EU CHEMICAL REACH PROGRAM

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BACKGROUND:

THE REACH PROGRAM

THE EUROPEAN UNION (EU) CHEMICAL REACH PROGRAM (REACH = REGISTRATION, EVALUATION, AUTHORIZATION OF CHEMICALS) WAS ENACTED IN 2007. TO A LARGE EXTENT, REACH IS MODELED AFTER USEPA'S TSCA AND FIFRA PROGRAMS, WITH THE INTENTION OF "REGULATING" HAZARDOUS AND EXTREMELY HAZARDOUS SUBSTANCES AND PRODUCTS. REACH WAS SPECIFICALLY ENACTED TO HELP ENSURE THAT THE HUMAN HEALTH AND THE ENVIRONMENT IN THE EU ARE NOT COMPROMISED BY THE POTENTIAL ADVERSE IMPACTS OF CHEMICAL PRODUCT MANUFACTURE OR IMPORT. MUCH LIKE TSCA AND FIFRA, THE FIRST INTENTION OF REACH IS TO ADDRESS SUBSTANCES OF VERY HIGH CONCERN (SVHC) FOR WHICH VERY STRICT RULES APPLY.

REACH is regulated by the European Chemical Agency (ECHA), and covers most chemical products manufactured in or imported to the EU. This encompasses:

- Chemicals on their own
- Substances contained in a mixture of paint, ink or similar chemical product
- Substances that make up an article (products within a defined shape, surface, or design)

Exemptions from REACH include:

- Any substance or material manufactured or imported at less than one (1) ton per year
- Radioactive substances or materials otherwise regulated by an EU directive
- Substances otherwise under the supervision of customs requirements either on their own or used independently in an article, provided they do not undergo any form of processing or treatment, and are in temporary storage awaiting exportation
- Most wastes
- Materials in transit by air, sea, land, rail, truck

- Human or animal medicinal products
- Human or animal food stuffs
- Cosmetic products
- Medical devices
- Mineral ores or mineral extractions, provided they do not undergo any chemical processing or a change in chemical form

REACH APPLICABILITY

REACH applies in all 27 EU countries, plus Norway, Iceland, and Liechtenstein. It does not apply in Switzerland. Only European legal entities can register, including European chemical manufacturers, European importers and the "representatives" for non-European chemical manufacturers or formulators. Companies based outside the EU cannot themselves do registrations, notifications, or whatever is necessary for REACH compliance.

By example: U.S. companies with facilities in the EU are subject to REACH. U.S. manufacturers exporting to the EU are still subject to REACH but via a 3rd-party registration agency in the EU. Typically, the EU-based importer of the goods is fully responsible for REACH compliance, but most often at the cost and guidance of the U.S. exporter.

REACH REQUIREMENTS

Assuming that a company and product are subject to REACH, there are pre-registration, registration, evaluation, and authorization requirements to the overall process.

PRE-REGISTRATION

Pre-registration of a chemical or chemical product is tantamount to intent to manufacture or import subject products into the EU. Pre-registration encompasses a brief dossier of the chemical product, its chemical identity, and the intended markets for the product. It is mainly an administrative act that distinguishes between 'phase-in substances' and new substances. Even if there is no intention to actually register a substance, as may be the case for importers of mixtures, it should still be pre-registered. This is necessary to avoid being obliged to register at all or at a very inconvenient moment.

Pre-registration brings all potential registrants of the same substance together in a virtual network called Substance Information Exchange Forum (SIEF). They are expected to exchange information, mainly to avoid animal testing, as much as possible.

The REACH pre-registration deadline was November 2010. However, new chemicals or chemicals products are pre-registered on a case-by-case basis. Late pre-registration is possible for first time manufacturers and importers, up to 12 months before the relevant registration deadline (see these registration deadlines below).

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REGISTRATION

Almost every chemical marketed in the EU in a quantity over one ton per year must inevitably be registered under REACH. Registration involves submitting a large and complicated technical dossier. New substances must be registered immediately. 'Phase in' (i.e. existing) substances may be registered over time; this timing depends on the volume and toxicity. Registration must be preceded by pre-registration.

Deadlines for Chemical Registration:

- CMR ≥ 1 t/y (Carcinogenic, Mutagenic, Repro-toxic Cat. 1 & 2. EU Risk phrases R45, R40, T/R46, R60, R61, T/R60 and T/R61): **Registration deadline November 2010**
- EU Risk phrase R50-53 ≥ 100 t/y (Very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment): **Registration deadline November 2010**
- Other substances ≥ 1000 t/y: **Registration deadline November 2010**
- Other substances ≥ 100 t/y: **Registration deadline May 2013**
- Other substances ≥ 1 t/y: **Registration deadline May 2018**

REACH registration includes the submission of information on:

- Substance identity
- Physicochemical properties
- Mammalian toxicity
- Eco-toxicity
- Environmental fate, including abiotic and biotic degradation
- Information on manufacture and uses, as well as risk management measures

The registrant must compare the information requirements with the information gathered to identify information gaps and consider how to generate missing information. Information gaps are filled by data sharing and using different sources of information other than in vivo testing. The registrant may use a variety of alternative methods such as (Q)SAR, in vitro tests, grouping of substances/a category approach, and a read-across approach.

Registrants who manufacture or import a substance at ten or more tons per year must conduct a chemical safety assessment to define the conditions of use under which the risks can be controlled. The conditions of use include operational conditions, such as temperature and risk management measures, for the requirement to use personal protective equipment. Downstream users may choose to carry out a chemical safety assessment if they use a substance outside the conditions described in the exposure scenario provided by the supplier or if the use is advised against by the supplier.

