Lewmax
programming

REACH Regulation

Lewmax Programming Limited
Unit 1, Meridian South, Meridian Business Park,
Leicestershire, LE19 1WY, United Kingdom

Tel : +44 (0)845 519 3838
Fax : +44 (0)116 263 0985
e-mail: sales@lewmax.co.uk
website: www.lewmax.co.uk

FOREWORD

It has been estimated that one in three of all occupational diseases recognised in Europe every year are caused by exposure to workplace chemicals. In the UK the TUC believes that around 18,000 deaths a year are caused by cancers due to work-place exposure. There are also many tens of thousands of others who suffer from skin problems, breathing problems or neurological damage caused by exposure to chemicals.

At the moment there are a confusing range of European directives covering the manufacture of chemicals but, not only are they complicated, they do not really work. At present there are many chemicals in use which we know very little about from a safety point of view. The burden of proof is on the authorities to show that a chemical is unsafe before they can impose any restrictions. In addition different rules apply to new and existing substances so many chemicals that have been on the market for some time have never been properly tested. At the same time the different rules applying to new and existing chemicals means that employers are often discouraged from introducing new substances to the market and instead could be more likely to use existing untested chemicals which might actually be more dangerous.

The new regulations will ensure that, within 11 years, we will have much better information on around 30,000 different substances. There will be one single system and the burden of proof will be on industry to demonstrate how a chemical can be used safely.

The REACH Policy is a key document of Lewmax. The Company is committed to the protection and the health and safety of its employees, customers and neighbours.

It is the intention of Lewmax to meet all its legal obligations under REACH, but given the complexity, this legislation is still being evaluated. At present, there are no plans to withdraw any Lewmax product because of supplier registration issues and we have not been informed by our suppliers of any raw material withdrawals.

If the situation changes with any of our raw material suppliers then we will communicate with those customers potentially affected at the earliest possible moment.

This detailed publication comprises the latest revision of the Lewmax Environmental Policy, as approved by the Lewmax Board of Directors in August 2009.

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1 The position of Lewmax on REACH

Although Lewmax is a distributor, the Company does not fall outside the scope of REACH. We will be working in cooperation with our suppliers to ensure that any products imported or purchased within the UK containing any raw materials are themselves registered.

The REACH legislation will have a significant impact on all manufacturers, importers and downstream users in the EU, which will demand close collaboration across all supply chains. In the future we may be contacting our customers to provide additional information and also ask for information on the product's use.

Lewmax fully supports the underlying goals of REACH, which include placing a much greater responsibility on industry to manage the risks that chemicals may pose to health and the environment. This is consistent with our own commitment to promote the responsible use and handling of the products we distribute.

We are continuing to work with our industry colleagues to develop implementation guidelines for the industry.

A key priority for Lewmax at this point is to prepare for the implementation of REACH, both internally and externally.

This will include coordinating closely with our customers and suppliers to gather all of the required information on the products we sell and those we buy.

Please do not hesitate to speak with one of our customer services or sales team members, if you have any questions regarding this matter.

2 What is REACH?

REACH is a significant new piece of European legislation. The acronym stands for:

- **R**egistration
- **E**valuation
- **A**uthorisation
- and restriction of **CH**emicals

It is the system for controlling chemicals in the EU/EEA. It became law in the UK on 1st June 2007.

The new regulation replaces numerous European Union Directives and regulations and places the responsibility squarely on to the chemical industry to demonstrate the safety of its products.

Approximately 30,000 chemicals will have to be registered over an 11 year period following the legislation's enactment on 1 June 2007.

The European Commission believes REACH will deliver significant benefits by:

- providing a very high level of protection to human health and the environment;
- fostering innovation within the EU chemicals industry and ensuring high safety standards for its products and providing a single EU regulatory system with a streamlined decision-making process and clear timelines.

REACH covers most chemical substances that are manufactured in, or imported into, the EU. This can be:

- A substance on its own
- A substance in 'preparation' form (a mixture, for example, ink or paint)
- A substance that makes up an 'article' (an object that is produced with a special shape, surface or design, for example, a car, a battery, clothes, etc).

The REACH regulation distinguishes between substances, preparations and products as well as between users, downstream users, manufactures and importers (e.g. dealers).

Under REACH, the typical distributor is regarded as a dealer who procures products.

If he procures his goods from EU states, he has no direct obligations under REACH.

