

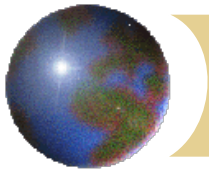
REACH –for Businesses

Stephen Greene

May 7, 2009

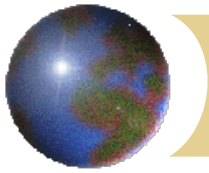
TURP Continuing Education Conference

Devens, Massachusetts



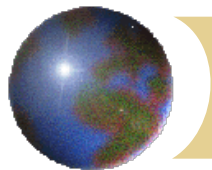
Translating REACH into business actions

- ✚ REACH is complicated and is/will have a significant impact on MA business
- ✚ In 60 minutes we are just touching on the important elements
- ✚ The devil is in the details and there are many
- ✚ I will only cover key business issues



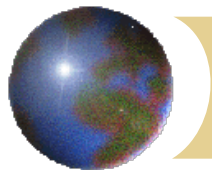
At the end of the day(year)

- ✚ You want continued sales growth to or in the EU
- ✚ Protection your business interests and information
- ✚ Plan a smooth transition for substances that may leave the market
- ✚ Have a system for managing the flow information up and down the supply chain



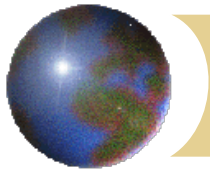
(con't)

- ✚ Pre-Register or Register
- ✚ Assure that Registration supports your interests
- ✚ Know your article obligations
- ✚ Pass safe use information on to downstream users
- ✚ Manage authorized substances



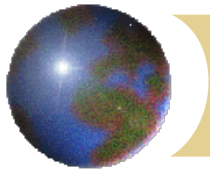
Key points to keep in mind

- ✚ Articles are made of substances and are very much in the impact zone for REACH
- ✚ 95+ % of your effort is going to be on gathering and managing information
- ✚ No registrations are likely for you
- ✚ You are a Downstream User (DU)
- ✚ You may be an importer, or,
- ✚ You are supporting a DU or importer



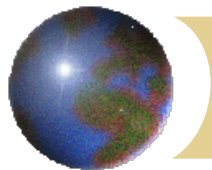
Key Points con't

- ✚ Will your company need information from suppliers to make sure they will register substances for your use? (Has more to do with special use substances)
- ✚ Your company will want to know if substances that are withdrawn from the market will affect your products
- ✚ REACH will impact EU sales
- ✚ Forget about exemptions



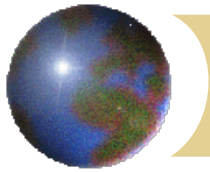
How do you avoid trouble?

- ✚ Know what is in your products, especially substances of very high concern (SVHC)
- ✚ Make sure that substances you sell in the EU will be pre-registered or registered
- ✚ Know what is imported into the EU
- ✚ Understand that articles are made of chemicals
- ✚ Manage your product information



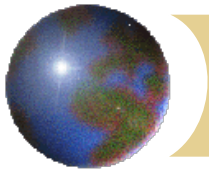
Was Pre-Registration Important?

- ✚ Yes, in most cases
- ✚ It is the difference between Dec 1, 2008 and 3, 6 or 10 year delay based on weight thresholds
- ✚ It is the difference between being able to use a substance legally in the EU
- ✚ It does not help for new substances (newly invented or new to the EU)



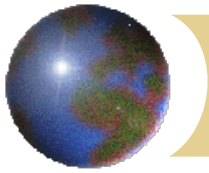
Needed information

- ✚ What is the are substances that you use
 - ✚ As substances or in preparations
 - ✚ In articles
- ✚ Are there intentional releases
- ✚ Are there likely Substances of Very High Concern (SVHC)
- ✚ What are the amounts of SVHCs



