

# Registration, Evaluation and Authorisation of Chemicals (REACH)

## The effects of new chemicals regulation on information security

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Since the regulations regarding Registration, Evaluation and Authorisation of Chemicals or REACH were issued by the European Commission, many organizations that operate on the European market have been struggling trying to find an answer to these questions. As documentation about the REACH regulations is already available from various sources we will focus in this article on the impact the regulation will have on the information systems of a wide range of organizations.



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Are companies which use chemical substances aware of the REACH regulation?  
 Do companies know what chemicals they use?  
 To what extent do these chemicals have an impact on people and our environment?  
 Are companies going to meet the deadlines set by the European Commission?  
 Do companies know what their role is in the supply chain regarding REACH?  
 How can companies effectively and efficiently register chemicals before the deadlines?  
 Who should have access to which information on the tonnages of chemicals registered?  
 Who actually has access to this information and are they allowed to?  
 Are confidentiality and integrity guaranteed when exchanging information with others?  
 Is intellectual property regarding chemicals safeguarded from theft?

In the daily work of an auditor REACH might be a subject that is discussed with the client or even part of the audit. Therefore we recommend (IT) auditors to read this article. REACH is of interest to (IT) auditors, as companies will have to rely on information technology to support the registration process. (IT) auditors play an important role in highlighting possible risks that might arise when companies implement these regulations. First, we will provide a brief overview of REACH and its impact on the industry for readers who are unfamiliar with the new regulations. Secondly, we will take a closer look at the implications on the IT in use by organizations to which REACH regulations apply. We will conclude this article with an explanation on how (IT) auditors can support these organizations to prepare for compliance and to protect their business from undesired effects.

### REACH background

The REACH regulation is a new European regulatory framework for chemicals. The goal of REACH is to improve the protection of human health and the environment. REACH is based on the idea that industry itself is best placed to ensure that the chemicals it manufactures and puts

**Figure 1:** Only ¼ of what goes in comes out as goods and services – can Chemistry in Europe do better?

(HLG Chemicals Innovation WG presentation 1st October 2007)



on the market in the EU do not adversely affect human health or the environment. It simplifies EU legislations in that 40 rules are replaced and creating a single system for all chemicals. The new regulation should also stimulate industries to make use of less harmful chemicals through innovation. The new regulation requires the industry to provide information on the chemicals used by each company. REACH will require that over a period of eleven years approximately 30.000 chemical substances that are used today are registered. This process allows to fill information gaps on the hazards of substances and to identify appropriate risk management measures to ensure their safe use. The proposal for the introduction of REACH regulations was adopted by the European Commission on October 29<sup>th</sup> 2003. On June 1<sup>st</sup> 2007 the REACH regulation came into force and new obligations will gradually be applied within the timeframe of eleven years. All companies operating within the European Union that deal with chemicals, have to comply with the REACH regulations. The day-to-day management of the new requirements will be carried out by the European Chemical Agency (ECHA), which is established in the capital city of Finland: Helsinki.

Companies that have to comply with the REACH regulation can be categorized as manufacturers, importers, downstream users, distributors or any combination of these roles. Companies are subject to obligatory responsibilities depending on the relevant role they have in the supply chain. REACH requires companies to *register* the knowledge and information necessary for effective risk management of almost all chemicals produced, processed or distributed within the European Union. The REACH registration process was designed as a collaborative process. For each pre-registered substance a Substance Information Exchange Forum (SIEF) is formed to facilitate the sharing of information and costs between companies within industries and supply-chains. For registrants of a substance participation in the SIEF is obligatory after pre-registration, but they are free to decide how collaboration will be organized. The information provided by the industry allows for *evaluation* of the possible risks involved with each

