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EU REACH and the U.S. SUPPLY CHAIN

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THIS MORNING'S GOALS –

- Explain "Pre-registration" and what it is intended to accomplish.
- Provide timeline for specific actions under REACH (based on the required thresholds). Discuss Supply Chain Communications.
- Distinguish Registration, Notification, and Authorization.

OVERVIEW

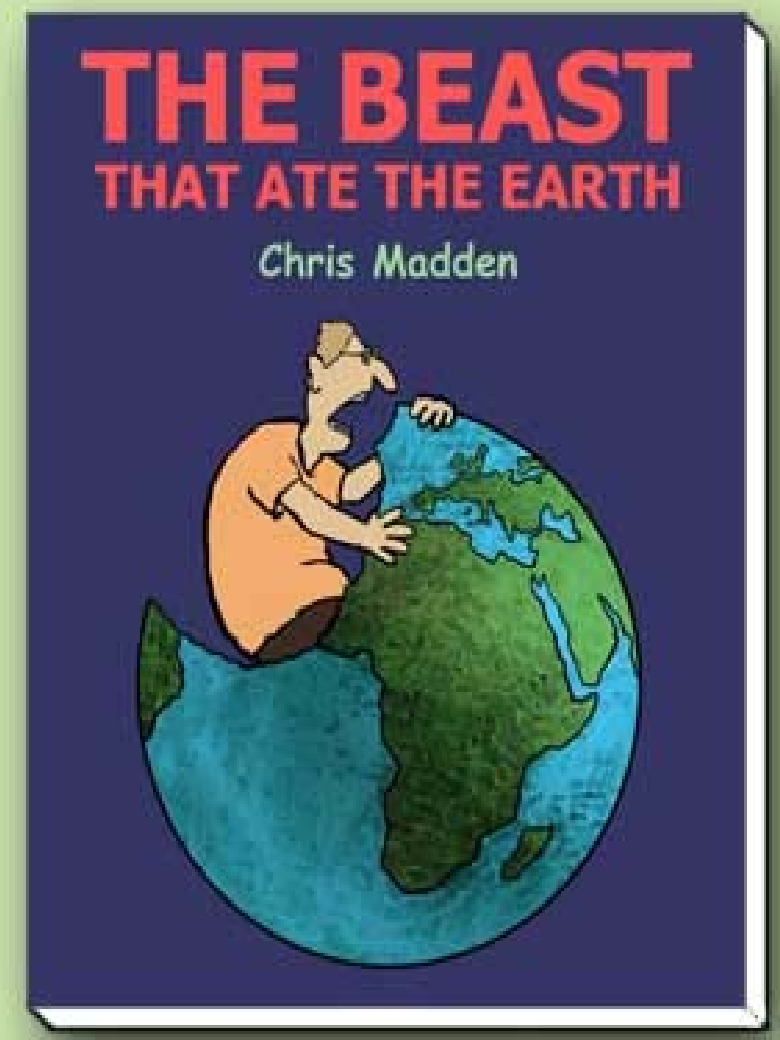
- REACH stands for the **R**egistration, **E**valuation and **A**uthorization of **C**hemicals.
- The REACH Regulation will replace most of the EU chemicals legislation in place.
  - For new and existing substances.
- It will have an impact on U.S. companies whose products, either alone or when added to another product, will be exported to the European Union (EU).