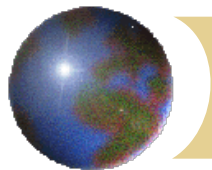
Understand your role in the EU

- ✚ Are you a producer? Not likely unless you are an importer
- ✚ Are you an exporter
- ✚ An importer
- ✚ Downstream User
- ✚ Consumer
- ✚ Each position has rights and responsibilities



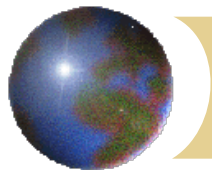
Definitions that may matter

- ⊕ Article
- ⊕ Downstream User
- ⊕ Importer
- ⊕ Only Representative
- ⊕ SVHC
- ⊕ Safety Data Sheets
- ⊕ Pre-Registration (probably not applicable)
- ⊕ Registration (probably not applicable)
- ⊕ Authorization Restriction – if an SVHC is listed



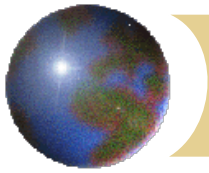
Significant Business Impact

- ⊕ REACH is an European chemical registration, approval, use and disclosure law
 - ⊠ Chemical production is only part of the law
 - ⊠ **Downstream use is our major concern**
- ⊕ An article now needs to be viewed as a list of all its chemical constituents
 - ⊠ For example - a plastic spacer is a polymer, a plasticizer and stabilizers – 3 substances, 2 of which are likely to be impacted by REACH
- ⊕ Chemical toxicity data will be associated with your product and may be a marketing concern



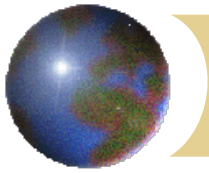
Do You Know all the Chemicals in Your Products?

- ✚ Though European in origin, REACH will have worldwide impact
- ✚ Chemicals, preparations and products produced and/or imported into the EU are directly impacted
- ✚ Outside of the EU, the business impact will result from the “blacklist” of toxic chemicals that will develop under REACH



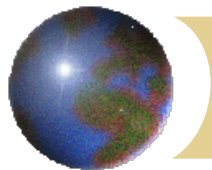
You survived RoHS, so?

- ✚ REACH is like RoHS but for every thing because it covers the use of chemicals in products as well as the use in production
- ✚ Phases out SVHCs and substitutes safer chemicals
- ✚ REACH is based on tonnage and a 0.1% threshold based on the whole product weight
- ✚ Important debate – should 0.1% be based on homogeneous material, not the total product



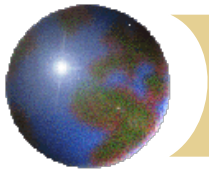
RoHS and WEEE Revision

- ✚ The drafts were out December, '08
- ✚ They did not propose to add any of the 46 initially list substances
- ✚ Will use REACH for additional chemical restrictions
- ✚ Proposing to CE Mark as assurance that RoHS is met



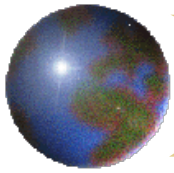
US and State REACH

- ✚ Pending Federal Legislation - Kid Safe Chemicals
- ✚ California Green Chemistry
- ✚ Massachusetts
- ✚ Joel will cover



REACH Transparency

- ✚ Mainly an IT based system
- ✚ Data entered electronically
- ✚ Data accessible electronically

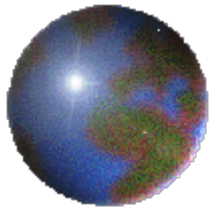


REACH Guidance

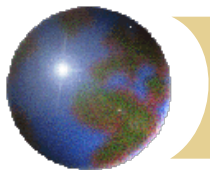
http://guidance.echa.europa.eu/guidance_en.htm

This is probably more information than you wished for.

The guidance does evolve. It is not binding nor is it law.



