



Tips for registrations (1st revised on Nov 2008)

Introduction

The new European chemicals legislation, REACH, has been entered into force in this June. Basically, the implementation of REACH will demand extensive preparative work to any company involved. Consequently, companies industry should initiate concrete steps now - How to cope with the future requirements under REACH. From a general point of view these concrete steps have to take into account several aspects which may include are resources, timing, guidance, tools, processes, structures and awareness. In this document, three sections including (1) About the pre-registrations, (2) Internal preparation, and (3) Foundation knowledge of IUCLID 5 are described in brief to help industries to prepare the upcoming pre-registration stage of REACH.

About the pre-registrations

To prepare for REACH, as well as to meet the broader challenges of addressing public concerns with chemical use, companies need to develop and implement a batch of sophisticate and cost-effective tools for evaluating their product risks. The need to begin putting in place the processes for managing testing and evaluation to comply with REACH is a major near-term challenge, especially for the first stage of REACH, the pre-registration stage. The Objective of pre-registration is to ensure industry shares information and submits joint registration when REACH begins to execute. Any manufacturer/importer (M/I) who manufactures or imports a phase-in substance in quantities excess one tonne annually and intends to register this substance under REACH should therefore pre-register. If the M/I do not pre-register, he has to register the phase-in substances without delay when Title II "Registration of Substances" applies to phase-in substances. Thus, the M/I who does not pre-register cannot expect to rely on the support from SIEFs (Formed by pre-registrants after the pre-registration phase ends) and potential consortium (Joint submission).

Information requirements for all other substances subject to registration depend upon the quantity in which the substance is manufactured or imported. The reason for this is that, generally, the higher the quantity of a substance manufactured or imported, the higher the potential exposure to the substance to humans or the environment, and thus the higher the potential risk. Higher quantities therefore justify a greater amount of both data and a comprehensiveness of assessments that need to be submitted. For each substance a technical dossier is required whose content depends on the quantity of the substance manufactured or imported per year, the levels are set at 1, 10, 100 and 1000 tonnes. Theoretically, all substances which are intended to be release during use (including preparation and articles) are subjected to pre-registration. Indeed, if there is a preparation that consists of several phase-in substances, that preparation will require doing pre-registration for each substance separately.

Internal preparation for registration

The implementation of REACH will demand comprehensive work from industry. This work comprises amongst others the set-up of internal processes, awareness raising, enhancement of IT systems, the establishment of information platform, contacts to associations and authorizations as well as assessment tools. By the fact of this, company should adjust their management system to cope with the change bring up by REACH legislation. Section below shows some interim strategy that company could follow when adapting REACH.

I. Conduct a regulatory risk assessment

Find out which sectors of the company that will be affected by the implementation of REACH. And characterize the degree and nature of likely impacts. Company should first understand what chemicals the company manufactures, use and the impacts brought. Estimate the annual volume of each chemical manufactured, used or imported. Normally, CMRs should be the primary focus a company to pay attention, as they are most likely to be subjected to use restrictions and/or mandatory substitutes requiring phase-out by manufacturers and users in the medium term. In addition, work with chemicals which used in volumes over 1,000m.t./yr, because these chemicals will have to be registered within three years of REACH beings. Also company should understand supply chain uses of each chemical and communicate with users to gather exposure and use information and more effectively characterize supply-chain material flows.

II. Set-up corresponding IT system and technical units

The preparation of the new IT formats and software to formulate the technical dossier and submit these dossiers to the Agency within time frame, as well as the development of a database system for substance to fulfill further requirements of coming REACH phases.

III. Create an effective management plan

Determine what needs to be done, when and by whom. Convene the necessary functions and business units. Company should identify information the company is missing and actions needed to gather that information. Besides, company can develop a risk characterization process for products based on chemical risk screening and prioritization. Identify and evaluate advanced computer modeling tools being developed by various organizations, such as the European Centre for Eco-toxicology and Toxicology of Chemicals (ECETOC).

IV. Prepare management information systems (MIS)

'MIS' is a planned system of collecting, storing and disseminating data in the form of information needed to carry out the functions of management. Every enterprise have MIS can have at least one core

competency – that is, a function they perform better than their competition. By building an exceptional management information system into the enterprise it is possible to push out ahead of the competition. MIS systems provide the tools necessary to gain a better understanding of the market as well as a better understanding of the enterprise itself.

REACH compliance will require ongoing internal systems to track registration data. Determine whether changes should be made to existing systems or if new systems are required. Also, company should communicate in the supply chain and outside to develop partnerships and discuss how to meet all needs. Set-up a MIS can store all data related to REACH and phase-in substance in a central portal, which can assist management in understanding the effects of their strategies, and help to make an effective decision-making.

V. Develop an internal communications strategy

An internal communications strategy defines the formal communications mechanisms used for management and employee communications. Effective communications is an essential business component. The overall objective of this strategy is to create a culture of internal communications that reflects one organization with many valuable ways of working, and to help people understand individual and corporate communications responsibilities, which enable staff to work more effectively and efficiently towards the strategic aims of smooth implementation. Company should develop a cross-function effort which provides support, understanding and authorization for different level of company units and their unique supply chain. Defining an internal communications strategy starts with identification of the stakeholders. Because the needs of the various stakeholders may be significantly different, in order to build an effective information-flow system, it is always important to talk to representatives of the stakeholder groups (e.g. senior executives, middle management, line supervisors, first-line employees, representatives from remote sites, etc.).

