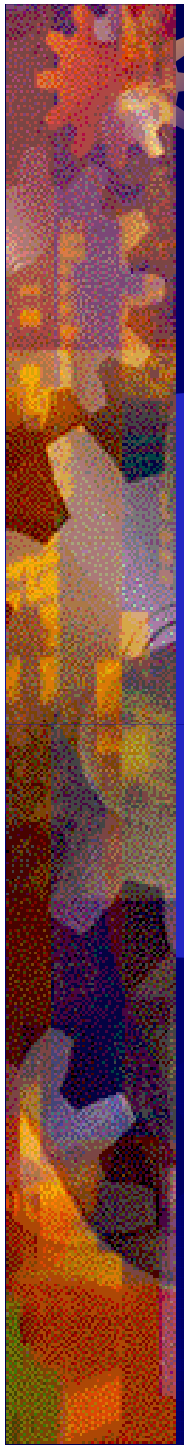

REACH

Registration, **E**valuation and **A**uthorization of **Ch**emicals

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Today's Presentation

- History - Brief comparison between US and EU (European Union) Chemical Regulations
- Outline of the major provisions of REACH
- Implementation Schedule
- Implications for US Companies that sell chemicals and/or chemical-containing materials into the EU (and implications for Industrial Hygienists)

Today's Presentation is NOT:

- An in-depth examination of the cost-benefit of REACH

History

- US – TSCA (1976-Toxic Substances Control Act)
  - Applied to manufacturers of “new chemicals” or “new uses” of existing chemicals
  - EPA could require testing prior to sale or distribution if they felt its use could pose an environmental or health hazard - has power to ban chemicals

History
-continued-

- EU – Dangerous Substances and Preparations
- 1979 - Required testing of all “new” chemicals
- Loophole - “New” chemicals could be registered until 1981 - without having toxicity testing (about 3,000 v. 100,000 ‘existing’ chemicals)

History
-continued-

- Under current EU chemical regulations "New substances" were heavily regulated, but made up only a << 1 % of total chemicals in volume
- Existing substances were essentially unregulated, yet made up >> 99 % of volume

History

-continued-

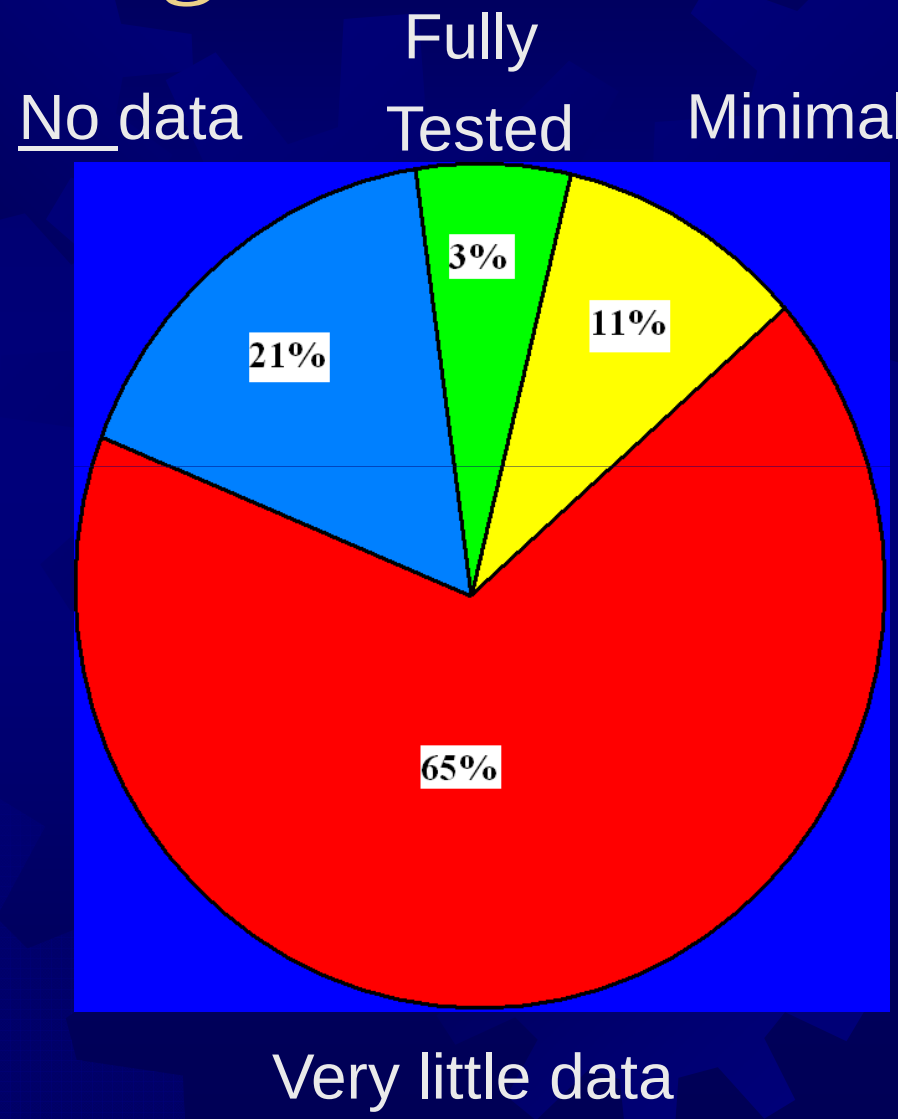
- Concern that EU chemical policies didn't provide sufficient protection, led to a debate at the informal Council of Environment Ministers in 1998.
- The EU Commission made a commitment to assess the operation of existing regulations.
- The report on the findings was adopted by the Commission in late 1998 and REACH was conceived....