Introduction to REACH



What is REACH

REACH = Registration, Evaluation and Authorization [and Restriction] of Chemicals

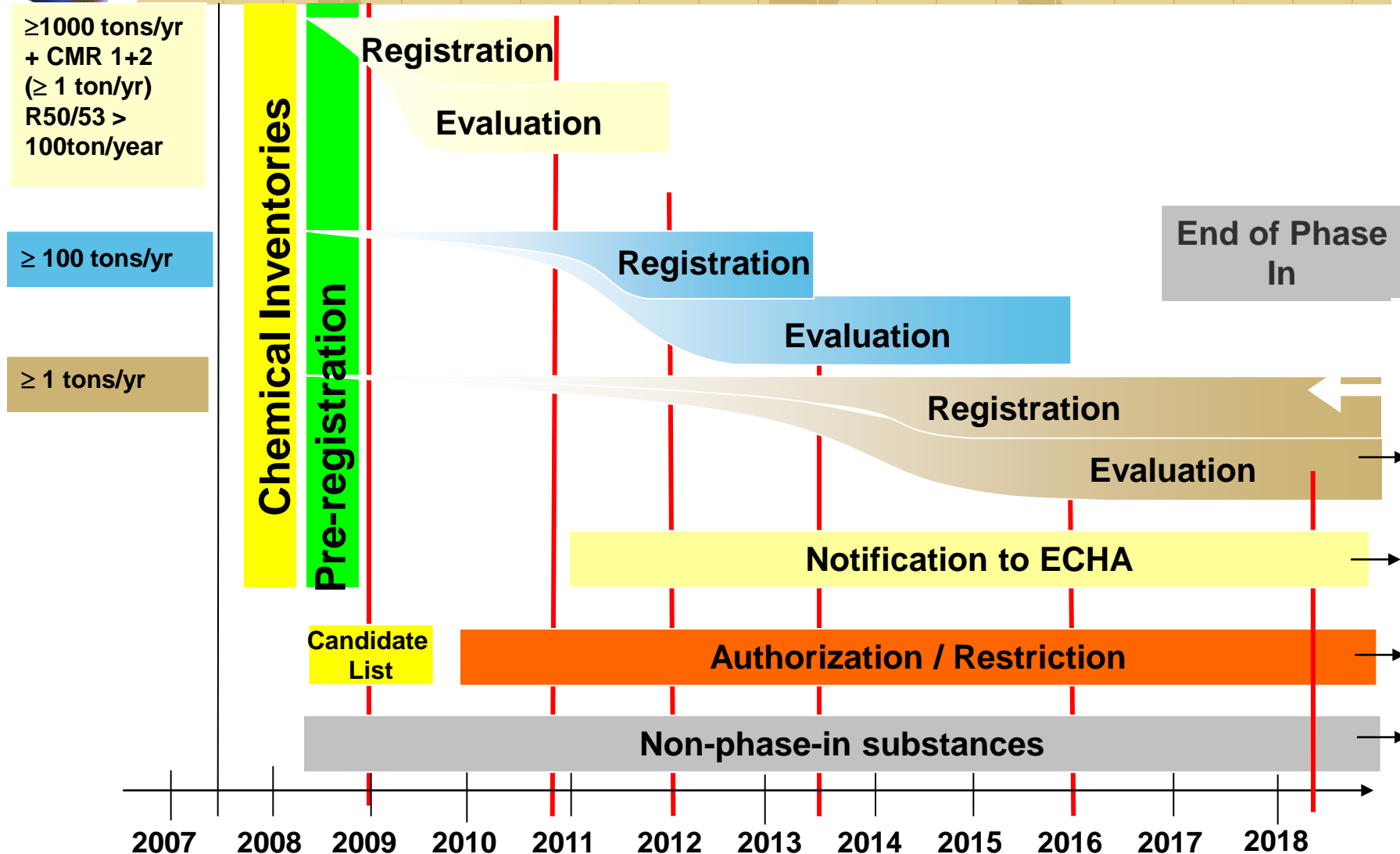
- Came into force on June 1, 2007
- An EU “regulation”, meaning it is immediately applicable and needs no transposition into national legislation
- Gradual introduction of the obligations through to 2018 (for pre-registered substances)
- Puts all responsibility for demonstrating the safety of chemical substances on industry, not government. Reverses the burden of proof
- Replaces most of the current EU directives and national laws on chemicals

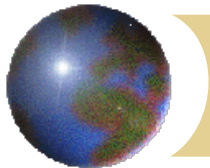


REACH is an EU regulation, but it has a global impact.



