Jul 1st, 12:00 AM

REACH-IT: The European regulation on chemicals and the impact of information technology

Gerlinde Knetsch

Follow this and additional works at: https://scholarsarchive.byu.edu/iemssconference

REACH-IT: The European regulation on chemicals and the impact of information technology

Gerlinde Knetsch, Federal Environment Agency, Woerlitzer Platz 1, D-06844 Dessau,

Germany, Gerlinde.Knetsch@uba.de

Abstract: REACH is the Regulation in the European Union for Registration, Evaluation, Authorisation and Restriction of Chemicals. This EU-Regulation 1907/2006 [EU 2006] is entered into force on 1st June 2007 to streamline and improve the former legislative framework on chemicals of the European Union. REACH places greater responsibility on industry to manage the risks that chemicals may pose to the health and the environment. In principle REACH applies to all chemicals: not only chemicals used in industrial processes but also in our day-to-day life, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. The concept of REACH in a short term means: No data – no market!

The data management and the handling of large data bases require the use of several tools and methodologies. To ensure support to all REACH processes, Information Technology tools have been developed to store and exchange information and data on chemicals: REACH - IT, the portal for the management of the workflows, including the management tools to control and operate the processes, the data base management system with the application of IUCLID 5 – the International Uniform Chemical Information Database. The European Chemical Agency [ECHA 2008] is the central management head quarter to tackle all these processes.

The aim of the REACH-IT Project is to develop IT-support for the implementation of the REACH legislation and to fulfil their duties and obligations as defined in the REACH Legislation, Art. 111. This IT – applications underpin the daily work of the Agency (ECHA) and the Member States Competent Authorities (MSCAs), enabling them, to communicate together with Industry in an electronic manner.

Keywords: REACH; Chemicals; International Uniform Chemical Information Database; IUCLID, Chemical Safety Reports;

1.   INTRODUCTION

Information and communication technology (ICT) plays an important role in the European economy. Computational infrastructures and networks, with well documented data and information, underpin the possibilities to deliver target oriented messages to politicians and the public on a regional, national and global level. So, ICT has an impact for the well being of citizens in the world. ICT brings together various databases containing, for example, information about chemical substances and their properties, their behaviour and effects on

the environment and in human beings. Consequently ICT has been an innovation factor in our society, particularly from the point of view of "Green IT".

1.1 Issues of the FEA

The Federal Environment Agency (FEA) of Germany is one Competent Authority of the European Member States nearby other involved with the data management of chemicals. For more than 20 years the German Environmental Agency (FEA) has been designing and producing complex environmental and chemical databases [Knetsch 2009]. The Information System on Chemicals (ICS) and the Joint Substance Data Pool of Germany (GSBL www.gsbl.de) are two reference projects.

Reliable information on the environmental state and properties of chemical substances and preparations is of immense importance for all areas of environmental protection and for averting danger. Regarding the information and technology aspects of the REACH-Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures [EU 2008] our Agency contributes to the implementation of REACH-IT.

2. OBJECTIVES

The aim of the REACH-IT project is to develop IT-support for the implementation of the REACH legislation [ECHA 2008a]. That means the development of concepts for IT-tools and applications, the harmonization of the formats for data exchange and reporting, the design of websites and the implementation of portals for data dissemination. "Headquarter" for coordination and cooperation is situated in the European Chemical Agency in Helsinki (ECHA). The Working Group of REACH-IT underpins the realization of these objectives. Members of this Working group are the Member States Competent Authorities (MSCAs), the European Chemical Industry Council (Cefic) and the European Commission.