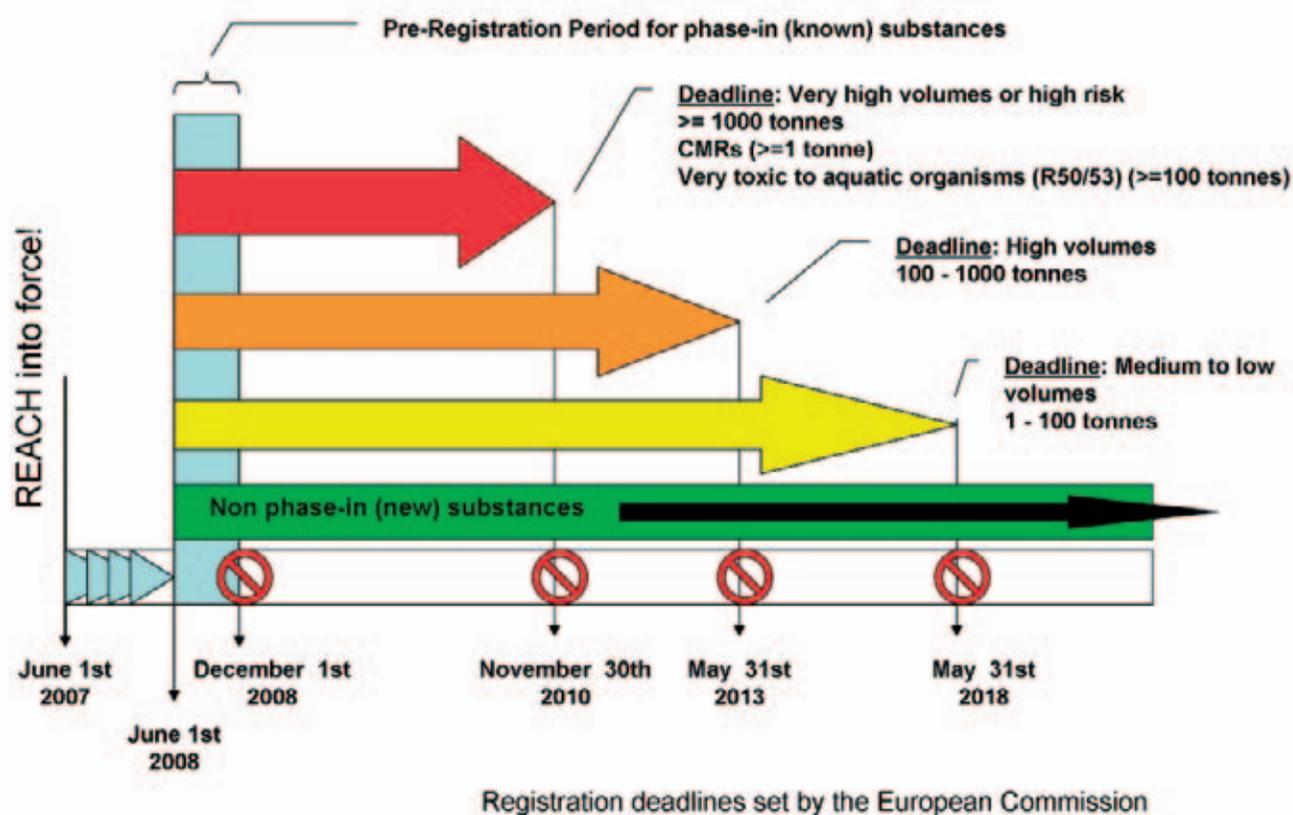
chemical substance by the ECHA. For the use of substances regarded to be of high concern an *authorization* system is in place. The use of these hazardous chemicals is not banned, but for the use or distribution of these substances one has to apply for authorization. If an unacceptable level of risk is identified during evaluation of a substance the use of it will be completely banned.

The REACH regulation is expected to generate a flow of information about the risks inherent in the use of substances throughout the entire supply chain. The first phase of REACH is pre-registration, which is required for manufacturers and importers from June 1<sup>st</sup> to December 1<sup>st</sup> 2008. Any substance that was not pre-registered by a company within this timeframe requires full registration, which is a much more extensive procedure. For all pre-registered substances the given timeframe for complete registration is extended. The deadline for completion of registration and submission of the required information is dependent on the level of risk involved in a substance and the yearly volume imported or manufactured by a company. A detailed timeline with deadlines for the completion of registrations was published (refer to Figure 3: REACH Registration Deadlines (Source: European Commission [1])). Companies that have not performed the required registration of chemicals will not be allowed to use the particular substances anymore. The risks of getting this wrong are enormous. Unless prepared for the registration requirements a company could find itself out of business. When hearing the word ‘chemicals’ people can easily come to believe that the new regulation will only apply to the chemicals industry. While the chemicals industry is indeed heavily affected by the new highly technical regulation, it has an impact on a wide variety of manufacturing industry sectors. Other industries which are also affected range from mining and the manufacturing of computers, textiles, pharmaceutical products, and indeed to some extent all products which may contain chemicals.