REACH Time Frame





REACH Requires

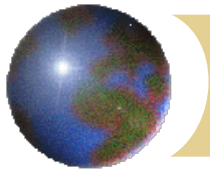
- The same level of risk assessment and analysis for **existing chemicals** as required for registration of new chemicals
- The **reduction in risk** for the 30,000 most frequently used substances throughout their life cycle
- The gradual **withdrawal** of substances of very high concern from the EU market

Implementation and Monitoring:

European Chemicals Agency based in Helsinki, Finland

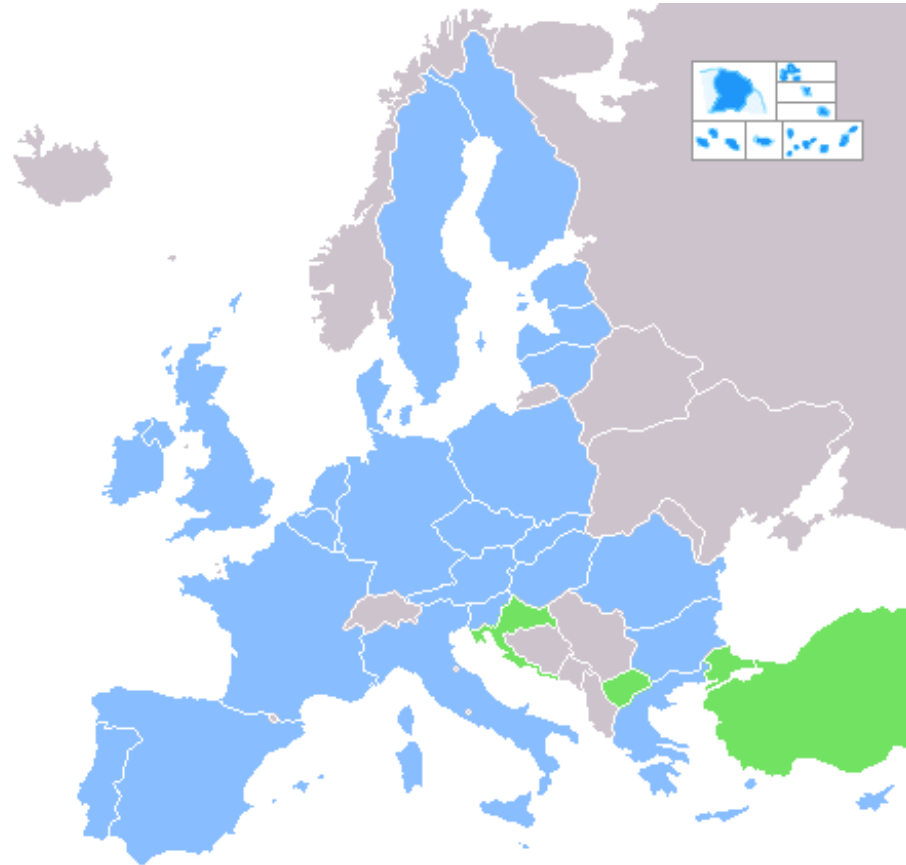


REACH will lead to the withdrawal of substances from the EU



REACH Applies to the EU

- ✦ 27 Member States of the European Union
- ✦ Norway, Iceland and Liechtenstein
 - ✦ considered **WITHIN** the EU for REACH (these countries will also apply the regulation)
- ✦ Switzerland is **OUTSIDE** the EU





Substance - a chemical element and its compounds in the natural state or obtained by any manufacturing process

