



Looking Deeper into Registration Impacts on the US

**REACH Training Development
Workshop
October 15, 2009**

The Registration in REACH



- **EU-based M/I of substances have to register them with ECHA**
 - Registration will involve identification of all USES of a particular substance (such as use as a paint thinner, in an alloy, etc) and supporting information
 - Failure to register USES of a material by predetermined deadlines can interrupt the supply of that material



“No Data, No Market”

The Registration in REACH



- **Requirements for REGISTRATION apply to:**
 - Substances on their own (*acids, alcohols, organic solvents*)
 - Substances in preparations (*paints/primers, NDT fluids and powders*)
 - Monomers of polymers imported into the EU (*paints/primers, resins*)
 - Substances in **ARTICLES** when the substance is **INTENDED TO BE RELEASED** during normal & reasonably foreseeable circumstances
- **If those substances are manufactured or imported in quantities > 1 tonne/year per legal entity**

Registration Requirements are now in Effect!

Article Exemption

- Registration is **not** required for substances in an article, if that substance is **not intentionally released** from the article
 - If you **manufacture an article in the EU**, then the manufacturer or importer of the chemical substance must register the substance for your use
 - If you **manufacture an article outside the EU** and it is subsequently imported into the EU, registration is not required **UNLESS** the article contains a chemical substance that is intentionally released during use



Registration of Substances in Articles



- Substances in **ARTICLES** when the substance is **INTENDED TO BE RELEASED** during normal and reasonably foreseeable circumstances:
 - The **INTENTION** is important
 - The key test is whether the core function of the article is to release a substance (example: *a scented candle*)
 - A hydraulic cylinder does not have an **INTENDED** release
 - Normal wear is not considered to be an intended release
 - Release during disposal is outside the scope of this requirement
- **Additional guidance available on the ECHA website**

There are still some Grey Areas

Intended Release?



No	Yes
Welding fumes	Fragrance from candles
Wearing parts	Dyes from clothes
Combustion products	“Packaging materials for metal parts, releasing grease/ corrosion inhibitors”
	Stop-off for etching

Articles with Intended Releases



- The EU published guidance on articles - RIP 3.8 on May 28, 2008
 - Additional guidance available via ECHA “Guidance in a Nutshell” documents
- The **AeroSpace & Defense** Industries Association of Europe (ASD) published REACH Interpretation Guidelines, which includes an opinion document on what constitutes a substance, preparation, and article
- The AIA prepared a document to be incorporated into the ASD opinion doc, an opinion on the application of **REACH** Registration Req’t’s to munitions
- More specifically, this provides guidance on several types of munitions:
 - Containing High Explosives, With Secondary Effect, Containing Energetics, Utilizing Directed Energy, Serving as Container or Delivery Mechanism, ...
- A rationale has been provided for each assumption
- Both individual documents are in the process of being merged to form a final joint opinion document
 - Although not a legally binding document, it is expected to be influential when official guidance is formulated on these categories of articles

Estimated Registration Cost for One Substance



Volume tier	Individual registration (euro) ¹	Average testing cost per substance (euro) ²
1 - 10 tonnes	1,600	56,360
10 - 100 tonnes	4,300	279,838
100 - 1000 tonnes	11,500	799,562
> 1000 tonnes	31,000	1,582,616

¹ Draft Regulation on Fees and Charges, Individual Submission under Article 6, 7, or 11, October 2007, p. 16.

² Source: Fleischer, M., "Testing Costs Testing Capacity According to REACH Requirements - Results of a Survey of Independent and Corporate GLP Laboratories in the EU and Switzerland," September 2007, pgs. 96-114

Some EU companies may look at these costs and decide the cost of REACH compliance is not worth "it" and terminate some products

The Pre-Registration Option in **REACH**



- **Pre-Registration of Existing Substances**
 - M/I can avoid some supply chain risks by pre-registering substances in their products
 - **Even if they suspect that registration will not be necessary!**
 - Pre-registration allows for substances to continue to be used until the full registration is completed
 - Companies that pre-registered can take advantage from a potential 11 year phase-in period for full registration
- The pre-registration period was June 1 – December 1, 2008
 - ~65,000 companies pre-registered ~150,000 substances
 - 2,700,000 total pre-registrations
 - Companies that did not pre-register **must register now**; prior to M/I within the EU market, or they are in violation of the law as of June 1, 2008
 - Unless you qualify for late pre-registration...

