Navigating the minefield of EU Chemical regulations
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The scope of EU’s ‘REACH’:
The EU’s REACH Regulation is the most complex legislation yet implemented in the European Union. It was designed as the primary legislative instrument for the control of hazardous chemicals within the 27 EU member states.
The EU chemical agency, ECHA, is centrally overseeing the registration process from Helsinki, whilst a slew of national and local enforcement agencies ensure that registration requirements are being correctly implemented by Industry.
Other articles have reviewed the primary elements in REACH: inquiry, pre-registration, SIEFs, restrictions and registration.
But a task frequently overlooked is that, for substances over 10 tonne per annum, the REACH registrant must conduct documented Chemical Safety Assessments to formally risk-assesses all potential exposures from approved marketed uses. Extensive communication with Downstream Users is required to determine what the safe and acceptable uses are, and whether the required Risk Management Measures (RMMs) can be implemented by the entire use chain.
Uses assessed as unsafe must be contraindicated, which restricts marketing choices. In the end, if a downstream user cannot implement the recommended RMMs, the law prevents them from being supplied until they can demonstrate safe use.
Also, substances that are regarded as highly hazardous to the environment (PBT), or are carcinogenic, mutagenic or repro-toxic (CMR) may be subject to a further Authorisation procedure, whereby the manufacturer/importer must actively seek less hazardous alternatives, whilst in parallel maintaining a separate dossier of acceptable Socio-economic reasons for allowing the substance to stay on the market. ECHA is continuously building a list of substances that they want to see taken off the market. Eventually this list will extend into the hundreds of chemicals.
To complicate matters, not all chemical substances are subject to REACH requirements, whilst others subject to REACH require yet further approval under other directives, for example The Cosmetics Directive, that may have competing requirements.
With all this activity, and the strict requirements involved, one could be forgiven for thinking that submitting a REACH registration would provide instant and unfettered access to EU markets.
In some ways this is true, but in others it is not yet reality. Europe is still struggling with the harmonization of national legislatures, and
several countries continue to retain additional requirements on the marketing of chemicals in their territory. A certain amount of chaos still exists in the system. Legislation exists for classification and labelling of substances and mixtures (CLP). Manufacturers, importers, downstream users and distributors are obliged to label any chemical substance or mixture which is classified as hazardous and is contained in packaging. This labelling generally conforms to the Global Harmonized System, yet there remain country-specific classification and labelling requirements. Manufacturers and importers must notify the classifications of their chemicals to an EU Inventory.

**Safety data sheets (SDS)** for substances and products used in Europe must now contain additional information from the Chemical Safety Assessments. These ‘extended’ or eSDS can require extensive management. For preparations and mixtures, tThe data from each of the substance registrations must be combined to provide the overall profile of the chemical product. This in itself can be a mammoth task, especially for formulators.

**And it never stops...**

Companies involved with the transport of chemicals and some other goods need also to be aware of the various international transport regulations, ADR (Road), RID (Rail), IMDG Code (Sea), and ICAO Technical Instructions/IATA (Air).

**Hazardous waste** has yet another separate EU directive, including waste classification codes and sub-directives covering waste from electronic devices (EEE) for example.

**Also**, additional EU directives often come into play. For example, there are special directives covering:

- Biocides ([Directive 98/8/EC](#))
- Plastics (2002/72/EC),
- Toys(88/378/EEC)
- Detergents (648/2004/EC)
- Food Contact materials(EC/1935/2004)

Companies may further require **CE marking** for certain types of potentially-hazardous products, as indicated by application specific legislation.

**EU Importation**
The EU has very similar concerns about imports to those of the US, but the approach is far less systematic and much more is left to the local country to determine and enforce. Structurally, the matrix is the reverse of that in the US, in that the EU has enacted policy statements that are specific issue oriented, but which do not always claim overarching priority or exclusive jurisdiction. The body of regulations and the procedures have a breadth of difference that adds difficulty to compliance.

**Consumer Legislation**

General product safety in the EU is regulated by the **General Product Safety Regulations 2005 (GPSR- 2001/95/EC)**. This applies to all products (new and second-hand) used by consumers. Member states maintain a vigilant watch on the consumer market and frequently identify non-compliant products which are notified to other countries via a special database (RAPEX).

**Individual Countries, Individual needs.**

Most countries have been content to adopt REACH, CLP and GPSR in lieu of their own legislations; however others have retained existing product inventories and registration requirements.

