



# REACH from a Business Perspective

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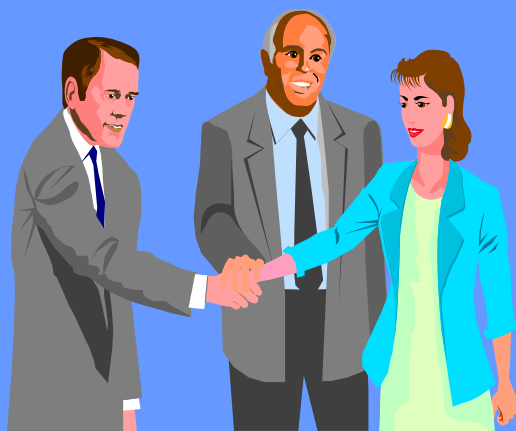
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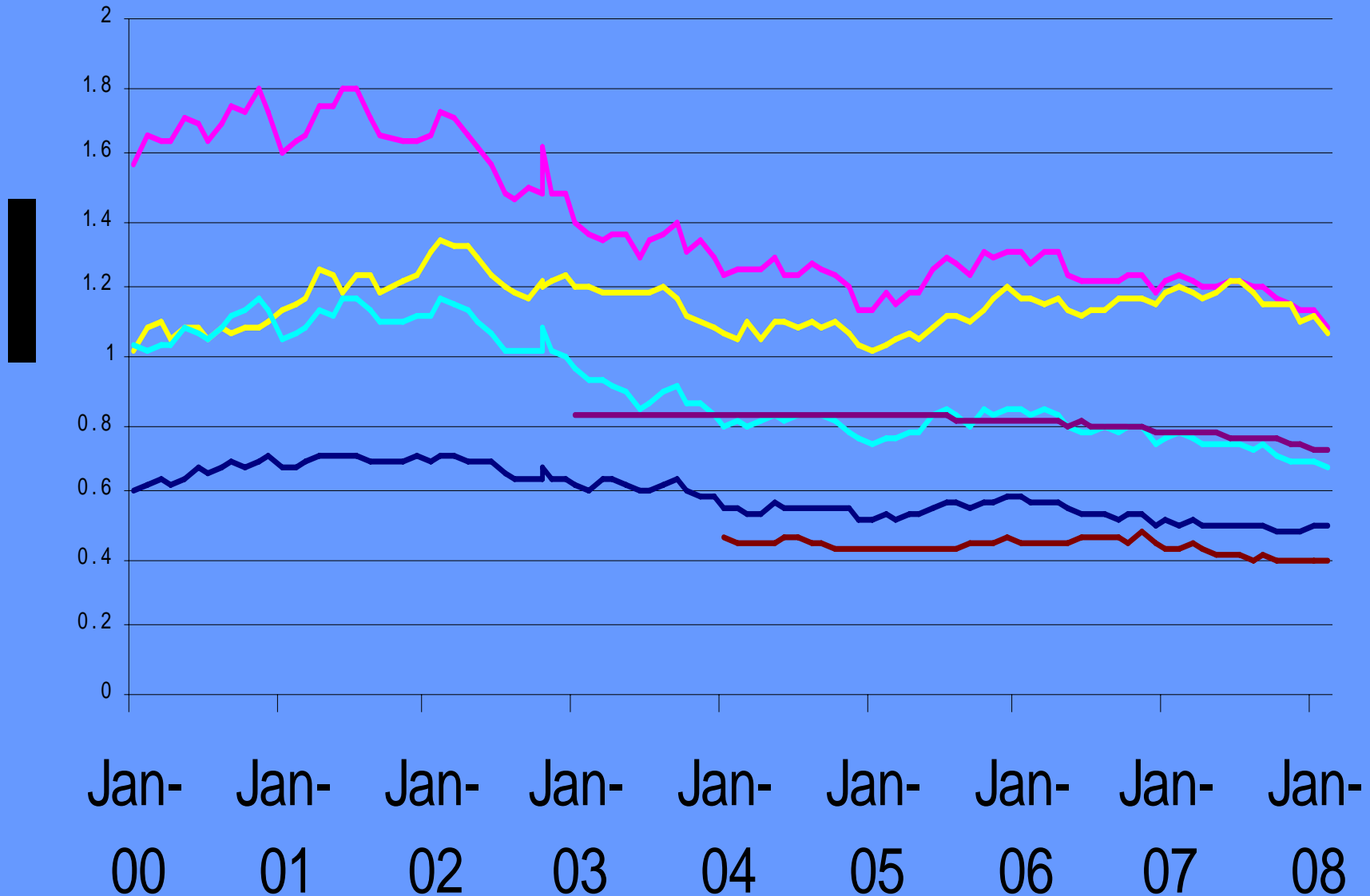
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# International Currencies