The Pre-Registration Option in **REACH**



- Late pre-registration option available for substances new to the EU market as defined by:
 - Substances as listed on EINECS, being imported by the legal entity or manufactured in the EU for the first time
 - Substance manufactured in the EU, but not placed on the market, at least once in the past 15 years
 - Substance is a NLP (No Longer Polymer):
 - Defined based upon a gap in previous regulations; currently 776 NLPs require notification under REACH (likely applications: elastomers, plastics, fibers)
 - Late pre-registration must be completed at the latest six months after its manufacturing or importation exceeds the 1 tonne threshold, and at least 12 months before the relevant deadline for registration
 - See Article 28.6 for additional information on late pre-registration
 - If you did not pre-register and do not qualify for late pre-registration, you must complete full registration prior to entering the EU Market

What if my Company Supplies to the EU? What is an Import?



- **Imports into the EU may be subject to Registration requirements**
 - Applies to chemical substances by themselves and in preparations
 - Applies to articles when there is intended release during normal and reasonably foreseeable circumstances
- Unless already pre-registered, full registration would be required
- The latest thinking on the definition of an import
 - When something crosses the customs boundary into the EU / EEA
 - When something is introduced into the EU market and is no longer under customs control
 - *This is not explicit in the regulation, but how it is likely to be interpreted*
- **The Importer of Record is responsible for registration of imports!**
 - Your customers may be the importers – what is your distribution model?
 - How important is your EU market?

“Only Representative”



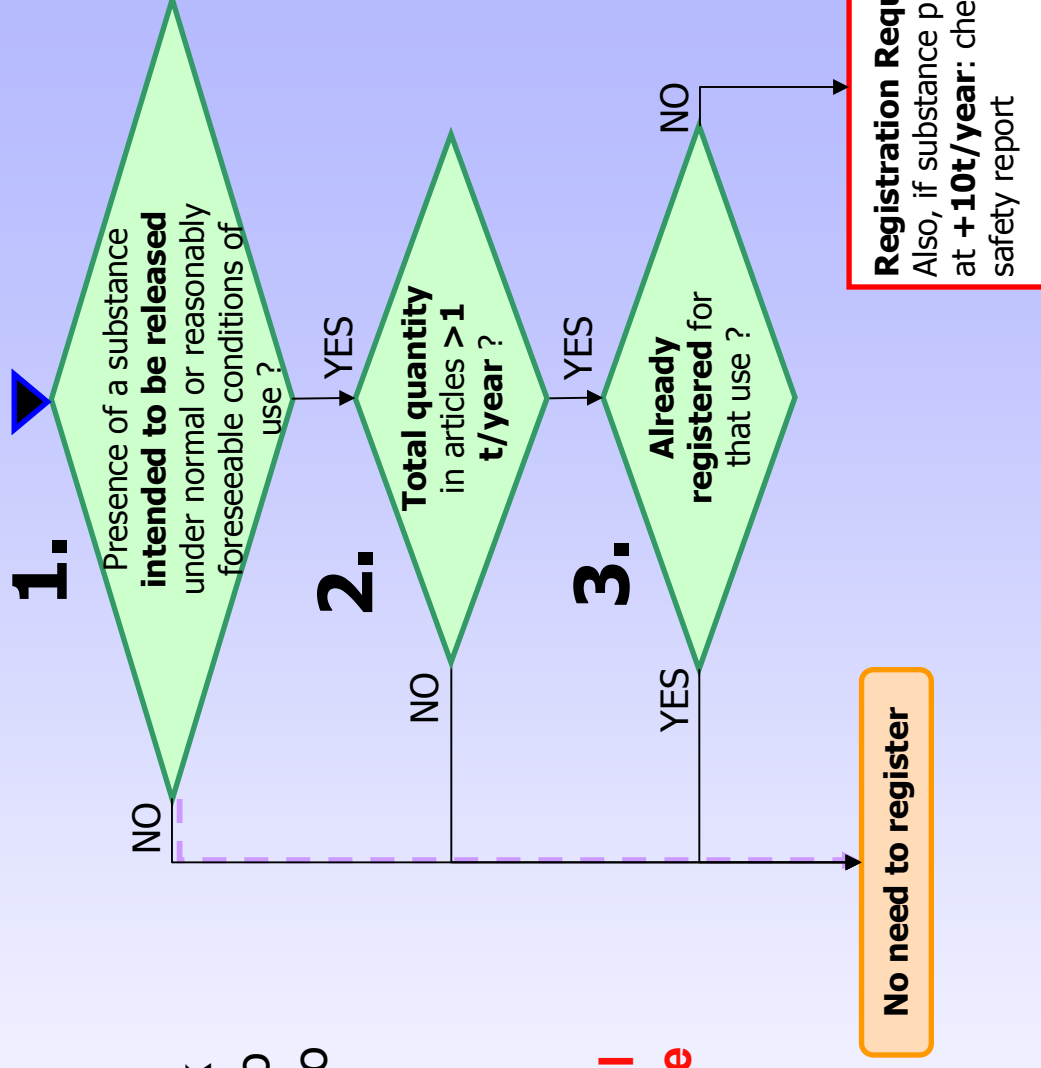
- To comply with the registration requirements of REACH, you will need an “**Only Representative**”
 - “Only Representative” - EU-based natural or legal person acting on behalf of a Non-EU manufacturer fulfilling the duties of an importer
 - As of April 2008, the “Only Representative” will need to file a separate registration for each substance/legal entity it represents
- Non-EU companies can Register on their customer’s behalf, but only by using an “Only Representative” (OR)
- If a non-EU M/I decides to nominate an OR to register the substance exported to the EU, the importers from that non-EU manufacturer would no longer have duties as importers, but will be regarded as “**downstream users**”
 - The downstream user will need to know who will act as the registrant
 - The OR has the legal responsibility to comply with REACH obligations

