

REACH Readiness: Smart Solutions to Challenging Problems

Executive Summary

Changes in laws and regulations directly affect the way organizations operate. The impact is more acutely felt by multinational corporations, which need to comply with rules in every country in which they operate.

Modifications to existing regulations or adoption of new laws can profoundly impact a corporation's data management system, even if the laws and regulations are not related to information technology. Computer systems and networks are indispensable tools that have revolutionized the way organizations function and work. It is, therefore, not sufficient to understand and respond to just the business impacts of rules and regulations; the ability to seamlessly integrate these impacts with existing data management systems is vital for most corporations, not only from a compliance perspective, but also from the point of view of corporate responsibility.

Governmental agencies enforce environment, health and safety (EHS) regulations that are critical for protection of human health and the environment. The REACH¹ regulation recently introduced by the European Union aims to improve this protection in the EU through better and early identification of the intrinsic properties of chemical substances. This white paper provides a brief overview of REACH regulation and articulates the areas in which we

are assisting a U.S. multinational conglomerate in its pursuit of REACH readiness.

What is REACH?

REACH stands for Registration, Evaluation, Authorization and Restriction of Chemical substances.² It is a chemical policy designed, developed and implemented by the EU in the second quarter of 2007. Starting in 2011, manufacturers and importers selling products in the EU must adhere to REACH regulations to continue selling their products. The name "REACH" refers to the requirement that compliance occurs over several phases, including registration, evaluation, authorization and restriction.

To comply with REACH, manufacturers must capture additional chemical data, such as physical and chemical properties and toxicological and ecotoxicological information, and provide it to the European Chemicals Agency (ECHA).

Why the EU Needs REACH

REACH is one of the first chemical policies uniformly applicable to all EU countries. Before REACH, countries in the European Union followed individual regulations. In addition, these regulations were arbitrary, causing existing chemicals to be regulated differently from newly developed chemicals. Stringent regulations were



applied to “new” chemicals, whereas the regulations used to monitor older chemicals were considerably lax. This bias against new chemicals encouraged manufacturers to make use of existing chemicals and avoid inventing new ones.

Another problem was that the substances and chemical information were not stored in a single repository, making it difficult to analyze their health and environmental impact. A single, uniform, unbiased regulation was, therefore, needed to capture all relevant information about the chemicals/substances.

The aim of REACH is to not only improve the protection of human health and the environment, but also to enhance the innovative capability and competitiveness of the chemicals industry in the EU.

Chemical Data Repository (CDR) and Chemical Volume Tracking Application (CVTA) are two REACH-related projects in which we are assisting a client that manufactures thousands of chemically diverse products and operates in a number of countries. It has worldwide sales of over \$20 billion, with revenue from its EU operations accounting for a significant percentage of that total. Non-compliance with REACH regulation is, therefore, not an option for this company, and the goal is to complete all major REACH-related software development by the second quarter of 2010. Our solutions enable this client to:

- Integrate the distribution of REACH-compliant, local-language data and documents with existing U.S.-centric data and document processing functionality.
- Pool and manage data from various organizational sources (including manufacturing, purchasing, sales, etc.) into a common format that is then presented to the REACH regulatory body, ECHA.

Chemical Data Repository

CDR stores all chemical- and substance-related information for products manufactured by the client. This system allows users to generate documents such as MSDS (Material Safety Data Sheet), Safety Labels, GHS (Global Harmonized System), RTC (Request for Transportation Classification), etc. With the introduction of REACH regulations, CDR was required to

generate, collect, process and distribute REACH-compliant data and documents to different agencies and customers.

Challenges in CDR REACH Readiness

CDR was initially designed primarily for users in the U.S. The heart of CDR is an application that populates a Microsoft SQL Server database with chemical and document data. Approximately 70 batch jobs run against this and other associated databases to distribute documents and data to numerous regulatory agencies, customers, manufacturing plants and other software applications.

When REACH was enacted, the system was required to capture and distribute information specific to the EU and, in many cases, prevent EU data from being sent to other U.S.-specific systems or agencies. This stipulation required modification to a majority of the batch jobs distributing data to different internal and external applications. The challenge was to implement this functionality with minimal impact to existing source code, add additional REACH functionality that integrated seamlessly with existing code, and meet the extremely aggressive timelines set by the client.