Pink = Swiss, Yellow = Japan, Turquoise = Euro, Purple = China, Blue = UK, Brown = India



Warning: It's now final, but the implementing rules and regulations have not yet been finalized

# REACH

- R – Registration
- E – Evaluation
- A – Authorization
- Ch – Chemicals

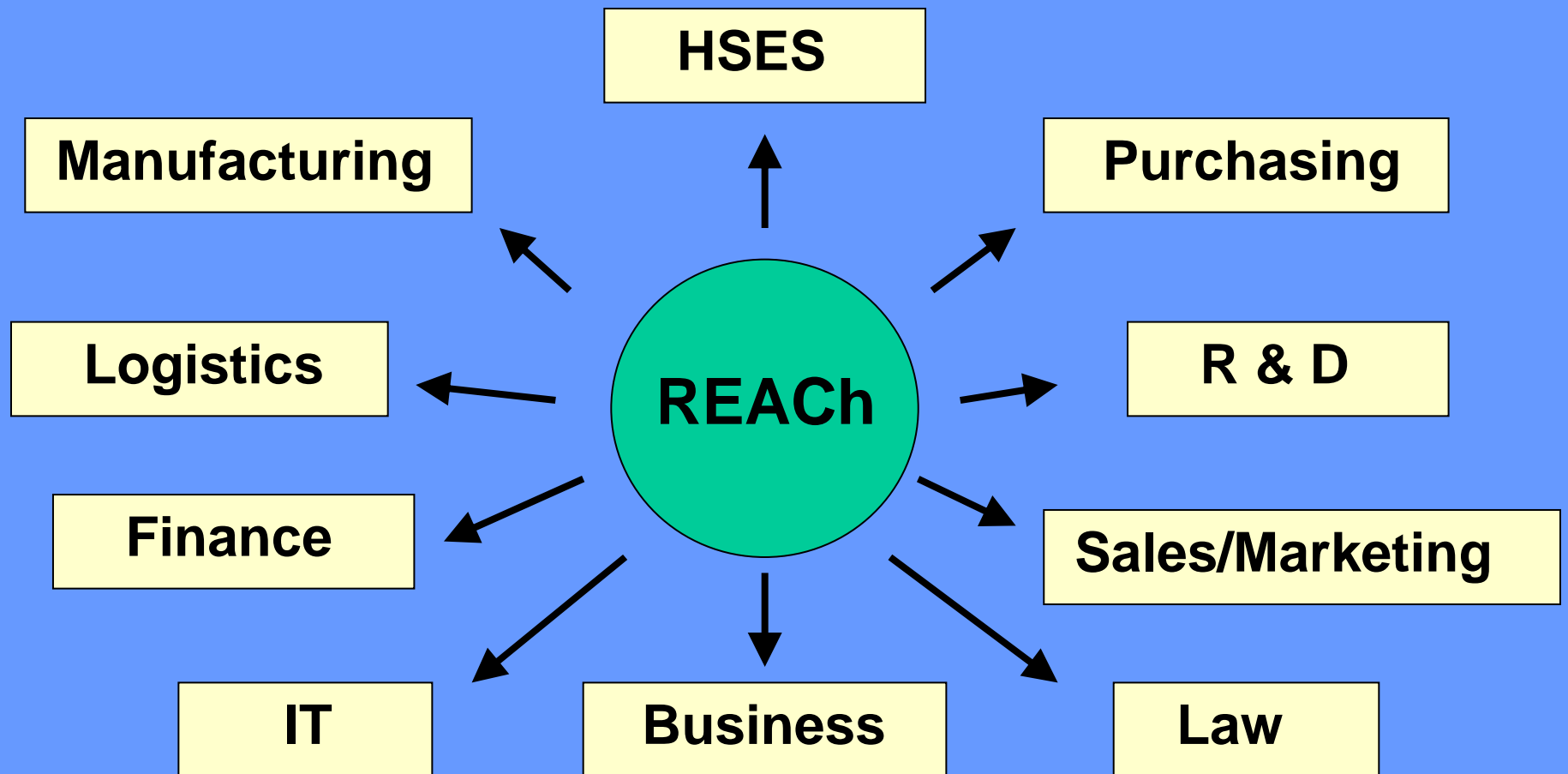
Foundation

Precautionary Principle

Substitution Principle

# REACH Implementation

(courtesy Afton Chemical)



# Business Concerns

- Withdrawal of products.
- Confidential Business Information.
- Many SMEs (small, medium enterprises) will disappear under this burden.
- Antitrust
- 1 substance – 1 registration: May make it very difficult to differentiate your product from your competitors.

# Business Concerns Continued

- May expose “niche” markets since registrations are “use specific”.
- Mixtures & Blends (Preparations) can not be registered.
- “Downstream users” many of whom don’t “care” about “chemicals” will need to understand these regulations.
- Unlike EINECS and TSCA, includes materials produced in the EU but not consumed in the EU.

# Estimated Costs

- Testing costs – assumes no usable data – source NOTOX
  - >10 MT ~ \$100,000
  - <10 MT but >100 MT ~ \$300,000
  - <100 MT but >1,000 MT ~ \$1,500,000
  - <1,000 MT ~ \$2,000,000
- Fees payable to the Agency
  - expected to vary from about \$1,500 for >10 MT to about \$31,000 for <1,000 MT per registrant. SME's to receive a 25% discount. There also is expected to be discounts for consortium participants
- Product substitution and reformulating costs – **Immeasurable.**
- **HPV Data** will need to be purchased from its rightful owner.

## Agency / Member States EU

Establishment of Agency

Pre-Registration/  
Establishment of database