Articles: Will your Customer / EU Subsidiary have to Register? (7.1)



The questions to ask to know if you have to / your customer has to register....

This flowchart shows the general case for aerospace articles



Registration and YOU



- Suppliers/importers will need information to write chemical safety reports (if needed) and to identify ‘Exposure Scenarios’, including:
 - Epidemiological studies, animal testing
 - Typical uses and exposure data
- EU manufacturers and importers will be utilizing “Substance Information Exchange Forum” (SIEFs) to share information and minimize testing
 - SIEFs comprise any company that pre-registered a substance
 - Will likely comprise a few large companies who manufacture / import majority of the substance, and a myriad of others who utilize or import smaller amounts
 - It is expected the larger companies will form consortia, to carry out the testing that relates to the majority of their uses
 - Where the uses that you need to register overlap, you will need to obtain and/or purchase the relevant data from the consortia as part of the SIEF
 - If the primary consortia does not address your needs, you may need to develop a “mini-consortia” with others in the SIEF who need the same info

Registration and YOU



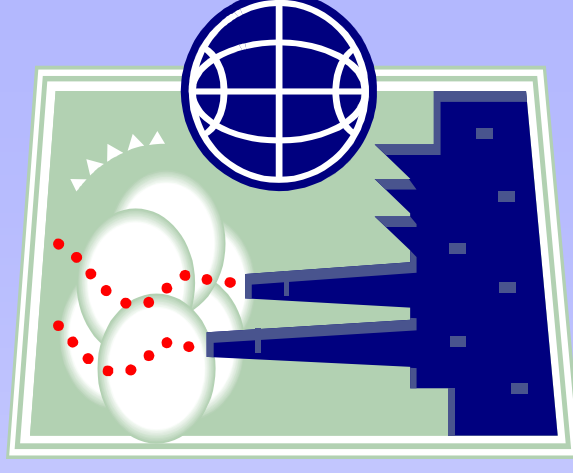
- If you export a substance, preparation, or article with intentional release of a substance to the EU:
 - If you are the importer of record, you are obligated to complete full Registration
 - Can take advantage of gradual phase-in deadlines for registration if the product has already been pre-registered for that use
 - If you're not the importer, the EU importer should be contacting you for information required to satisfy its Registration requirement
 - For an article with an intentional release, the information required includes a composition by weight of all the chemical substances (at a CAS number level) that are 'intended to be released'
 - If the importer is required to register your product but fails to do so, and they did not complete pre-registration, **they will be importing your product illegally!**

Even If You Don't Export to the EU...



You still may be affected...ask questions!

- Are any of your or your supplier's raw materials made in the EU?
 - Ensure your supply is not interrupted
- Do your customers export to the EU?
 - Your customers will need information on your products



Understand how REACH Impacts your Supply Chain!

Questions