He must assume that the products are manufactured in accordance with the legal regulations, i.e. that the substances they contain have passed through the REACH procedure.

The situation is different when it comes to the procedure for products that originate from any of the non-EU countries.

If the distributor procures goods from outside the EU, according to the REACH regulation, he is regarded as an importer.

According to article 7 of the REACH regulation, this may imply an obligation to register. This article governs the registration and/or disclosure of substances in products.

REACH applies to all chemical substances of at least one tonne or more in volume that are manufactured in, or imported into, the EU each year.

The REACH Regulation gives a much 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 chemical substances, which will allow their safe handling, and to register the information in a

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central database run by the European Chemicals Agency (ECHA) in Helsinki. The Agency will act as the central point in the REACH system: it will manage the databases necessary to operate the system, co-ordinate the in-depth evaluation of suspicious chemicals and also run a public database in which consumers and professionals will be able to find hazard information.

The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

Everyone in the chemicals supply chain has a role to play in the implementation of REACH. Each party needs to be aware of their respective obligations and be prepared to communicate information on product usage and safe handling procedures, up and down the supply chain.

3. The Customer

As a customer, it is important to ensure your supplier within the European Union (EU) registers the product for the ways in which you use it. In support of this, be prepared to provide information to your supplier about how you use the product. You should pay particular attention to the potential for human and environmental exposure.

Make sure you review the safe handling procedures proposed by your supplier and inform the supplier if these procedures are not applicable in your workplace. If your supplier is outside the EU, you may have obligations as an importer – see next section.

4. Importers

As an importer of a product into the EU, you may have registration obligations. As a non-European company cannot register substances under the REACH regulations, how can a non-European company achieve REACH Registration to ensure that they can continue to do business in the EU?

In these circumstances you may need to appoint the services of an “Only Representative”. This can have many advantages:

- An Independent third party takes on all obligations of the importers under REACH. The Importers then become downstream users.
- If an importer registers a particular product the importing company will own the registration. It may then be more difficult for the manufacturer to expand or change the route to the European market.
- If an importer changes supplier the non-EU manufacturer may then lose access to the European market.

5 Suppliers

As a supplier, you are required to understand how your product is handled throughout the supply chain. This information is important, in particular the potential for both human and environmental exposure, will be required in your substance registration or that of the original EU manufacturer or importer.

6 REACH in more detail

This is a complex piece of legislation that will affect manufacturers and importers of chemicals, preparations (such as adhesives, paints, etc.) and “articles”, which include all types of electrical components, sub-assemblies and equipment. There are no exemptions for such as transport, aerospace, etc.

These regulations have been adopted because of the many thousands of high volume chemicals used in the European Union. Today there is no risk data available on 21% of them, inadequate data on 65% and only 3% are fully tested. This means that it is almost impossible to choose a “safe” substance due to a lack of data. REACH aims to ensure that all substances are fully tested.

The main emphasis is on the most dangerous substances and on those used in the largest quantities. The lower limit is 1 tonne per annum per producer. Therefore, if you are an importer of a substance that has a specific use, and if you use less than 1 tonne per annum, there is no need to register although you should pre-register if you expect sales to exceed 1 tonne in the future.

Usually chemical manufacturers will register but equipment producers will be affected. They should at least ensure that their suppliers have registered all of the chemicals they use and specified how they are used, the quantities and in what applications. Manufacturers who import unusual chemicals for their own use (>1 tonne p.a) will need to register these materials.

Essentially, most substances will need to be registered (there are some exemptions) otherwise they cannot be used. Certain more dangerous substances that will be classified as “Substances of Very High Concern” (SVHC) will need to be authorised before they can be used and authorisation will not be given if alternatives exist.

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When chemicals are registered, it will be necessary to submit toxicological information, physical properties data and any relevant information on environmental effects etc. to the European Chemicals Agency (ECHA). Where this data does not already exist, it will be necessary for the manufacturer or importer to generate this data and it could be very expensive.

Industry predictions are that the cost of producing data for a substance (if >1000 tonnes p.a. is used) that has no existing data available, could be as much as £2.5 million. If future profits do not justify this expense, the chemical will be removed from the EU market and there are already indications that some chemicals will be withdrawn, rather than registered. The result will be that materials and preparations are suddenly withdrawn from the market.