Foundation knowledge of IUCLID 5

IUCLID 5 is the key tool for the Manufacturers and Importers registering substances and for the ECHA and Member State Competent Authorities for evaluating the data submitted by industry. It enables industry to compile a complete & REACH-conforming registration dossier and to manage these data on-site.

According to Article 10 of REACH a technical dossier and, depending on the tonnage band, a chemical safety report (CSR) has to be submitted by industry to the ECHA. A technical dossier is to be created **based on IUCLID**, which provides sections (13 sections in total). The dossier covers an identity of company and its substance, information on manufacture and uses, guidance on safe use, classification and labeling, exposure information (if applicable), and all standard information requirements set out in the

REACH Annexes VI to XI. Typically, IUCLID 5 can manage three types of information, which included (1) company / organization- -related information; (2) Substance-related information; and (3) Assessment reports (as attachments only). The Company/organization is the main actor in IUCLID. All information created or imported in an IUCLID installation is always associated to one Company/organization which is the owner of the dataset. In addition, all information describing a Company/organization is maintained in a specific IUCLID element called a Legal entity. On the other hand, all substance-related information is managed in the Substance dataset. This is the central core of information in IUCLID. It contains all data related to a chemical substance like the chemical identity including the substance composition, information on manufacture, use and exposure, information on the classification and labeling, and all required and available endpoint study summaries.

For more information, please visit:

www.echa.europa.eu

Chemical Safety Report (CSR)

For all companies who export their products to EU, with a substance in quantity is over 10 tonne per year, according to REACH regulation, a Chemical Safety Report is needed to fulfill the registration requirement. The CSR can be downloaded from this website:

http://reach.jrc.it/docs/formats/Chemical_Safety_Report_Format.dot

The main goal of the chemical safety report (CSR) is to document the chemical safety assessment (CSA), including its conclusions and results. This part is meant to assist the registrant to write a chemical safety report that documents the chemical safety assessment as laid out in Parts A to E of the Guidance on Information Requirements and Chemicals safety Assessment. The chemical safety assessment needs to be conducted according to REACH Regulation ((EC) No 1907/2006). The elements to be included in the report are listed in the format provided in Annex I, point 7 of the Regulation. The CSR should be readily understandable as a stand-alone document. The principles applied, the assumptions made and the conclusions drawn should be transparent. The key data should be easily identifiable without the need to revert to the underlying substance data sets (i.e. the IUCLID substance data set). All relevant information for the chemical safety assessment should be presented. The CSR is the source from which the information to be communicated further down the supply chain is to be extracted.

Writing the CSR

The CSR should enable all users to understand the chemical safety assessment and the scientific arguments that support the conclusions of the hazard assessment, and, if the substance meets the criteria for classification as dangerous or is considered to be a PBT/vPVB, exposure assessment and risk characterization. It is emphasized that key information in the CSR on hazard and exposure must be clearly

presented and justified, must be traceable to its sources and documented properly with regard to equations, units, references and calculation or IT-tools used. The CSR should be consistent on the assumptions with regard to hazard, exposure estimation and the recommendations in the exposure scenario. The assumptions on operational conditions and risk management must be traceable in the exposure estimation and consistent with the final exposure scenario in the CSR. This is needed to evaluate whether the exposure scenario, if present, is based on the conclusions of a chemical safety assessment and the recommended risk management measures are valid to ensure control or risks. Therefore, the CSR should clearly present the key studies or information for each section, document the key assumptions and provide an interpretation and conclusion narrative for each section. Key information that is present elsewhere (e.g. in the technical dossier³) should be presented in a brief table format and referenced, rather than repeat the details. A narrative interpretation and conclusion section is usually needed. When there are multiple sources of key data for hazard or exposure, the choice of the key information needs to be justified. This justification can also be reported in the “endpoint summaries” in the IUCLID 5 substance data set and then reported in the CSR.

Annex I of the REACH Regulation includes general provisions for assessing substances and preparing a Chemicals Safety Report (CSR). Section 7 of Annex I includes a format with standard headings that shall be included in the CSR. The CSR needs to contain

- i. Conclusions from the CSA. If results were derived by means of quantitative methods, details should be presented to allow an evaluator to reproduce the results. If results were derived by means of a qualitative (weight of evidence) reasoning, this should be reported.
- ii. For any endpoint in the hazard or PBT/vPvB sections for which no relevant information is available, the relevant section shall contain the sentence: ‘This information is not available’. In addition, a statement could be added if the information is not required for a tonnage band or that the results of the CSA do not indicate that it should be taken into account (e.g., when the CSA does not indicate an exposure-triggered risk to soil organisms as in REACH Annex X-9.4).
- iii. For any endpoint in the hazard section a statement that although the hazard information is or could be required, the information can be waived. This needs to be argued and documented in a weight of evidence or quantitative reasoning.
- iv. For any endpoint in Annex IX and X or REACH a testing proposal when needed.
- v. The reason why information on specific exposure pathways is not reported. This should be clearly stated and argued. The absence of exposure information need to be argued in order to evaluate if exposure based triggers have been correctly considered.

The information of each section of the CSR usually contain both

- i. Factual information on hazard or exposure. Where possible, overview information should be



presented in a table format, presenting the relevant information and identify the key information or study.

- ii. A narrative and an interpretation of results for the chemical safety assessment.

For more details about writing CSR, please download the official guidance from the following website:

http://reach.jrc.it/docs/guidance_document/information_requirements_appendix_part_f_en.pdf?vers=20_08_08