Sustainability Reporting – applicable to Chemical Safety Reports under REACh?

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Abstract

REACh is the European regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1st June 2007 to streamline and improve the former legislative framework on chemicals of the European Union. To fulfil the regulation, industry has to generate Exposure Scenarios (ES), Chemical Safety Assessments (CSA) and Chemical Safety Reports (CSR) in a standard format. The European Chemical Agency provides this process with a workflow for registrants in carrying out the assessment for identified uses, to conduct exposure estimates, and to generate an Exposure Scenario and a Chemical Safety Report. Internet-based sustainable reporting is an approach for companies to replace from traditional reporting practice by more advanced sustainability communication. The methodology of “Sustainable Reporting Taxonomies Architecture” (SRTA) could be transferred and applied to Chemical Safety Reports under REACh. In total, internet-based sustainable reporting provides a useful source of methodologies that all stakeholders involved in the closely related field of REACh should take into account and then finally exploit the various insights.

Keywords: Sustainability Reporting; Taxonomies Architecture; XBRL; Chemicals; Chemical Safety Report, Registration; REACh;

1. Reporting under REACh

In December 2006, the Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACh) and establishing a European Chemical Agency of the EU (ECHA) was adopted. Under the Directive 67/548/EEC and actions taken by the European Chemical Agency (ECHA) under Article 15 and 16(1) a complex and extensive IT-network and collaboration system for REACh has been installed. This system allows managing the pre-registration, dossier submissions (regis-
tration, PPORD\(^1\) notification and inquiry) and assignment of registration numbers for notified substances. REACh-IT ensures an efficient, consistent and secure exchange of data and information for the evaluation, authorisation and restriction processes for chemical substances across the European Union. The REACh-IT network is designed to provide additional information on chemicals, to ensure their safe use and to ensure competitiveness of the European industry. The Annex I of Regulation (EC) No. 1907/2006 (REACH) sets out the details of how to carry out a Chemical Safety Assessment and document it in a Chemical Safety Report. The Annex has been supplemented by a technical guidance document on Information Requirements and Chemical Safety Assessment.

1.1 Objectives and information requirements for reporting

The main objective of the chemical safety report (CSR) is to document the chemical safety assessment (CSA), including its conclusions and results. For substances manufactured or imported in quantities of 10 tons or more per year and per legal entity, a chemical safety assessment (CSA) must be carried out and recorded in a chemical safety report (CSR). This information is required for the risk characterization of a chemical substance and to control the risk for health and environment. For this purpose the relevant information from the CSR is compiled into one or more exposure scenarios (ES) to be communicated via extended safety data sheet (eSDS).

Figure 1: Overall process related to information requirements and elements of chemical safety assessment under REACH Source: The Guidance of information requirements. ECHA 2009

Figure 1 presents an overview of the process of collecting and assessing existing information on the intrinsic properties of a substance, including identification of needs to generate new data. It describes the workflow of chemical safety assessment, the steps for risk characterization, the documentation in a chemical safety report and the communication chain of the Exposure Scenarios via extended safety data sheet.

\(^{1}\) PPORD: Product and Process Oriented Research and Development
Important issues for generating the reports and data sheets are reliable and valid data and information. In accordance with Annex I, section 7 of the regulation the registrant must collect all physicochemical, toxicological and ecotoxicological information that is relevant for the chemical substance and available to him. This contains inter alia data about:

- Manufacture, use and supply chain
- Physicochemical properties
- Environmental fate and pathways
- Ecotoxicological and toxicological characteristics
- Residues in food and feeding stuffs

For the template for a chemical safety report see REACH homepage: http://guidance.echa.europa.eu/formats_en.htm

The effective implementation and communication of the exposure scenario concept depends on harmonized language across the European market. Consequently, a standardized descriptor system for uses has been developed in the last years. In context of an OECD project on Harmonised Templates for reporting summary information from testing results on chemical safety, XML-templates were developed and first published in March 2006. These templates are the backbone of a complex data base - the International Uniform Chemical Information Database 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. The plug-in concept of IUCLID 5 allows implementing functionalities for generating chemical safety report and extended safety data sheet.

1.2 Interaction between IUCLID 5 and the CSR plug-in

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:

- Extract data from IUCLID 5 data set or dossier in order to prepare the CSR. The rules for the selection of data relevant to the CSR are fixed.
- Generate from the extracted data a structured document in XML or RTF format.
- Pre-fill the 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. 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 2:
As shown in figure 2, 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

- verifying that relevant information has been entered in IUCLID 5 and in the appropriate fields;
- 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.

### 1.3 OECD templates – one way for sustainability reporting?

The OECD templates are the key for harmonizing all information under REACh and other legislations e.g. the High Volume Programmes (HVP). The aim of the OECD project on templates is to facilitate the reporting of summary data in the same format so that such information in one system can be exchanged across other systems used by other programmes and governments. For example, information collected via IUCLID 5 based on the OECD templates and XML schema could be exchanged with other governments that use the same templates/schema.

Up to now 98 specific templates, picklists, pre-defined tables have been developed by expert groups under the OECD-leadership. These templates can be used for reporting summary results on any type of chemicals inter alia industrial chemicals under REACh (see IUCLID 5), pesticides and biocides.
OECD template is a guide for structuring data entry and/or database management systems for reporting a summary of the results of a test on a chemical to determine its properties and the effects on human health and the environment. It also contains introductory material about the formats and conventions used for the templates. Table 1 shows an example of the structure of an OECD template for the item “Carcinogenicity” with detailed description of the items and the format.