Traffic Cop

Introducing a traffic cop concept allowed us to decide when a document needs to be generated and distributed and to whom it needs to be sent. A routing table was created that stored information pertaining to generating and routing documents as business rules. This table was then introduced in existing SQL queries that were involved in data selection and distribution in various batch jobs, ensuring that the documents were generated and routed correctly. This idea restricts modifications to a very small part of code (i.e., SQL queries). Another benefit of this approach is that any addition or update to a business rule requires just an update to the routing table rather than batch job source code. Documents belonging to a particular country can, therefore, be distributed according to a specific

The aim of REACH is to not only improve the protection of human health and the environment, but also to enhance the innovative capability and competitiveness of the chemicals industry in the EU.

With the introduction of REACH regulations, CDR was required to generate, collect, process and distribute REACH-compliant data and documents to different agencies and customers.

country's regulatory requirements, without modifying existing batch processes.

Documents on the Fly

MSDS's generated for countries of the European Union require some data not available in the CDR databases. Instead of modifying existing applications to accommodate this data (which was a very significant change), we added an extra preprocessing step to the MSDS document distribution process. When an MSDS belonging to a country in the EU is now available for distribution, it is parsed, and additional data is introduced into the document in the required sections in a pre-determined format consistent with the overall document. This idea, though complex to design and implement, requires minimal modifications to existing source code or current applications.

Introducing a traffic cop concept allowed us to decide when a document needs to be generated and distributed and to whom it needs to be sent.

We modified the client's existing chemical data management system to ensure correct distribution of REACH-compliant documents and data. This allowed the client to meet strict deadlines per its REACH regulation compliance strategy. The solutions described above will help mitigate the impact of regulations with similar requirements in the future, as implementing a regulation would not entail modifications to existing source code and would only require the updating of a routing table.

Chemical Volume Tracking Application

REACH impacts all companies manufacturing or importing chemical substances into the European Union in quantities of one tonne or more per year. It requires all such companies to register these substances with a new European Chemicals Agency in Helsinki, Finland. The

IUCLID does not enforce security and grants full data access to any user.

European Commission supports businesses affected by REACH by offering a free software application known as IUCLID (International Uniform Chemical Information Database).^{3,4} IUCLID aids in submitting chemical data, which is a mandatory part of the registration process. Under certain circumstances, REACH mandates a Chemical Safety Assessment (CSA), along with a Chemical Safety Report (CSR). This is done using Web-based software called REACH-IT.

REACH's IUCLID vs. CVTA

IUCLID is a generic tool intended to serve conformant companies at large. However, it is highly likely that IUCLID will not perfectly align with the fields on which an organization's repository has to report. Moreover, IUCLID does not enforce security and grants full data access to any user. It does not offer the ability to search/browse the data being submitted or the ability to export data in user-friendly formats such as Excel spreadsheets.

CVTA, on the other hand, is an online tool that acts as a middleman between organizational data sources and IUCLID. It provides global data for weight-based regulations such as REACH. In doing so, CVTA complements IUCLID and addresses the above-mentioned weaknesses.

CVTA is intended to complement, not replace IUCLID. It abstracts the complexities involved in data export to IUCLID behind a simple interface. It bestows more control to the user, who decides how, when and what data is obtained; what manipulation the data is subject to, inclusive of data categorization; and how, when and what data is exported to external systems such as IUCLID, where a "push" model of execution is required. In a nutshell, CVTA is a tool that allows users to manage data before submitting it to regulations.

Why CVTA with IUCLID?

It is quite probable that the data repositories of many major chemical organizations have not been set up in anticipation of REACH. It is also likely that the data itself is scattered across multiple diverse sources. CVTA can work with all such data sources, regardless of the underlying database, thanks to database portability made available by ORM technology. Object relational mapping (ORM)⁵ is a technique that guarantees portability of an application by bridging the gap between the object-oriented and the relational jargon adopted by programming languages and database servers, respectively. CVTA neatly fills the gap of dissimilar data sources by importing information from these disparate sources and integrating them into a common format.

The process of obtaining information (by SQL queries) from a data source is called "extraction." Extracted contents can be amended to align with the fields of an organization's data repository. Integration of dissimilar data sources might require ad hoc

processing for some of these extracts. CVTA extracts can preprocess or post-process raw or processed data obtained via extraction, where such ad hoc processing can be accommodated.