What precautions can design engineers take to guard against this? It will not be easy but measures include:

Determine the composition of materials and their preparation and whether any ingredients are unusual and so might be withdrawn. Chemicals used in very large quantities (this could be by other industry sectors) will almost certainly be registered, even if the data has to be generated and so are unlikely to be withdrawn. Ask suppliers if the substances and preparations that you use will be registered and continue to be sold in EU. They are under no obligation to tell their customers and may evade the question.

Where there is doubt it might be worthwhile considering alternatives should the current material be withdrawn. It is widely known that some chemical suppliers are planning to withdraw some certain chemicals although they will not publicly admit that this is the case.

REACH could add more substance restrictions. These are likely for any substance that is regarded as a SVHC, which include carcinogens and toxic substances. Examples will almost certainly include lead, cadmium, mercury, arsenic and beryllium as metals and their compounds.

REACH will affect the use of SVHCs in the production processes of some (solvents, plating chemicals, etc.) as well as when they are present in finished products. One example is hexavalent chromium which is a carcinogen and is used for hard chrome plating although there is no hexavalent chromium present in the product, only chromium metal. It is worthwhile avoiding any substance that might be regarded as a SVHC if this is possible in both the production processes for making new products and in finished goods, even if they are not currently restricted by either RoHS or the Marketing and Use Directive. It is likely that REACH would impose significant costs even if restrictions are limited.

European manufacturers may consider avoiding the cost of REACH by manufacturing finished products outside of Europe. This will certainly avoid the need to consider process chemicals but REACH also includes substances that are intentionally released by a product or if release is foreseeable. The actual interpretation of this requirement is not yet totally clear but may extend to substances that are present and are released during recycling at end-of-life.

Lead in glass, ceramics or solders in equipment will not be released in normal use but can possibly be released during recycling processes and, as this is foreseeable, it could mean that the lead will need to be registered and also authorised if it is classified as a SVHC. If alternative materials or processes exist, SVHC authorisation will not be granted and so designers should try to find substitute materials wherever possible in new products, even if they are not manufactured in Europe. Registration of all “releasable” substances may also be required in the future.

When considering the design of a new product such as a printer for example, there are several issues to consider:

The ink in the print cartridge used for ink jet printers is a “preparation” and so will need to be registered.

- Many chemicals and preparations are used to manufacture the product: solvents, inks, paints, coatings, etc.
- Ensure that the suppliers have registered all of these materials, and that there are no chemicals present that are likely to be withdrawn, or will be classified as SVHCs.
- The printer will be recycled at end-of-life and this will release mainly metals: tin, lead, copper, etc. If the authorities decide that release as a result of recycling is within the scope of REACH, then as some of these could be SVHC, they will then need to be authorised before they can be used. Check that suppliers have registered all substances that will be released during recycling.

7 Exceptions

As with every other law, there will always be an exception to the rule. In this case the type of substances contained within products falling within the scope of the following European Directives and Regulations are exempted from the following parts of REACH:

Title II (Registration);
Title V (Downstream Users);
Title VI (Evaluation) and
Title VII (Authorisation).

7.1 Medicinal products [Article 2(5)(a)]

- for human use within the scope of Directive 2001/83/EC;
- for veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC.

Food and Feeding stuffs in accordance withRegulation (EC) No 178/2002 [Article 2(5)(b)] including use.

- as a food additive in foodstuffs within the scope of Directive 89/107/EEC;
- as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Directive 1999/217/EC drawn up in application of Regulation (EC) No 2232/96;
- as an additive in feeding stuffs within the scope of Regulation (EC) No 831/2003;
- in animal nutrition within the scope of Directive 82/471/EEC.

Substances contained within products in the finished state, intended for the end user, falling within the scope of the following European Directives and Regulations are exempted from the following Parts of REACH: Title IV (Information in the supply chain) [Article 2(6)]

- Medicinal products (as per the earlier bullet point);
- Many market cosmetic products as defined in Directive 76/768/EEC;

Medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as Directive 1999/45/EC;

- Food and feeding stuffs (as stated earlier).

As described in Article 2(7), there are further groups of substances exempted from the following Parts of REACH: Title II (Registration); Title V (Downstream Users); Title VI (Evaluation). These groups are:

1. Substances covered by Annex IV or V;
2. Substances specifically named in Annex IV, as sufficient information is known about the intrinsic properties of these substances that they are considered to cause minimum risk;
3. Substances covered by Annex V, as registration is deemed totally unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation.