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The chemical safety assessment is an iterative process involving the following steps:

1. Collection and generation of information on intrinsic properties of the substance
2. Human health hazard assessment
3. Physicochemical hazard assessment
4. Environmental hazard assessment
5. Persistent, Bio-accumulative and Toxic (PBT) and very Persistent and very Bio-accumulative (vPvB) assessment

If, after these steps, the substance is deemed hazardous, the following steps are also needed:

1. Exposure assessment
2. Risk characterization

The process needs to be repeated by re-assessing the hazard information and/or revising the conditions of use, the exposure information, or the scope of exposure scenarios until it can be concluded that the risks are controlled. The results of the chemical safety assessment are documented in a chemical safety report (CSR), which is submitted as part of the registration dossier to ECHA.

EVALUATION & AUTHORIZATION

Registration dossiers for large volume chemicals are evaluated by ECHA or a designated representative entity of ECHA. Evaluations and subsequent approvals may take 12-24 months, depending on the veracity of the data and registration information submitted.

This is a process, again, very much like the U.S.EPA's process for evaluating and registering TSCA or FIFRA chemicals. A large amount of quantitative and qualitative data is assembled regarding toxicity of the chemical and potential fate and transport mechanism of those chemicals or products. Then the agency reviews, comments, and has the option to approve or disapprove. The typical evaluation of a dossier includes items such as:

- The identity of the substance
- Information on the manufacture and use of the substance
- The classification and labelling of the substance
- Guidance on its safe use
- (Robust) study summaries of the information on the intrinsic properties
- Proposals for further testing, if relevant
- For substances registered in quantities between one and ten tons, the technical dossier also contains exposure-related information for the substance (main use categories, type of uses, significant routes of exposure)

HELPING U.S. COMPANIES COMPLY WITH REACH

Most U.S. companies were caught off-guard by the 2007 promulgation of the EU REACH program requirements. Those U.S. companies with physical facility locations in the EU were largely aware of the REACH obligations and mostly met the 2010 deadlines. U.S. companies without an EU entity were and continue to be late to the registration process…and continue to submit pre-registration and registration dossiers on a case-by-case approval and under the guidance of ECHA for products exported to the EU.

There are a number of companies that may still need assistance navigating the REACH process, including:

- Chemical companies
- Forest and wood products companies, including paper companies
- Petroleum companies
- Companies supporting the petrochemical industry (e.g., drilling muds, polymers, lubricants, retention aids, surfactants)
- Mineral, cement, and lime companies (or similar) that have processed a base mineral (exempt) into a new chemical product

The proviso here is that each of these company types is exporting chemical products to the EU that have 2013 or 2018 REACH deadlines, or that missed the 2010 deadlines and are now submitting registrations on a case-by-case basis.

Sage's role is to:

- Help affected companies navigate the REACH requirements
- Coordinate related product and exposure and eco-testing
- Prepare registration documents and assemble all technical data
- Help affected companies negotiate final registration terms and conditions

In order for Sage to provide these services, Sage needs to:

- Create a subsidiary company able to do business in the EU;
- Work in combination with a consultancy or agency in the EU already approved to handle REACH work; or
- Work only for those U.S. or other multi-national companies that have physical facilities or business locations established in the EU

Even the most simple of REACH registrations is often a $50,000 effort. Most typical REACH registrations range from $150,000 to $250,000. Chemicals or products with atypical toxicity issues can often be $500,000 to $1,000,000 registration efforts.

OUR SERVICES AND APPROACH:

HELPING U.S. COMPANIES COMPLY WITH REACH

TARGETS FOR REACH PROGRAM CONSULTING

Given deadlines, Sage's most critical focus is on those companies and products needing immediate registration help (e.g., those companies with a May 2013 registration deadline, then those with the longer term registration deadline of May 2018). There may also be opportunities with companies that missed previous deadlines and still need assistance on a more fast-track basis.

Here are a few examples of how Sage has assisted this market segment:

- JELD-WEN Co. is a forest/wood products company manufacturing doors, windows, and architectural trim and moulding products. JELD-WEN is a U.S.-based company with manufacturing entities in the EU. They presently spend between $2MM - $3MM annually on their REACH compliance activities.
- Sage had a separate inquiry from a petrochemical company in Oklahoma that wished to register a drilling lubricant and begin exporting to the EU. This company ultimately decided that it was simply too costly of a venture.

In addition to individual companies, those companies periodically use law firms to transact REACH program business. Those law firms engaged in TSCA and FIFRA work likely also do Chemical REACH work on behalf of their clients, especially those law firms with law offices in various EU countries.

Last but not least, industry technical associations have REACH high on their priority lists. The Composite Panel Association and American Plywood Association, for example, have committees dedicated to helping member companies with REACH questions. However, their expertise is limited and these associations would benefit from voluntary help.

SUMMARY:

SAGE'S REACH PROGRAM SERVICES

In summary, the EU Chemical REACH program is much like USEPA's TSCA and FIFRA program. REACH affects any manufacturer within the EU producing a chemical product, or any company exporting product into the EU. The biggest issue is often that companies are often not prepared for the cost or time necessary to register a product through REACH.

Sage approaches the REACH program in very much the same manner that we address a potential TSCA or FIFRA registration. We address the regulatory guidance associated with REACH; coordinate the extensive amount of laboratory work involved in the forensic chemistry, as well as the health and eco-tox impacts of the chemistry; and, most importantly, compile the registration document such that it is complete and accurate and has the highest probability of approval. The art in these registration activities is weaving a compelling story about the product; it is as much about what the narrative looks like as the data itself