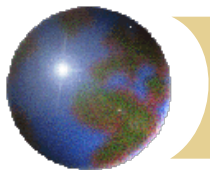


Examples:

- Methanal (Formaldehyde) – CAS N° 50-00-0
- Nickel metal – CAS N° 7440-02-0
- Tetrachloroethylene (Perchloroethylene) – CAS N° 127-18-4

Phase in substance - a substance having an EINECS number (European Inventory of Existing Commercial Chemical Substances)





REACH *Regulates*

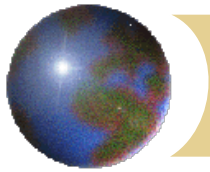
Preparations - *mixture or solution*
composed of two or more *substances*

*Examples: paints, glue, lubricants, varnishes,
adhesives, alloys*

Intermediate - *substance* that is manufactured
for and consumed in or used for chemical
processing in order to be transformed into another
substance [*non-isolated; on site isolated;
transported isolated*]

Polymer – *substance* consisting of molecules
characterised by the sequence of one or more
types of monomer unit. Such molecules must be
distributed over a range of molecular weights.



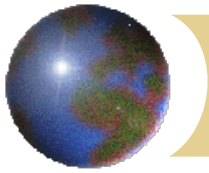


REACH Regulates

- ✚ Articles - object which during production is given a specific shape, surface or design which determines its function to a greater degree than its chemical composition (*Important definition*)

The shape, surface or design is more important than what the substances it is made of.



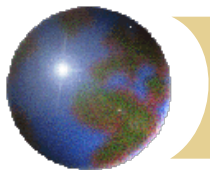


What are Articles

- The product that you make is probably an article

Wire	Laptop
Circuit Board	CPU
Power Assembly	CRT
- The spare parts you make are articles (component, spares-kit, maintenance kit (minus the chemical preparations), test equipment)

BUT, service kits may contain substances such as paint, lubricants and sealants.
- You might BUY articles – close-to-form forgings, bolts, memory chip...



Substances in Articles

> 1 tonne /year per Manufacturer/Importer

Registration

Intended to be Released
(regardless of hazard)

Obligation to Register

- In accordance with phase-in deadlines

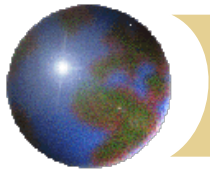
Notification

Substances of very high concern, that are placed on candidate list, and are contained in the article in concentrations >0.1% weight by weight

Obligation to Notify EU Chemicals Agency

- Except when there is no exposure
- At the earliest June 1, 2011 and then 6 months After SVHC added to candidate list

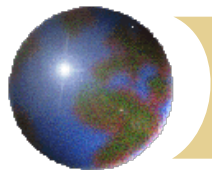
Agency May require Registration



Registration of Substances in Articles

Substances in ARTICLES when the substance is INTENDED TO BE RELEASED during normal and reasonably foreseeable circumstances:

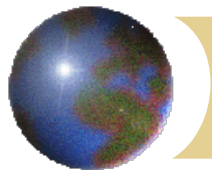
- The **INTENTION** is important
- The key test is whether the core function of the article is to release a substance. (Example: *a scented candle*)
- A hydraulic cylinder does not have an INTENDED release
- Normal wear is not considered to be an intended release
- Release during disposal is outside the scope of this requirement



Registration

- ✚ This will MAINLY be for chemical/metal manufacturers and importers (M/I)
- ✚ Pre-register from June 1 – December 1, 2008 to benefit from a potential 11 year phase-in of registration
- ✚ Manufacturers and importers will need information from Downstream Users



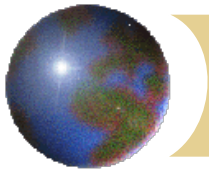


The Pre-Registration in REACH

Pre-Registration of Existing Substances

- M/I can avoid some supply chain risk 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 - benefit from a potential 11 year phase-in of registration
- The pre-registration period is June 1 – December 1, 2008.