**Germany**

The German Food, Consumer Goods and Feed Code is the legislative instrument for consumer protection. The Chemicals Act of 1980 ("ChemG"), fuses with the emerging EU regulatory structures for Chemicals and Biocides. ChemG represents the German legal framework allowing the transposition of newer EU directives directly into German law. **ChemG** was first established to regulate hazardous chemical substances and products for environmental, consumer and labour protection. Since 2002, ChemG has also covered biocides. Not all hazardous substances are covered in EU frameworks therefore Germany has additional national legislative acts with independent national rules. For example:

- National bans on some substances that are either not or only partly regulated by EU law (e.g. formaldehyde, artificial mineral fibres)
- National rules for the (bio) degradability of ingredients in detergent and cleaning supplies go beyond the scope of EC Regulations, including maximum limits for phosphates
- Additional regulations covering ozone depleting substances and fluorinated greenhouse gases.
- Other special cases where EU community law is absent, or conflict with specific national requirements - for example nanotechnology.

**United Kingdom**

The Health and Safety Executive (HSE) and Health and Safety
Executive Northern Ireland (HSENI) are the primary National Authorities for the UK. The Department for Environment, Food and Rural Affairs (DEFRA) contributes to international risk-reduction strategies for the most hazardous chemicals. Both departments are serviced by the Chemicals Regulation Directorate (CRD).

Manufacturers and suppliers of chemicals also need to comply with the Chemicals (Hazard Information and Packaging for Supply) CHIP Regulations. CHIP requires the supplier of a dangerous chemical to identify the hazards of the chemical (classification), give information about the hazards to their customers, (label), and package the chemical safely. Gradually, CHIP will be replaced by the European Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation).

Correct Classification and labelling are critical to the effectiveness of the COSHH (Control of Substances Hazardous to Health) regulations. COSHH extends the duty to perform risk assessment to the workplace. The Control of Major Accident Hazards (COMAH) Regulations ensure that hazardous substances that are stored in large quantities are adequately controlled to reduce the possibility of accidental release and to mitigate the potential consequences.

**Sweden**

Sweden maintains its own database of chemical products and their uses – the Products Register, maintained by KEMI, the Swedish Chemicals Agency. Every year companies registered in the Products Register must provide information on their product quantities for the preceding year. Discontinued products and existing products whose compositions have changed must also be reported along with new products.

Companies intending to begin manufacture or import of chemicals in Sweden are obliged to report their activities. Any company manufacturing, importing or changing names of chemical products to the minimum amount of 100 kg must file a product report. The information contained in the register has been submitted by companies reporting data on approximately 145,000 chemical products.

An enterprise may also obtain a permission to make a product report on behalf of its customer.

**France**

INRS is the official body for the declaration of chemical substances and preparations (Ministries of Labour, Health and Agriculture).
Beyond EU directives, France maintains a separate chemical product safety database. The registration requirements are applicable to:

- all preparations classified as very toxic, toxic or corrosive within 30 days after marketing in France;
- all biocides marketed in France (existing or new) without delay
- all products upon request of INRS within 15 days.

The data to be notified include detailed qualitative and quantitative composition of the preparation involved. Safety data sheet, labels and technical specification for the declared product are also required.

**Italy**
Instituto Superiore di Sanita registers all preparations placed on the Italian market, ostensibly for provision of information to poisons centres.

**Outside the EU:**
**Russian Federation (RF):**

Chemical legislation in Russia is complex and often conflicted, however recently much attention has been given to harmonising standards internally, and also with co-members of trading blocs (CU, EurAsEC, CIS). The requirement to provide safety data on chemical products is now generally aligned with OECD, EU REACH and GHS.

Broadly, imported products must conform to the harmonized standards of the various trading blocs and in the majority these are derived from the Russian standards. These standards are mostly adopted across the former soviet countries of the CIS.

The standards are referred to as GOST (‘state standard’). Currently there are over 20,000 separate GOST standards used extensively in conformity assessment activities in the 12 countries of the CIS, and covering every area of commercial activity.

Chemical products must relevant ‘safety passports’ from the Federal Agency on Technical Regulating and Metrology.

There are ongoing efforts to harmonise chemical control issues with the other members of the **Customs Union (CU) of Belarus,**
Kazakhstan and Russia, EurAsEC - Eurasian Economic Community, and CIS - Commonwealth of independent states

Switzerland:
Switzerland is in the process of moving towards Reach implementation. The Swiss Chemicals Ordinance (ChemO, RS 813.11) was partially revised in 2009 to adopt Reach-like registration requirements. However these only cover new substances placed on the Swiss market in quantities over 1 metric tonne/year, and PBTs over 10kg/year.

REACH also applies to the wider European Economic Area (EEA) States (Iceland, Liechtenstein and Norway). This means that imports from Norway, Iceland and Liechtenstein will be considered as intra-Community trade for the purposes of REACH.
Other countries in the EU and the region (i.e. Turkey) have specific regulations regarding the placement of chemicals. Not discussed above are the various international conventions (Montreal, Rotterdam, Stockholm), which globally control the movement of chemicals.
One can see that while REACH has resulted in progress towards uniformity and transparency of chemical information in Europe, there still remain other regulatory schemes to which the importer must be aware. Having a substance dossier accepted in REACH is only the first step of an evolving process in which vigilance and attention to detail are required.

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