Completeness check of registration dossiers, assignment of registration number  
Maintenance of Classification and Labelling Inventory  
Agency: Dossier evaluation; + Member States: Substance evaluation  
for substances of very high concern: Authorisation procedure

### REACH in force



## Registrant (Placer on the market)



# Intermediates – must be registered!

- Exempted from the Authorization Regime.
- Not isolated or not transported – no testing required.
- Transported, over 1,000 MT/year – 3.5 years – with reduced testing requirements if rigorously contained.
- Transported, less than 1,000 MT/year, rigorously contained – no testing required.
- Not rigorously contained – should still not be subject to authorization – but will require the testing protocol of a substance in the quantity range.
- Monomers are substances, but not subject to Authorization Regime.

# Only Representative

- The “Only Representative” must be a legal person within the EU that has been appointed by a manufacturer outside of the EU to fulfill his obligations under this regulation.
- This representative shall also comply with all other obligations of an importer under this regulation and shall have sufficient background in the practical handling of the substance and keep available sales data, including a customer list, as well as up-to-date MSDS, etc. An “Only Representative” cannot be merely a “shell”.

# Only Representative

- If an “only representative” is designated, importers will then be considered down stream users.
- Non EU based traders will need the permission of the manufacturer prior to engaging an “Only Representative”.
- Current RIP suggests that “OR” may only be acceptable for one step into Supply Chain.