Modus Operandi

It's often the case that data for a given month or year is not readily available until after a specific period of time. CVTA spawns asynchronous execution threads, called "tasks," that can be scheduled at regular intervals or manually operated to obtain the extracts at the appropriate time. These tasks can import from multiple extracts at the same time -- sequentially or concurrently -- and are completely traceable via the CVTA UI or e-mail notifications. Once tasks are scheduled, user intervention is not needed unless issues arise with the infrastructure. Infrastructure problems will duly trigger e-mail notifications with appropriate cause of failure.

CVTA Overview

Extracts thus obtained can be evaluated to check validity and integrity based on various criteria. The consolidated set of extracts are sliced and diced into various dimensions to provide a vivid snapshot of the garnered data in the form of

several reports and with a powerful search functionality. Search can be performed based on the majority of the extract fields. This integrated data may be subjected to further tuning to fit the requirements of the regulation. For instance, information made available from various extracts can have a plethora of units of measure (UOM) associated with them for quantity, while REACH requires kilograms. Such UOM conversions can be performed before the gathered data is made available to IUCLID. Data tuning activities inclusive of but not restricted to filling missing information in the garnered data can also be performed at this stage.

In a nutshell, CVTA is a tool that allows users to manage data before submitting it to regulations.

This augmented data is now available for IUCLID. It can be pushed by CVTA or pulled by any external system like IUCLID. A task can be configured to push this data to external systems automatically.

The CVTA Edge

As a Web application, CVTA can work in concert with an organization's single sign-on and enforce regulated access to various

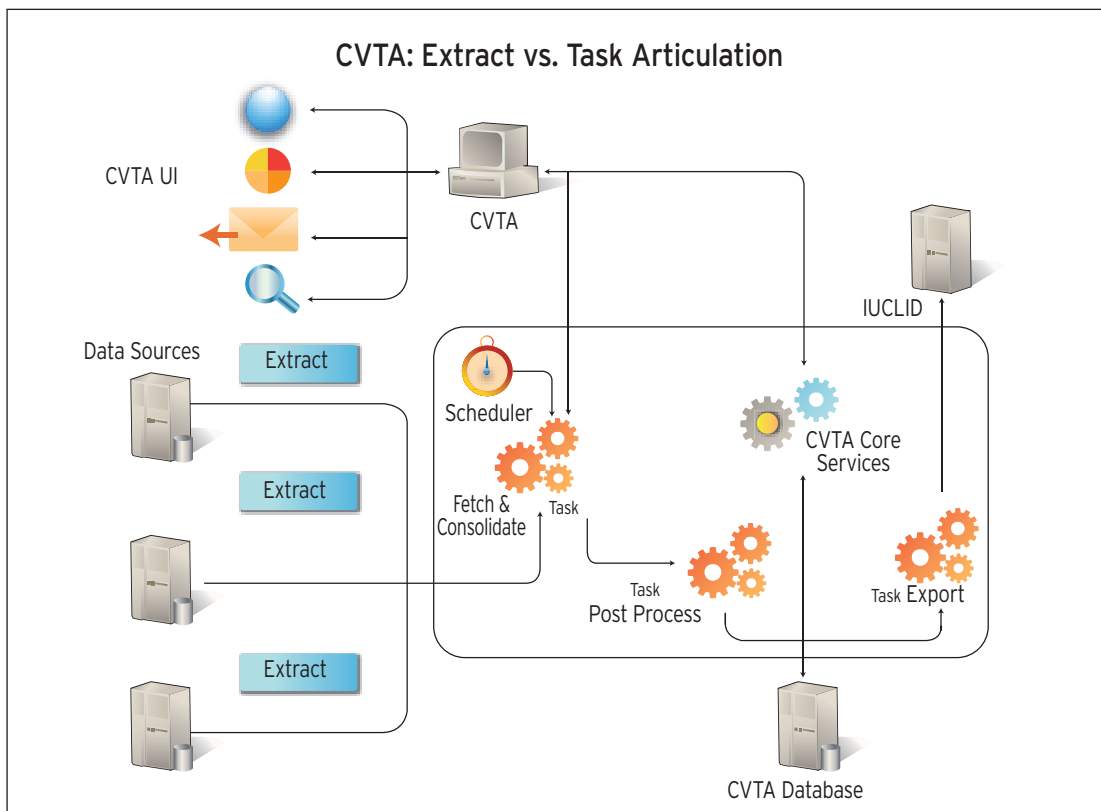


Figure 1

functionalities based on user roles. Though CVTA targets EU REACH at present, it is scalable to accommodate similar regulations by other countries, such as the regulation from Turkey⁶ and Taiwan's Taiwan REACH.