REACH will regulate chemical:
Manufacturing
Importing
Marketing
Use

REACH

- Main objective: to provide better protection of human health and the environment
- REACH results in a major shift of responsibility and costs to chemical manufacturers (from EU Governments)
- Innovation (especially for finding less hazardous substitutes) lacked incentives - U.S. rate of new chemical notifications nearly 4 times higher than in EU
- Replaces about 40 different pieces of existing legislation in the EU

How much information exists about High Volume Chemicals?



Some Exemptions from REACH

- Pharmaceuticals, Pesticides
- Radioactive substances
- Medicinal products (human or veterinary)
- Food additives, flavorings, Animal feed
- Polymers
- Some listed “naturally occurring substances”, e.g. coal, crude oil, natural gas, salt (provided they aren’t chemically modified)
- “Ubiquitous materials” - e.g. water, nitrogen
- Substances in use for R&D (5 yr. Exemption)

Registration

- Testing is required only when current chemical safety data is not adequate
- If more than **1 ton/year,** producers and importers must assemble limited information (generally in-vitro data only)
- If more than **10 tons/year,** a full “Chemical Safety Report” is required
- The ***burden of proof*** is now shifted to industry from government

Registration

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- Companies must register, or their product(s) can't be manufactured or imported into EU market
- "High-risk" substances are registered first
- Articles (hard goods) must be registered if:
  - they contain substances that meet criteria for "dangerous substances", and;
  - the substance(s) will be released during *normal and reasonably foreseeable conditions of use*

Evaluation

- Evaluation - Review coordinated by a **new** EU regulatory body: European Chemicals Bureau (ECB) in Helsinki, Finland
- Dossiers - will only be checked for completeness, unless they are selected for evaluation (5% of all submissions is the goal)
- Enforcement can **only** be done by Member States (per EU Constitution)

Chemical Safety Reports

- Required for all substances subject to registration if >10 tons/year
- Part of the “Registration Dossier”
- Exemptions for substances in preparations below certain concentration limits
- Defined in Annex I - “Analysis of hazards, exposures, and safe uses..”
- Components of a CSR:
  - Human health hazard assessment
  - Environmental hazard assessment
  - for PBTs and vPvBs - exposure scenarios