# “OR” Advantages/Disadvantages

- Maintains your control of the entire process
- Maintain control of your market.
- CBI – “OR” can participate in SIEF’s without identify their principal.
- No need to change existing supply chain.
- Allow you to concentrate on core business.
- COST

# Key Issues for Importers from Europe

- Items produced in the EU solely for export, some of which are not currently ENIECS registered, are included in REACh. Could cause product withdrawals. May also “catch” materials such as agrochemicals food additives, etc. that would otherwise not be included if registered in the EU.
- Competitiveness - REACh testing costs will not be included in chemicals sourced from other lands.
- Product reformulations necessary to maintain EU market presence may affect your end uses and economics.

# Key issues for Exporters to Europe

- Selling into the EU on a “CIF” basis will be impossible unless your customers are willing to be “Registrants”.
- Confidential Information, including registration level, end uses and exposure data may become public.
- Will all of the components your customer needs “survive” this process?
- Substitution Principle – could effect operations in other parts of the world, as the “Greens” will be carefully monitoring any action taken by the agency.
- Strict Liability – Producer Pays – including downstream liability.

# Authorization - Key issues for Exporters to Europe

- It will be difficult and expensive for EU consumers to use items subject to authorization. (Note: All four of the currently used base oils in news inks are class 2 carcinogens in 67/548/EEC)
- Suppliers need to understand if other components consumed by the customer are potentially subject to Authorization since this might effect your sales.
- Will accelerate the movement out of Europe for finished chemical products as well as articles including printed matter, furniture, tires, etc.

# Pre-Registration Strategy

## EU Person

- Pre-register everything!
  - There is “no cost” for pre-registrations.
  - May allow you to enter a new market if no one else pre-registers.
  - Will provide you with priceless market intelligence.
- Begin to consider how best to capitalize on SIEF formation.
- Perform “Gap Analysis” on Key Products.

# Pre-Registration Strategy Not an EU Person

- Plan registration strategy:
  - Independent “Only Representative”.
  - Agent, Distributor, or Customer.
  - Parent or Wholly Owned Subsidiary.
- Pre-register everything you can think of!
- Perform “Gap Analysis” on Key Products.
- Begin to consider how best to capitalize on SIEF formation.

# OPPORTUNITIES for Non-EU Economies

- Support “article” producers in non-EU economies.
- Someone else’s product withdrawal may become your opportunity.
- Increased awareness of customer end uses in the EU may give insight into other markets.
- Offer toll production services to EU producers, especially where significant quantities are exported from the EU, could delay or eliminate their need to satisfy this regulation.

# OPPORTUNITIES for Non-EU Economies

- Seek out companies tolling materials in the EU that are not consumed in the EU.
- Mine your own and/or suppliers data files, including HPV, for potentially valuable testing protocols, even if you have no exposure to these rules.
- Clearly – it will be quicker, easier and less costly to innovate outside the EU – do it in the USA!!!

# “Opportunity”

- Approach all of your EU customers that act as “importer of record” and offer to relieve them of this burden.
- Approach all of your US Customers and offer to be their “Only Representative” for substances they ship to the EU.
- Offer to provide “registration services” for both competing products as well as companion products used by your customers.
- Consider offering “up-stream” products where continuing production in the EU will be problematic.

# REACH - Way Forward

- Domestic customers may be exporting your substances.
  - Survey customers to determine if they are exporting to the EU.
- Purchases from the EU.
  - Survey suppliers to be sure that they intend to comply with this regulation, even if they do not have any EU customers.

# REACH - Way Forward

- Sales to the EU – either direct or through others.
  - Prepare to pre-register all of the ingredients in all of your formulations – may mean that your supplier needs to release confidential business information on any formulations you purchase.
  - Survey all of your suppliers to find out if you can “piggy-back” on their registration, where appropriate.
  - Become an “EU Person” or Appoint an “only representative” to administer your needs.



# Thank You

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