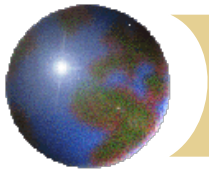
If a substance is not pre-registered by December 1, 2008 it cannot be manufactured/imported (M/I) into the EU until it has been registered!



Who Registers IMPORTS

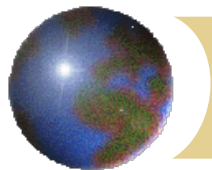
The importer of record is responsible for Registration. This could include:

- ✚ You
- ✚ Your EU Subsidiary
- ✚ “Only Representative”
- ✚ Your EU importing customers



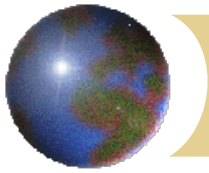
REACH Thresholds

- ✚ One tonne of substance released
- ✚ 0.1% of SVHC in Article and 1 tonne placed on the market
- ✚ 0.1% of an SVHC in an article for safe use information (no weight threshold)



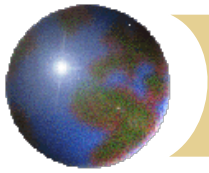
Key Dates

- ✦ June 1, 2007, in force and SDS information
- ✦ June 1, 2008,
- ✦ October, 2008 Safe Use info for candidate SVHC
- ✦ December 1, 2008
- ✦ January 1, 2009 Pre-Registration List available
- ✦ June 1, 2009, SVHC Candidate list in Annex XIV
- ✦ Dec, 2010 register intentional release >1,000 or >1 tonne for CRM
- ✦ June 1, 2011 + 6 months for SVHC notification
- ✦ 45 days for listed annex XIV SVHC



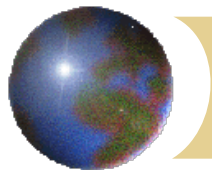
Business Steps

- ✚ Recognize REACH as a significant business issue
- ✚ Organize the business, high level (cutting across) and operational (drilling down)
- ✚ Gather information (yours and your supply chain)
- ✚ Manage the information
- ✚ Execute your strategy for managing REACH



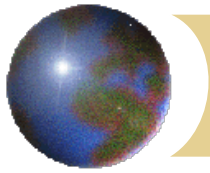
If you don't have to register -

- ✚ Perform due diligence to show you don't have to register
- ✚ Be prepared to manage information you are obligated to share when a SVHC is added (started in October). Effective on formal listing as a candidate SVHC
- ✚ Notification to ECHA when article contains listed SVHC (2011)



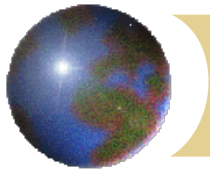
If you do have to register –

- ✚ Pre-register to give you the allotted time
- ✚ Budget for significant expense for each substance or to work with substance information evaluation forum (SIEF)
- ✚ Manage confidential information
- ✚ Note – the expense of registration is expected to eliminate some chemicals



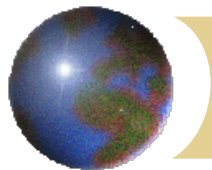
Substance Information Exchange Forum - SIEF

- ✚ Required step in the registration process
- ✚ Seen as important in information exchange and to reduce testing
- ✚ Great range in number of participants
- ✚ Business controlled – only helps from the periphery



SVHC's – the bull in the china shop

- ✚ The list is expected to be contain 1,500 substances but could go to 3,000
- ✚ Will restrict substances that pose and unacceptable risk
- ✚ Will / has created the chemical black list
- ✚ Has spawned other lists.