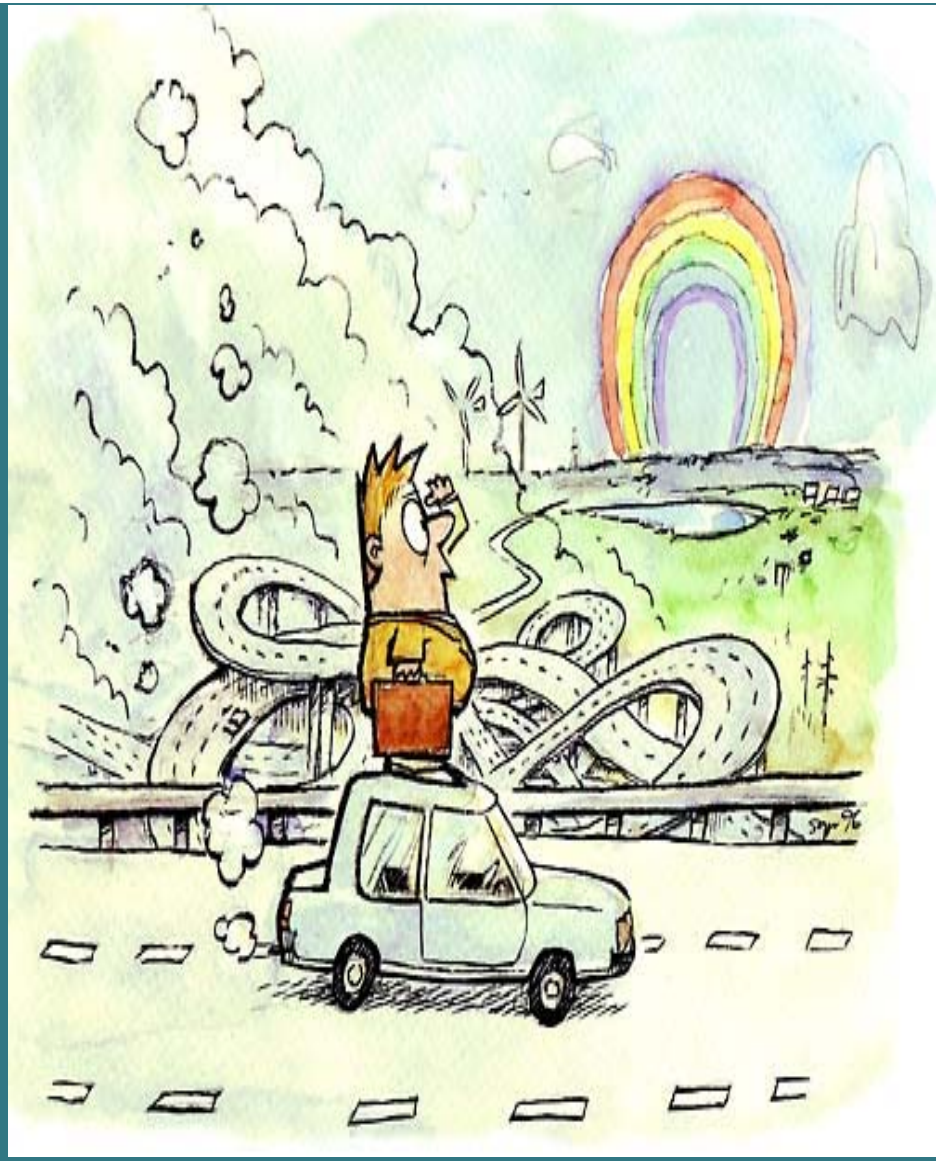
IMPACT

- Estimated direct costs to register products under REACH:
  - about €2.3 billion ($3.1 billion).
  - BASF: €550 million over 11 years and 2,500 substances.
  - BP: $60 million and 1,000 chemicals.

  Source: Chemical Week, 3/14/07, p. 7.
- Canada, Japan, South Korea, China, US, California chemical control policies.