Figure 1 shows a system overview of the interaction between the main actors of REACH. Information Management Tools (REACh-IT) and complex data bases with a software application (IUCLID 5) underpins the Data and information flows between Industry, Agency/MCAs and the Public.
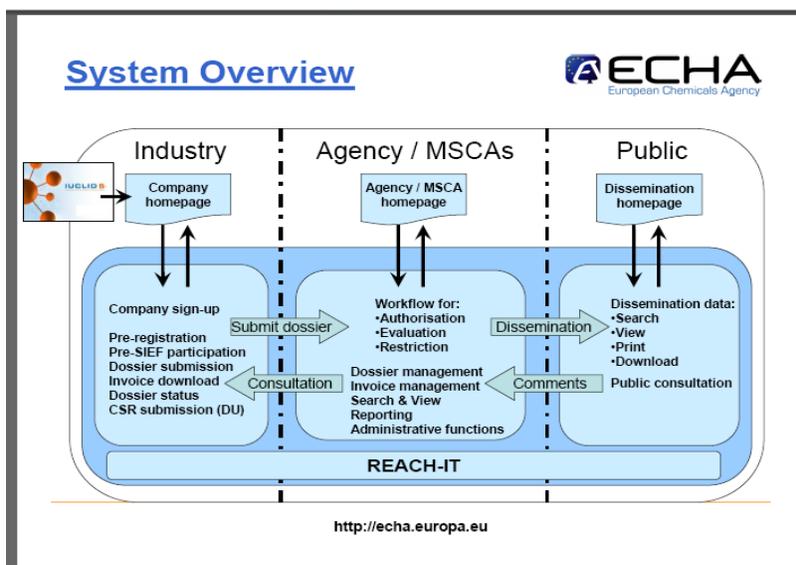

Figure 1. Flows of information between Industry, Agency/MSCAs and Public underpins by REACH-IT and IUCLID 5 [ECHA 2008a]

The main objectives of REACH-IT are:

(1)   To develop an IT-system that enables the ECHA to receive and store pre-registration and inquiry dossiers, registrations, notifications, reports and payments
(2)   To make the information easily retrievable by the Agency and MSCAs
(3)   To enable the dissemination of non-confidential registration dossier data and other relevant data.

3.   ACTORS

Three main types of actors in REACH-IT are in the focus and the retrieval of the data has to be profile specific. The user groups are:

> ➢ the Industry (manufacturers, importers, representatives, downstream user incl. distributors),
> ➢ the Agency / MSCAs (Agency staff, MSCA staff)
> ➢ The general public (consumer and environmental NGOs).

It is very important to define roles and rules for the processes for data submitting and managing. The profile specific retrieval is one of the aspects for the security network of REACH-IT. The development of XML-interfaces supplies these functions and gives the user groups the opportunity to login with a special profile. Another aspect is the down- and uploading function of data for authorized user. There are some rules:

- Each type of actor has its specific needs
- Each type of actor has its specific security requirements
- Separate web-sites for each actor
- Agency and MSCAs have access to the same type of functionality

In developing of the REACH-IT Portal and the special data base application of IUCLID 5 (**I**nternational **U**niform **C**hemical **I**nformation **D**atabase) the following technical requirements, among others, played a central role:

(1) Security Networking between the registrants – so called legal entities, the Member States (MS) and the European Chemical Agency (ECHA) in Helsinki for data transfer purposes (upload and download of dossiers and requests)
(2) Feeding pre-registration data must be done online via the REACH-IT portal to receive a Universal Unique Identifier code for the companies (company UUID)
(3) Profile specific retrieval to the REACH-IT portal including procedures for login, mailing system, inquiry and for the ECHA new alerts
(4) Using the IUCLID 5 (pre) - registration XML-Schemas with a specific format to generate the registration dossier with xml- based files.

The complex REACH-IT system with their tools and the technical infrastructure has been and will be highly influenced the new technological development of the Information System on Chemicals (ICS) in the FEA.

4.   FORMATS AND SOFTWARE FOR SUBMISSION

The REACH Article 111 "Formats and software for submission of information to the Agency" states, "The Agency shall specify formats and make them available free of charge [...] on its website for any submissions to the Agency. Member States, manufactures, importers, distributors or downstream users shall use these formats [...] in their submissions to the Agency pursuant to this Regulation. [...] For the purposes of registration, the format

of the technical dossier [...] shall be IUCLID 5. The Agency shall coordinate the further development of this format with the Organization for Economic Cooperation and Development to ensure maximum harmonization."

To fulfill this obligation the ECHA has been developed IUCLID 5 - the first IT system to implement completely the so-called OECD Harmonized Templates (OHT). In context of the OECD project on Harmonized Templates for reporting summary information from testing results on chemical safety, more than 87 templates were developed and are published on the OECD-Website:
 http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.html.

Figure 2 shows the chapters of IUCLID 5 with regard to the content of the templates. In respect of the FEA the well - structured information in the chapters are the requirement for extended queries. Searching for substances with the criteria e.g. persistent, bio-accumulative and toxic, the so called PBT-substances, needs a detailed data model with complex structure.