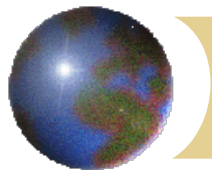
SIN List – Substitute It Now

- ✚ Developed by the Chemical Secretariat.
A NGO in the EU

<http://www.chemsec.org/>

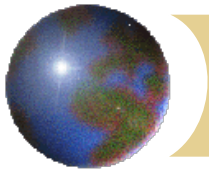
- ✚ Lists about 270 substances

- ✚ See at <http://www.chemsec.org/list/>



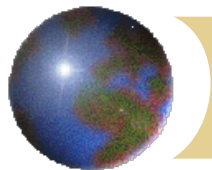
EU Trade Union List

- ✚ A variation on the SVHC and SIN list
- ✚ Contains about 300 (closer to 400 when you look at related compounds)
Substances
- ✚ Can be found at
<http://www.etuc.org/a/6023>



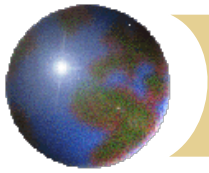
Authorized SVHCs

- ✚ Applies when added to appendix XIV
(this is the formal list of SVHC and their controlled uses and sunset dates)
- ✚ Starts when voted as a candidate SVHC
- ✚ Pass information on to the supply chain
 - ▣ Began October, 2008
- ✚ Provide information to end user – the Safety Data Sheet



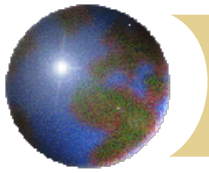
In closing

- ✚ REACH is going to have a profound impact on how chemicals are used
- ✚ The requirement to provide information about the chemicals will drive change
- ✚ Expect chemicals to leave the market
- ✚ Is driving a Global Harmonization System for chemical information sharing



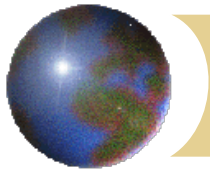
GHS

- ✚ Not to be covered - but
- ✚ Should not be forgotten
- ✚ International impact - for consistent classification and labeling



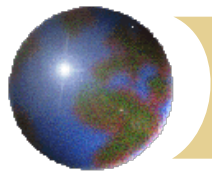
Enforcement

- ✚ Enforcement is a national requirement
- ✚ ECHA is playing a major coordinating role
- ✚ Early enforcement priorities are
 - ▣ Registration/preregistration
 - ▣ Safety Data Sheets



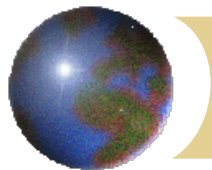
This presentation is only a small part of the REACH story

- ✚ REACH is a paradigm shift
- ✚ Much of the regulation may be irrelevant to your business
- ✚ Information management is key



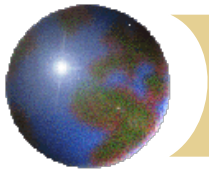
Information and the Supply Chain

- ✚ When it comes to articles, you are dependent on your supply chain
- ✚ REACH is going to be a long-term relationship with your supply chain
- ✚ Information will come from many tiers
- ✚ The target chemicals will be added over time



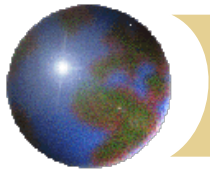
Chemicals removed from the market or information supplied

- ✚ Are you prepared?
- ✚ Which ones likely?
- ✚ Are you prepared?
 - ▣ June 1, 2008?
 - ▣ October, 2008
 - ▣ December 1, 2008?
 - ▣ November 30, 2010 (CMRs and 1,000 mt)
- ✚ Who will pay for the registration / testing cost of a low volume chemical?



Special Products you sell

- ✚ Are there any service kits that include substance that can be released?
- ✚ Sealed cooling systems? Not likely an intended release.
- ✚ Any unique additives?
- ✚ Will your OEMs want detailed information so they can add SVHCs up?



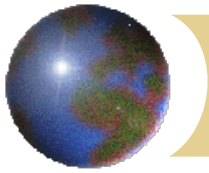
ECHA – European Chemicals Agency

- ✚ Web site

- ✚ http://echa.europa.eu/home_en.asp

- ✚ Go to REACH

- ✚ Also deal with your National Competent Authorities in each country you operate or do business



Thank you for your attention

✚ Questions?

✚ Contact

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