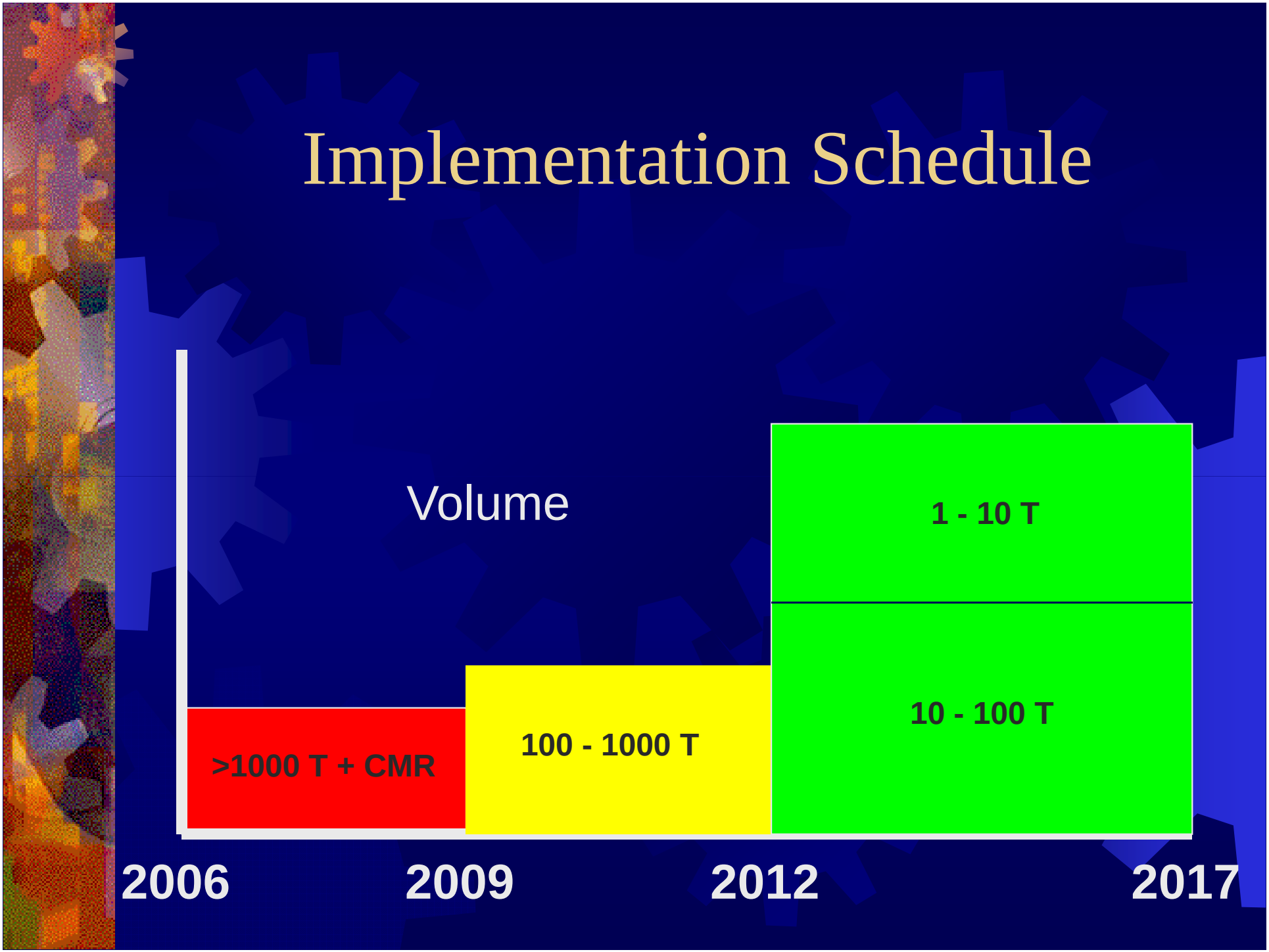
Authorization

- Authorizations (granted by the EU Commission) that are use-specific will be required for substances that are:
  - bioaccumulative
  - carcinogens
  - mutagens
  - reproductive toxicants