### Industry response

Now that REACH is into force large industrial enterprises, which are all strongly affected by the new regulation, have willingly responded to comply. While a large portion of the economic burden of REACH is to be carried by the large manufacturing and importing companies, they all state (for instance on their website) that they share the goal aimed at by the European commission. Large manufacturers such as Akzo Nobel, DSM, Shell, Dow Chemical and SABIC are preparing for registering the chemicals and the related properties within their organizations. They also actively seek collaboration with their suppliers, customers and even competitors. Controlled collaboration frameworks are being developed to enable formation and participation in consortia for the joint generation of the required information and the sharing of costs. Downstream users, such as the pharmaceutical industry expect to benefit from the REACH regulation. Pharmaceutical companies are actually set to benefit from

Figure 2: REACH Registration Deadlines (Source: European Commission [1])



### The economic impact of REACH

Before REACH came into force industry councils and governments of different European member states published criticism on the proposed regulation and showed their concern about the possible negative impact on European industries. In a 2002 report [4] by the European Chemical Industry Council (CEFIC), concerns were raised about the effect of REACH on international competitiveness of the European chemical industry [CEFI02]. The main concern was that expectations of high administrative costs would lead chemical production companies to relocate outside of Europe and others to go bankrupt, resulting in massive job loss and shortages of fine and specialty chemicals. In a 2005 study performed for Forfás<sup>1</sup> on the impact of the proposed regulation on the Irish industry [FORFo5] it was estimated that the chemical testing and administration costs to the upstream industry in the Irish industry would be over €180 million over eleven years. The cost to downstream chemical users was estimated to be even higher, at approximately €300 million. In Poland the ministry of economic affairs and labour made an impact assessment of economical impact of REACH on the Polish industry in 2004 [MINIo4]. The cost of REACH was estimated to be much higher in Poland due to the nature of the industry, which is small in scale and very diverse.

<sup>1</sup> Forfás is Ireland's Policy and Advisory board for Enterprise, Trade, Science, Technology and Innovation.

reduced testing requirements now that the new European chemicals regulation is in place and more information on substances becomes available. However, bulk manufacturers and ingredients suppliers could face increased burdens.

### Information technology requirements for REACH

The collection of chemical data required for the registration has to be performed with care. As companies are required to collaborate within industries or along the supply chain, the use of information technology to support the registration process is unavoidable. To enable a uniform, collaborative and open registration process software is provided at no cost to all stakeholders by the ECHA. The software consists of two main elements, which we will briefly discuss in this section.

### REACH-IT

The *REACH IT* system is hosted centrally by the ECHA and is made available online as a service to the various stakeholders. REACH IT consists of three main areas of interest. The first area of interest is the *Industry Homepage*, which is available to companies required to register chemical substances. It will offer functionality which allows them to enquire on, register and pre-register substances, and also offers private workspaces for online preparation of dossiers. The second area of interest is the *Authorities workflow*, which supports communication between ECHA and the different

European member states regarding the evaluation, classification and authorization of substances. Finally REACH IT contains the *dissemination website*, which is targeted at providing known non-confidential information of substances to the general public.

### IUCLID 5

The *International Uniform Chemical Information Database* (IUCLID) is a software application which can support companies with the management of chemical data. The first version of IUCLID was released in 1993 and has been modified throughout the years to meet the changing requirements. The latest version, IUCLID 5 released in 2007, is completely renewed to enable REACH-conforming registration of chemicals. IUCLID 5 was developed to be used on-site by companies to which REACH applies. The software comes in two versions: a two-tier version for use on stand-alone computers and a three-tier version for use in a network environment with multiple users. IUCLID 5 uses XML technology to facilitate easy exchange of data and dossiers. IUCLID 5 enables companies to easily exchange company information and chemical data with regulatory authorities, third-party applications and other installations of IUCLID 5 in use by customers, suppliers and competitors. IUCLID 5 was designed with collaboration in mind, which is why data exchange is expected to occur very often.

#### The impact of REACH on information security

The availability of software tools that enable companies to manage their chemical data, share information with other parties involved and build dossiers online is very convenient and should reduce the effort required for the registration process. It also sets a standard for registration of properties for any chemical substance that is used. On the other hand, the use of this software introduces new risks which, when not properly managed, can result in significant damage to a company's assets, market position and reputation. Only information intended to be shared should be made available to other parties, while confidential company information and classified chemical data should remain hidden from competitors and the general public. The information generated by an organization or obtained from suppliers, which is used within the organization's own processes or is distributed to customers, should be complete and reliable.