CVTA is a JavaEE⁷ application built in line with IUCLID, adopting the same best practices as object relational mapping using Hibernate3,⁸ which provides portability across different databases with very minimal changes to the application itself. Asynchronous processing aids in multitasking and prevents timeout issues of synchronous processing. E-mail notifications can be subscribed to, to alert administrators to various events during processing. Web 2.0 concepts such as AJAX have been adopted to provide a rich and responsive user interface. CVTA core services are capable of serving Java clients, as well as being exposed as Web services to serve any heterogeneous client.

The registration phase of REACH regulation is a crucial phase that lays the foundation on which the other phases operate. It is in this phase that organizations submit information about their EU imports and exports to ECHA. An organization's ability to scale up to reconcile such a data requirement determines the smoothness of the REACH compliance. CVTA was built ad hoc to aid such a scenario and can be leveraged by chemical organizations as a vantage point in their pursuit of REACH compliance.

Conclusions

The ability to comply with various regulations is imperative for the survival of most organizations. Companies should possess the ability to analyze the impacts to the business,

About the Authors

Vignesh Murali Natarajan is a Senior Associate at Cognizant. His interests include Web 2.0 concepts with JavaEE and photo-realistic modeling using Maya. He can be reached at vigneshmurali.natarajan@cognizant.com.

Hariharan Kulathu is a Senior Associate at Cognizant. His interests are project management, team building, problem solving and experimenting with cutting-edge technological advances. He can be reached at hariharan.kulathu@cognizant.com.

Siddharth Sharad Chandak is an Assistant Project Manager at Cognizant. His interests include architecting and designing enterprise software applications, software performance tuning and project management. He can be reached at siddharth.chandak@cognizant.com.

including the effect on IT processes and systems. They also must have the agility to respond to these impacts with viable solutions.

The successful implementations of CDR and CVTA projects provided our client with the flexibility to satiate the increasing appetite for EHS data resulting from REACH regulation. The client is now well positioned to easily incorporate and deal with disruptions caused by other similar regulations and policies. Our expertise in innovation, breadth of domain experience and depth of industry knowledge, make us an ideal partner for any organization looking to efficiently solve such challenging problems.

References

¹ http://en.wikipedia.org/wiki/Registration,_Evaluation,_Authorisation_and_Restriction_of_Chemicals

² http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

³ <http://iuclid.echa.europa.eu/index.php?fuseaction=home.development>

⁴ <http://iuclid.echa.europa.eu/index.php?fuseaction=home.project>

⁵ <http://www.hibernate.org/about/orm.html>

⁶ The official name of Turkey's regulation depends on whether the country becomes a member of the European Union. If Turkey becomes an EU member, then it will adopt EU REACH; otherwise, it will revert to its own regulation, known as Turkey REACH.

⁷ <http://java.sun.com/javaee/>

⁸ <http://www.hibernate.org/about.html>

About Cognizant

Cognizant (NASDAQ: CTSH) is a leading provider of information technology, consulting and business process outsourcing services. Cognizant's single-minded passion is to dedicate our global technology and innovation know-how, our industry expertise and worldwide resources to working together with clients to make their businesses stronger. With over 50 global delivery centers and more than 85,500 employees as of March 31, 2010, we combine a unique global delivery model infused with a distinct culture of customer satisfaction. A member of the NASDAQ-100 Index and S&P 500 Index, Cognizant is a Forbes Global 2000 company and a member of the Fortune 1000 and is ranked among the top information technology companies in BusinessWeek's Hot Growth and Top 50 Performers listings.

Start Today

For more information on how to drive your business results with Cognizant, contact us at inquiry@cognizant.com or visit our website at www.cognizant.com.



Cognizant

Passion for building stronger businesses

World Headquarters

500 Frank W. Burr Blvd.
Teaneck, NJ 07666 USA
Phone: +1 201 801 0233
Fax: +1 201 801 0243
Toll Free: +1 888 937 3277
Email: inquiry@cognizant.com

European Headquarters

Haymarket House
28-29 Haymarket
London SW1Y 4SP UK
Phone: +44 (0) 20 7321 4888
Fax: +44 (0) 20 7321 4890
Email: infouk@cognizant.com

India Operations Headquarters

#5/535, Old Mahabalipuram Road
Okkiyam Pettai, Thoraiipakkam
Chennai, 600 096 India
Phone: +91 (0) 44 4209 6000
Fax: +91 (0) 44 4209 6060
Email: inquiryindia@cognizant.com