and cooperation in the supply chain.
The project was initiated by Unilever in early 2005 and ran until the end of the year. The results were presented at a stakeholder workshop at the end of January 2006. For further information visit the PRODUCE website.

Guidance Documents

UKLA is aware that the process of drawing up guidance documents has already begun and UKLA has been contacted and has agreed to be involved in the iterative process of refining the Guidance documents, so that they are workable and relevant to industry.

LINKS
www.sport-project.info/
www.producepartnership.be

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Automated water detection and removal from hydraulic fluids

Water contamination in a hydraulic and lubricating oil system not only reduces the service-life of hydraulic fluid, but also that of the machine's components. Investigations at different companies and institutes have clearly shown that free water in hydraulic fluids considerably reduces the service-life of the complete system.

Major problems caused by water in hydraulic systems are:
- Corrosion of metallic system parts
- Hydrolysis of the hydraulic fluid (degradation)
- Bearing wear
- Premature blockage of filters (dependent on reaction products)
- Chemical degradation of hydraulic oil additives

Plus, if water ingress has been detected too late, high repair costs and expensive lost production are likely. When water ingress is detected machine users need to take very swift action, to avoid expensive repairs and lost production. There are two possible actions for larger plant; a complete replacement of the hydraulic fluid or the use of an expensive vacuum drying process. Plant with smaller hydraulic volumes, typical of those found at SMEs, can use an adsorption dehydration process to remove water.

After a detailed market analysis, Mahle have developed a new concept for water detection and removal. In 2001, at the Hanover-Fair, the results of this new project were presented to the experts and they have shown great interest. A demonstration system (see picture 1) showed the function of the turbidity sensor and of the water separator (coalescer).

1. Demonstration system

How can water contamination be identified simply?

There are a number of different options, together with their related instrumentation, available in the market for the measurement of water contamination in hydraulic oils. Some of these recognise the water qualitatively, others quantitatively. Some methods analyse the dissolved water while others the available free water. Operators have to make a choice when they seek to measure water content. Furthermore, all these systems have a common factor; they are all reasonably expensive and most require operators to incur additional costs related to calibration.

2. Turbidity sensor

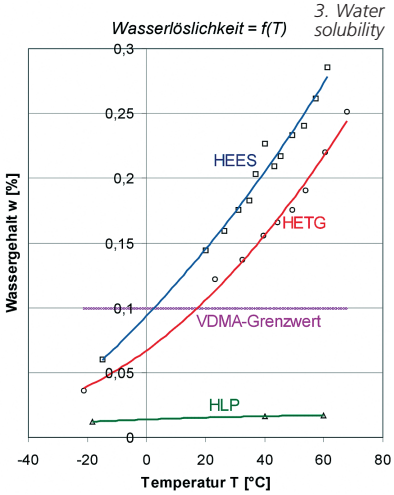
How does the new MAHLE turbidity sensor work?

Mahle's technology uses a light beam that is split into two beams that are used to penetrate the hydraulic fluid. After passing through the fluid these beams focus on sensors. This method allows interference factors to be eliminated from the calculations e.g. light source ageing. Best practice requires operators to ensure the optimal condition of their hydraulic fluids. The proposed turbidity sensor system provides positive evaluation, as it allows definition of optimal conditions and this information is logged and stored via a push-button set-up. Further calibration measurements are not required. If water enters the hydraulic circulation system, there is an increase in turbidity of the hydraulic pressure fluid and the light beam signal reduces. The data stored are compared and the electronics recognise the change and sends the operator a signal. The sensitivity of the turbidity sensor can be adjusted on site and at the front of the turbidity sensor (see picture 2), is a G1-thread connection used to attach the sensor to the machine. The turbidity sensor should be correctly sited within the hydraulic circuit using this connection. It is recommended that the turbidity sensor is integrated into the return pipe or directly into the tank near to the return flow. The system has been designed to have a 10-year service-life. The system's electronics will inform the operator if there is a component failure, such as the light source or some other component.

Not only dissolved, but emulsified water, leads to turbidity plus water solubility also has to be consideredand that depends on temperature. In picture 3, water solubility of three hydraulic fluid groups is graphed. The water's solubility of the HLP is very low and depends on the temperature. Data for the HEES and HETG are not so clear, which means that small water concentration can only be measured in a cold hydraulic fluid.

Connection details

There is a connection plug (M 12 x 1.4 poled) with a switching outlet (200 mA) at the turbidity sensor. The signal from the turbidity sensor can be used to control other equipment and/or awarning device. The output for the sensor can be routed to a terminal on the machine floor or to the control centre. Additionally, it is also possible to connect a water separation device to the turbidity sensor.



3. Water solubility

The sensor can be adapted as a mobile unit or set up in station-arysystems and has protection to type IP 65. The system meets a number of other standards: EMV-compatibility, EN 50081-2-interferience emission, EN 50082-2-interferience resistance plus others.

How can water be removed?

According to VDMA-unit sheet 24568, the limit for water content of hydraulic fluid of HE-group is set as less than 1,000 ppm (0.1%). There should be no free water available in HLP group. Free water always results in turbidity, which is visually recognisable. When viewed physically, turbidity is a two-phase mixture (emulsion) resulting from fine water droplets in the hydraulic fluid. To remove the water, it is necessary to perform a mechanical separation of these water droplets. This process is conducted in a coalescer. Coalescers are available in a number of sizes and the appropriate one should be selected. At the first stage the finest water droplets are collected and brought together to a larger unit. These droplets sized around a millimetre leave the coalescer layer and interact with a special hydrophobic equipped fabric. A separation of the hydraulic fluid takes place there. It is important to ensure that differential pressure limits are not exceeded in the coalescer. In addition the viscosity should also be considered for smooth efficient operation. The coalescer's operation can be set to a fully automatic mode. For this, there are different possibilities of control, e.g. differential-pressure controlled volume flow with a pump or also regulation of the volume flow with a pressure limiting valve. The less emulsifying additives are available in the hydraulic fluid, the better the coalescer works.

As a consequence: plant that have this equipment installed can replace more costly special oils by a less expensive general purpose hydraulic fluid. Machines equipped with a turbidity sensor can immediately detect the failure and the installed coalescer with its bypass-flow connection (see picture 4) can spring into action to resolve the problem. After a short period of time, the hydraulic fluid is dry again. The cause of water ingress can be addressed without damage to the machine and / or any lost production.

Design parameters areavailable for hydraulic fluid groups HLP, HETG and HEES. Details must be clarified for each application.

Conclusion: This newly-developed inexpensive turbidity sensor can quickly record water (above the absorption point) and when installed together with the new coalescer, water can be speedily removed. A large range of applications for both systems is available. A patent has been applied for the system.

Reinhard Wierling, IITL
Öhringen

LINK
www.mahle.com

4. Coalescer with automatic air bleeder