IUCLID 5 contains mechanisms designed to ensure data integrity and has built-in functionality which allows organizations to manage and restrict user access. It is important to emphasize that while these features enable mitigating the risks, they do not make the system perfectly water proof and will not guarantee data integrity and information security. Therefore it is important for organizations to have controls in place, which effectively allows them to determine who is able to access, enter, modify or submit data, both internally and externally. It is also important to have proper documentation on the control environment, which enables them to

Figure 3: IUCLID 5 main menu (source: European Commission)

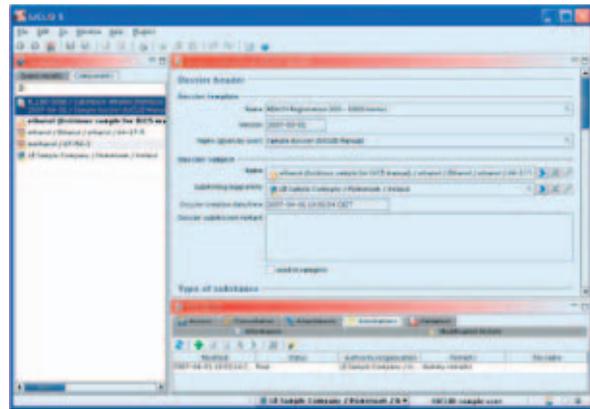


Figure 4: Failed user authentication in IUCLID 5 (source: IUCLID 5 design model v.2.3)



be trusted by their customers and suppliers. A properly documented control environment can be utilized by companies to communicate that any information provided by their organizations is reliable and that any information supplied to their organizations is secure.

#### How (IT) auditors can help organizations to efficiently comply with REACH

In this paragraph we will highlight how the expertise of (IT) auditors can help companies to effectively achieve compliance with the REACH regulation. We will look into reliability of building, using and maintaining the IT systems used by companies to which the REACH regulation applies. Among other things (IT) auditors can:

- check compliance with the registration requirements;
- audit the security of the registered data on chemicals;
- help implement the new regulations in organizations affected by REACH;
- perform an audit of the organization which transformed its IT-systems;
- perform a software selection program and develop criteria which meet the new regulations;
- audit the classification and labelling of inventory of dangerous substances;
- perform an audit on the security of the IT infrastructure at the ECHA and Member State Competent Authorities.

Besides the above mentioned roles for (IT) auditors they can support companies to audit the so-called ‘interim strategy’, which covers all the practical activities to prepare the implementation of REACH. There are a number of elements to the interim strategy, the main ones being:

- An audit of the preparation efforts regarding the new IT formats and software to enable technical dossier development by industry and Member States and the submission of these dossiers to the Agency under REACH.
- An audit of the development of a work flow IT system for dossier handling by the Agency and the Member States Competent Authorities.
- The evaluation of prepared technical guidance which provide advice to industry, Member States and the Agency on the detailed requirements of the new system. Experts from Member States, industry and NGOs (non-governmental organizations) work closely together with Commission staff to manage the detailed technical work.
- Reviewing test results of elements of the REACH system in strategic partnerships.
- (IT) auditors can perform an assessment and certify the control framework that should ensure the confidentiality and integrity of company information processing. Certified organisations can use a certificate granted by an independent auditor as proof to customers and suppliers that a control framework is in place and working effectively.
- The software supplied by the ECHA to the industries for installation (IUCLID 5) or as a service (REACH IT) is designed to facilitate collaboration and frequent data exchange with a variety of different stakeholders and applications. (IT) auditors can be consulted for the development of an effective control framework to mitigate the risks through the use of these applications within an organization’s IT environment.
- (IT) auditors can perform system audits on a company’s installation of IUCLID 5 and the interfaces to the other applications to provide assurance about the reliability of these interfaces and provide companies with advice on possible opportunities to improve the use of the information systems to support the registration process.

### Concluding remarks

As new requirements related to the REACH regulations will be imposed on industries, companies will have to stay involved with the developments. To protect the people and our environment all companies performing activities with chemicals in the supply chain have to take their responsibilities. In this article we briefly discussed the development of the new regulations and how it affects companies. We have seen that large enterprises active on the European chemicals market are aware of their responsibilities, but it might be that not all companies in the supply chain are aware of the effects the new regulations will have on their business and which actions are necessary. We hope that we have provided you with insight in the implications of the new regulation for the different stakeholders and the role of IT within the

processes of registration, evaluation and authorization of chemicals. We also hope that you have become aware of the information security risks introduced by the new regulations and the need for organizations to manage these risks with proper care. We encourage the reader to stay informed about new developments on this subject and carry out further research on how knowledge of REACH is relevant within their own profession. ■

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