Further details of exemptions covered by Annex V are given in the following section.

Substances that, on their own, or in the form of preparations, have been registered and are exported and then re-imported in the same supply chain, show that:

- the substance being re-imported is the same as the exported substance;
- they have been provided with the information in accordance with Articles 31 or 32 of the REACH directive relating to the exported substance.

Note: The advice of the European Commission and the European Chemicals Agency is that this exemption applies only when a substance has been fully registered and does not exempt re-imported substances from pre-registration.

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8 COMMON QUESTIONS AND ANSWERS

8.1 What are the goals of REACH?

The main objective is to protect human health and the environment by ensuring safe handling of chemicals throughout their lifecycle. The REACH Regulation is based on the principle of self-responsibility. In other words, chemicals may only be introduced if there is sufficient data on their properties (physical properties, toxicity, environmental impact, etc.). That makes producers and importers responsible for the safe handling of chemicals. They have to compile the data required for evaluation and make it available to all stages in the supply chain.

8.2 Which substances will REACH affect?

The new legislation applies to all chemical substances produced in the EU or imported in amounts of 1 tonne or more p.a. All chemicals that meet this criterion will have to be registered with the new European Chemicals Agency in Helsinki, Finland. The larger the quantity produced or imported, the more properties have to be evaluated. REACH does not require information on products that are not classified as hazardous and those where production is less than 10 tonnes p.a.

8.3 So, have these chemicals not been tested in the past?

REACH abandons the previous distinction between “existing chemicals” (i.e. products that were placed on the market before 1981) and new substances (introduced after 1981). New substances already have to be tested and evaluated for a range of risks to human health and the environment before they can be marketed. Unlike the roughly 4,000 “new” substances, whose potential risks are know, very little is known about the approximately 100,000 substances defined as “existing chemicals”. REACH will alter that.

8.4 What does that mean in practice?

Users are required to provide extensive information for their suppliers and customers. For example, suppliers must be notified of all applications of the chemicals purchased. They are required to take these applications into account in their chemical safety report. Based on this evaluation, the revised and expanded safety data sheet must contain details of how to ensure safe handling of the substance.

8.5 Does REACH also apply to textiles imported into Europe?

Finished products manufactured outside the EU are not subject to the legislation and under liberalised world trade agreements; they can be sold in Europe with virtually no restriction. Substances only have to be registered if use implies intentional release of the substance, for example, the ink used in a ballpoint pen.

8.6 What is the deadline for registration?

Relevant substances have to be registered between 2010 and 2018 to comply with the transitional arrangements set out in the REACH Regulation. The deadlines are between 3.5 and 11 years, depending on production volume and the properties of the substance.

8.7 Will REACH increase costs?

A number of improvements to the original draft were achieved during the legislative process. Nevertheless, implementing REACH will be one of the major challenges facing the sector in the coming years. The chemical industry will have to spend an estimated EUR 2 billion on additional tests and the production of over 80,000 registration dossiers.

8.8 How will the new legislation affect safety data sheets in the short term?

REACH introduced a new format for safety data sheets as of 1 June, 2007. Since the main additional data will only be required once each substance has been fully registered, the current changes only affect the format of the data sheets:

Section 2 Hazard Identification and Section 3 Composition/Information on Ingredients have been switched.

8.9 How will safety data sheets change in the long term?

As part of the registration process, usage and exposure data on each substance will be added. Lewmax aim is to support the widest possible range of applications for all products and substances.

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8.10 Can I produce a substance safety report myself?

You can produce your own substance safety report for a specific application and submit it to the European Chemicals Agency within 6 months. During this period you can legally continue to use the substance for your specific application. Applications not previously listed can be included in the safety data sheet without difficulty even after registration.

8.11 How will Lewmax be collaborating with customers on REACH?

Lewmax will be supporting its customers. We aim to merge and catalogue key data on chemicals and their conditions of use (if any). In the long term, our goal is to establish a standardised basis for communication, that would greatly facilitate our combined efforts. It is important that everyone in the supply chain provides documentary evidence that wide-ranging action has been taken to prevent harm to people and the environment.

8.12 Will Lewmax be withdrawing any products as a result of REACH?

At present we do not purchase or sell any products that fail to be covered by REACH. If there should be any changes in our products as a result of the registration process, which runs until 2018, we will inform our customers in good time and work with them to find the appropriate solutions.

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