Figure 2. Chapters of IUCLID 5 based on the OHT [ECHA 2009a]

These templates are the backbone of the IT-application of IUCLID 5. Information compiled in IUCLID 5 can be exchanged with other databases that use the same templates/XML schemas, even if the underlying computer systems are incompatible.

4.1   IT-Tool for extended query possibilities

The IUCLID 5 Query Tool provides easy access to predefined sets of business-relevant

information. It can be used to perform user-defined queries on both the administrative (e.g. company information, tonnage band, confidentiality flags) and the scientific data fields (e.g. substance datasets, materials and methods, study results). All dossiers are stored in the IUCLID 5 database. Hundreds of fields can be queried to retrieve only the relevant information from endpoint and study summaries recorded in substances, mixtures or templates. A wide range of query combinations are possible with a user friendly interface.

An overview about the query block allows selecting the block for witch to define search criteria:

> (1) Substance, Mixture,
> (2) Templates, Annotations,
> (3) Dossier Headers,
> (4) Endpoint Studies and Endpoint Summaries.

Results for the query are structured in a well formed way. There are functionalities implemented to link the short overview with more detail information about the item e.g. physical-chemical properties or information about manufacture, use and application.

4.2   IT-Tool for preparing Chemical Safety Report (CSR)

For manufacturers and importers of substances it is very important to gather information on the environmental and health properties of their substances, assess the risks arising from the uses of their substances and ensure that these risks are properly managed. To demonstrate these they have to submit:

- a technical dossier, for substances in quantities of 1 tons or more per year, and, in addition,
- a Chemical Safety Report, for substances in quantities of 10 tons or more per year.

The Chemical Safety Report documents the Chemical Safety Assessment consisting of the hazards assessment, classification of the substance and the   assessment   whether   the substance is persistent, bio-accumulative and toxic (PBT), or very persistent and very bio-accumulative (vPvB).

In order to help in the preparation of a Chemical Safety Report a plug-in has been implemented in IUCLID 5. It has been designed to assist in preparing a CSR. The plug-in has the following functionalities:

(1) Extract data from IUCLID 5 data set or dossier in order to prepare the CSR.
(2) Generate from the extracted data a structured document in XML or RTF format.
(3) Pre-fill sections for which information can captured from IUCLID 5

The document is an initial report based on the template published on the ECHA website. The user is able to edit the document manually, for example, to add or update data [ECHA 2009b].
The report 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 data sets e.g. the IUCLID 5 substance data set. Therefore only a part of the information reported in the technical dossier of IUCLID 5 is repeated.

The plug-in generates a document as rich text format (RTF), which can be edited and further updated as appropriate using any text processing program. The general principles of how the preparation of the CSR is supported by the CSR plug-in are shown in the following figure 3:
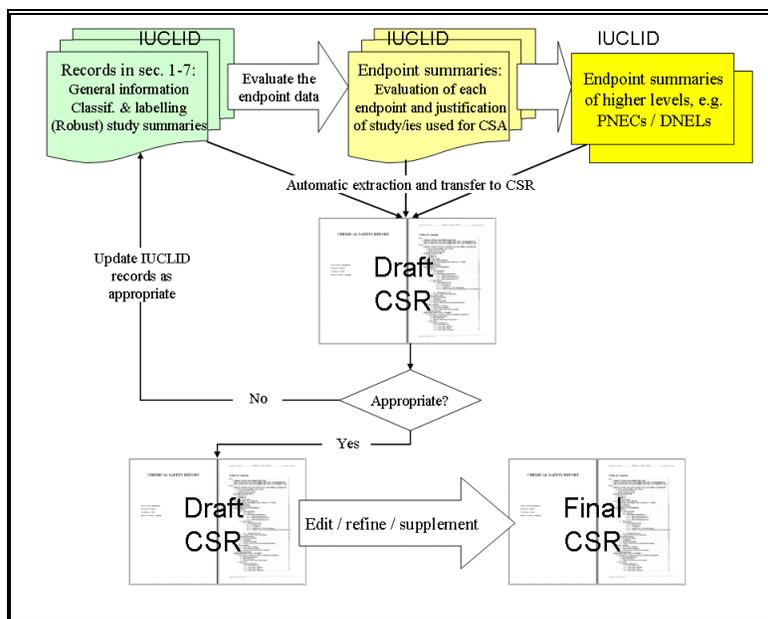
Figure 3. General principles for preparing of the Chemical Safety
Report [ECHA 2009c]