### 1.4 Chapter 78. OECD Template #72: Carcinogenicity

The following table gives a detailed description of the type of information prompted for by the data entry fields. Elements provided to guide the user include predefined picklist phrases, freetext templates and context-sensitive help texts. In addition, technical elements are provided, i.e. field and data types, explanations for use in Data Element Dictionary (DED) and the xml schema. The conventions used are explained in part 'Introduction and Format of OECD Harmonised Templates'.

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Table 1: Example for the structure of OECD template 72

The templates are aimed at developers of database systems as they prescribe the formats by which such information can be entered into and maintained in a database. By using these templates, governments and industry will easily be able to electronically exchange test study summary information.

Based on the OECD-harmonised templates the CSR plug-in evaluates the data content, generates a structure for the report, extract the data by managing of rules and prepares an editable report. But up to now there is no solution for reporting via web-based interface, to bring the non-confidential information to several target groups. It should be mentioned that service life can lead to wide dispersive emissions of chemicals to the environment including exposure to human beings via the environment, depending on substance and matrix properties. The CSR and the ESs contained in it should therefore take account of the potential for exposure by different or multiple pathways, and the emissions from articles during their service life and waste stage.

The methodology of “Sustainable Reporting Taxonomies Architecture” (SRTA) could be one solution for the currently emerging requirements under REACh. According to the regulation of REACh Art. 117 (1) and 119: “The Agency and Member States should allow electronic public access to information... to selected non-confidential data of the registration dossier”. That means information of chemicals registering by REACh should be published and reported in a user friendly way.
2. Sustainable Reporting Taxonomies Architecture (SRTA)

Internet-based sustainability reporting keeps companies in a position to provide sustainability reports and other communication vehicles on a variety of media, based on a single data source that serves as a shared publishing basis. Corporate information, in all its growing quantity and complexity can be communicated more effectively with the use of new ICT. Particularly internet technologies and services employed with XML and incorporated into a (web) content management system or a reporting software tool can do more than offer new channels for report distribution or presentation. The WWW is a service for distributing and presenting reports, including hypermedia features, online information and global access around the clock. Moreover, information management can be improved in various ways: data relevant for performance in terms of sustainability is captured from different data sources, combined despite different data formats, analyzed for decision making, professionally mastered and hypermedia-featured, customized according to specific information needs and certain guidelines, distributed and presented, e.g. via email, cross media, fax, or ordinary mail. The content and design of reports will need to be transformed: online availability, downloads, additional environmental documents, interactivity, feedback opportunities, contact details, automatic order forms, sustainability electronic forums, hyperlinks, graphically designed websites, navigation, search engines, web rides, regular updates, and site promotion are some of the form and content capabilities that are already implemented to a certain extent. The internet could be regarded as a “reporting facilitator”. Sensing that traditional sustainability reporting on printed media might have its limits, more companies are considering improving their reporting practice and making more use of reports in general. Improving reporting requires modern, flexible and cost-effective information technologies and channels. This also means to reach also small and medium-sized enterprises, and not just global players. Sustainability online reporting assists companies in moving away from traditional reporting practice towards more advanced sustainability communication.

One major current research in Sustainability Reporting effort is to develop a “Sustainable Reporting Taxonomies Architecture” (SRTA). This architecture is based on the Financial Reporting Taxonomies Architecture 1.0 (FRTA), intended to enhance consistency among the XBRL taxonomies used for sustainability reporting. An important design goal for sustainability reporting taxonomies is to maximize the usability of the taxonomy to the non-technical (from a computer science perspective) users and experts of the reporting domain, while not compromising the ability of the taxonomy to describe reporting requirements and possibilities in an accurate and XBRL-compliant manner (FRTA 2005). The FRTA is characterized through a number of so-called taxonomy schemas and link bases. A taxonomy schema is an XML schema, usually a standardized schema (XSD), and contains XBRL concepts (Isenmann et. al. 2008). A concept is a definition of kind of fact that can be reported about the activities or nature of a business entity. Taxonomies contain XBRL concepts represented by XML schema element definitions (FRTA 2005). Principles for defining sustainability report content (concepts) and ensuring the quality of reported information are standardized by the Global Reporting Initiative (GRI) with their Sustainability Reporting Guidelines. Version 3 (GRI 2006) also includes standard disclosures made up of performance indicators and other disclosure items, as well as guidance on specific technical topics in reporting. The GRI guidelines identify information that is relevant and material to most organizations and of interest to most stakeholders for reporting the three types of Standard Disclosures (GRI 2006):

\begin{itemize}
\item **Strategy and Profile**: GRI disclosure items that set the overall context for understanding organizational performance such as its strategy, profile, and governance.
\item **Management Approach**: GRI disclosure items that cover how an organization addresses a given set of topics in order to provide context for understanding performance in a specific area.
\item **Performance Indicators**: GRI indicators that elicit comparable information on the economic, environmental, and social performance of the organization.
\end{itemize}
Based on these results the developed methodology in document and software engineering for Sustainability Reporting could be transferred and applied to the European regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals and its currently emerging requirements for Chemical Safety Reports. For this reason, if no other, all stakeholders involved in Chemical Safety Reporting should benefit from prior experiences in the closely related field of sustainability reporting.

3. Literature


OECD (2006): Harmonized Template Project:

http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.html, access: 5.6.2009