Authorization

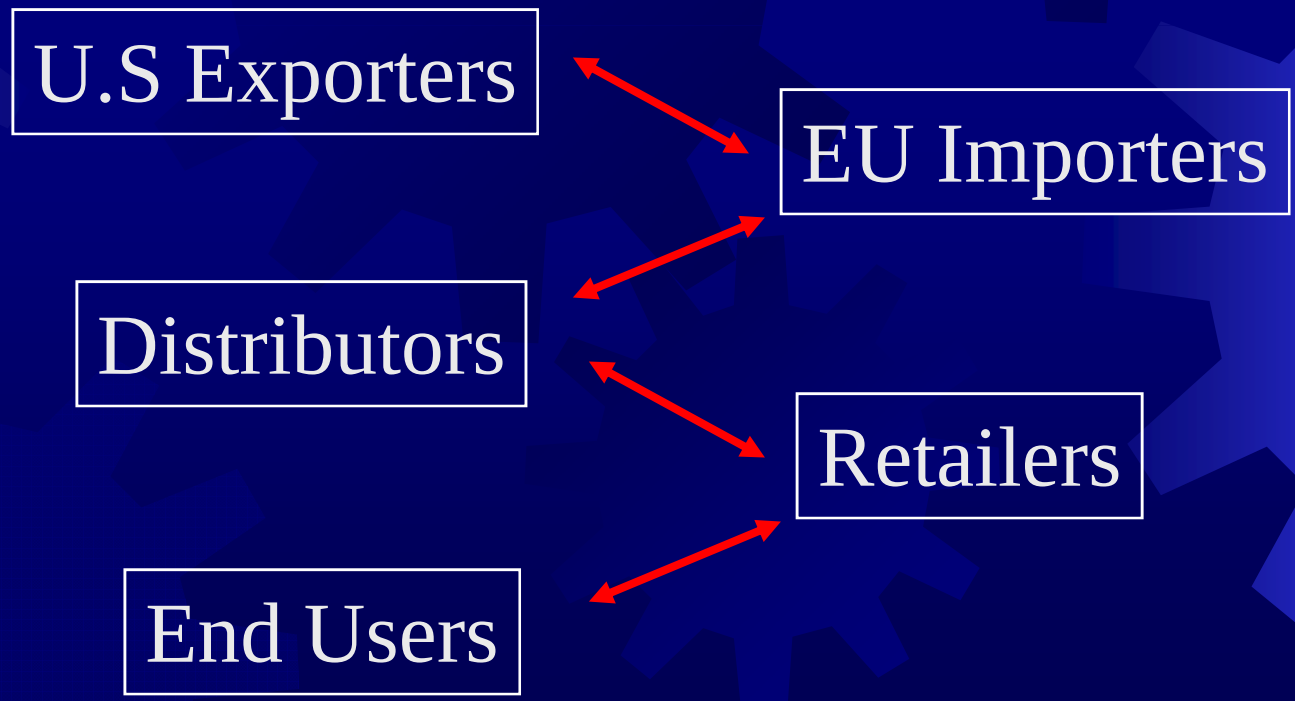
- EU Commission can decide to ban a substance or its use (just as U.S. can under TSCA)
- Companies must demonstrate that:
  - Risks are “adequately controlled” or;
  - The social and economic benefits outweigh the risks, and adequate alternatives are not available

Implementation Schedule



Controversial Aspects of REACH

- Covers articles and finished goods (not just raw chemicals)
- Less protection of trade secrets
- Will impact relationships between:



What are the implications for U.S. Companies with Manufacturing Operations in EU?

- "Use-approved" chemicals only
- Make sure use is consistent with manufacturer's intended use, for which tests have been conducted
- Downstream users are responsible for assessing risks arising from uses not covered by the SDS (Safety Data Sheet - equivalent of MSDS in US) received from their suppliers

What are the implications for U.S. Companies exporting only Finished Products/Articles?

- Must ensure end users have all necessary information for safe use of products
- Distributors must ensure safety information is provided with the substances they sell
- Must coordinate with vendors to ensure they will register the raw materials the U.S. Company uses

What are the implications for U.S. Companies exporting only Finished Products/Articles?

- Must coordinate with vendors to ensure that U.S. Company's product uses and exposure scenarios are included in the dossier
- Must modify all MSDSs to include the exposure and risk scenarios mandated by REACH

This should be interesting…….

- **Very** strong emphasis on alternatives to animal toxicity testing - will the info generated be adequate?
- REACH **requires** data-sharing for any safety information produced - will private corporations be willing to share (within the framework of confidentiality protections)?
- Requests for more info must be approved by ALL Member States
- How many times have you seen a label and/or MSDS with the phrase ***'under normal use conditions'***?

The Bottom Line

- REACH will have a major impact on U.S. Companies
- REACH will have a significant impact on the fields of industrial hygiene and toxicology

Additional Resources

- http://www.cefic.org/
- http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
- http://ec.europa.eu/echa/