As shown in figure 3, the CSR plug-in can be used for the generation of the CSR in
an iterative process. That is, entries in the IUCLID 5 source fields can be optimized as
appropriate. In this respect, the cyclic improvement of the IUCLID 5 data and re-run of the
plug-in can be useful in:

    a.   verifying that relevant information has been entered in IUCLID 5 and in
           the appropriate fields;
    b.   minimizing any manual adaptations to be done in the CSR.

Also, knowing forehand what kind of IUCLID 5 information is used or not used by the
plug-in may prompt the IUCLID 5 user for a more anticipating, i.e., CSR-oriented,
completion of the relevant fields.

5. CONCLUSION AND OUTLOOK

The complex REACH-IT system is a project between the European Chemical Agency, the
Member States of Europe and the Industry, financed by the European Commission. The
development of the tools and the technical infrastructure has been highly influenced by the
unique requirements of the several user groups. The discussion of possible approaches in
the context of the applications REACH-IT and IUCLID 5 has been closely related to
security aspects for confidential data. The submission of dossiers needs a special technical
infrastructure with crypto boxes and a security network so called VPN.

The REACH-IT Portal and the IUCLID 5 application are developed under the pre-
conditions of the W3C-Standards and of Open-Source Software. With this solution there is
no middleware necessary. The consequent use of XML allows communicating for the
registration process via REACH-IT and the IUCLID 5 database. The solution provides
advantages concerning the high scalability, platform and system independence, simple data
exchange, partition of the application logic user interface and the complete integration of
Java. A Web Service Interface enabled the directly communication of IUCLID 5 with other
software applications. The Federal Environmental Agency in Germany is going to
implement this data structure of IUCLID 5 in the internal IT-System - the Information
System on Chemicals via the Web Service of IUCLID 5.

The European Commission and other organizations, especially the OECD has triggered the activities, the methodology and the technology of the IUCLID 5 – application to use for other legislations of chemicals. Especially for pesticide and biocide the IUCLID 5 system could be a solution for efficient data collection and exchange of information between the parties. The IUCLID User Group Expert Panel under the steering of the OECD has to priorities issues to be fixed and new functionalities to be implemented in the future releases of IUCLID 5.

REFERENCES

Boberski, C. (2008): REACH – Handbuch, Leitfäden, Checklisten und Dokumente für die praktische Umsetzung der neuen Chemikalienverordnung. Forum-Verlag Herkert GmbH, ISBN 978-3-86586-126-9, München, 2008.

ECHA (2008a): Presentation for REACH-IT Stakeholder Workshop, Brussels, 2008a. http://echa.europa.eu/news/20080215workshop_en.asp.

ECHA (2008b): Presentation for REACH-IT Stakeholder Workshop. Helsinki, 2008b.

ECHA (2009a): REACH-IT – Website http://echa.europa.eu/REACHit_en.asp, Helsinki, 2009a.

ECHA (200b): Software Requirements Specification for CSA Tool development Project (unpublished draft). Helsinki, 2009b.

ECHA (2009c): IUCLID 5 Support – CSR Tool plug-in User Guide. Version 1.0, Helsinki, 2009c.

European Commission (2006): Commission regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

European Commission (2008): Commission regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V. Official Journal of the European Union L 268/14-L 268/19.

Knetsch, G. (2008): REACH – Workflows and Software Tools for the Process of Registration, Evaluation, Authorisation and Restriction of European Chemicals. In: Proceeding of the 22nd International Conference on Informatics for Environmental Protection (EnviroInfo 2008), Shaker Verlag, Lüneburg, 2008.

Knetsch, G. (2009): New IT-Trends in Collaboration and Networking for the Process of Registration, Evaluation, Authorisation and Restriction of European Chemicals. In: Proceeding of the European Conference on Towards eEnvironment Opportunities of SEIS and SISE: Integrating Environmental Knowledge in Europe, Prague, 2009.

OECD (2010): Harmonized Templates for Chemicals, Paris, 2010. http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.html