A STUDY IN CONTRASTING OPINIONS





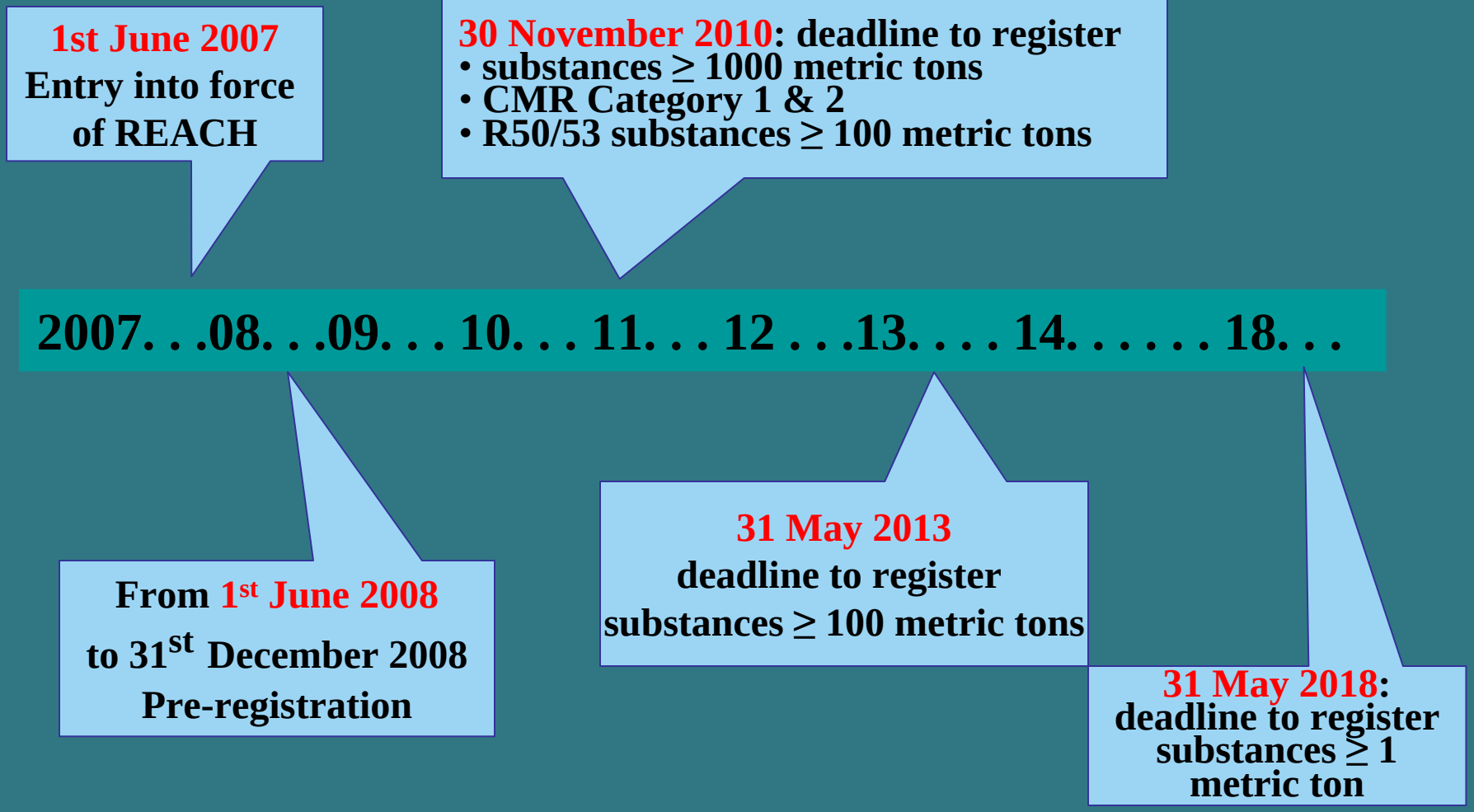
Arms and Legs of REACH

- The First Leg of REACH: Registration
- The Second Leg of REACH: Evaluation
- The Third Leg of REACH: Authorization
- The Fourth Leg of REACH: Restrictions
- Substantive Annexes (detailed information)
- REACH Implementation Plans (RIPs)
  - 3.1 POLYMERS
  - 3.4 PRE-REGISTRATION AND DATA COMPENSATION
  - 3.8 ARTICLES
  - 3.10 SUBSTANCE DEFINITION

SCOPE

- REACH covers the manufacture, import, placing on market and use of chemical "substances" on their own, in preparations, and in some cases substances in articles.
  - Registration applies to each EU manufacturer or importer.
  - Registration applies to each component of a preparation.
  - Multiple registrations envisioned for importers of preparations, like liquid polymer formulations.
  - Polymers are not registered but monomers and other reactants will be.
  - Volume thresholds and exemptions (i.e., articles) must be considered.

TIME LINE FOR SPECIFIC ACTIONS



REACH & Competition Rules

- Competition law issues in relation to Registration.
  - Access to market information.
  - Market restrictions.
  - Consortia formation and management.
- Responsibility of the Registrant increases if he is in a dominant position.

EU Competition Rules

- "This Regulation should be without prejudice to the full and complete application of the Community competition rules" (REACH, Council Common Position, Recital 44).
- Art. 81 governs anticompetitive agreements between firms at the same level of production cycle (horizontal) and between firms at different levels of distribution cycle (vertical).
- Art. 82 governs abuse of a dominant position.

SUPPLY CHAIN RECOMMENDATIONS

- Develop communications.
  - To ensure registration support.
- Consider how and whether to reach out – suppliers, distributors and customers (here and in EU if applicable).
- Letters to suppliers, distributors, customers.
  - One size fits all?
- Voluntary participation in consortia.
  - As opposed to mandatory SIEF.

INFORMATION REGISTRANTS MAY NEED FROM U.S. PRODUCERS

- Safety Data Sheets
  - remain the main tool for communicating information downstream.
  - must include exposure scenario for covered uses and recommend Risk Management Measures in certain cases.
- Use Information and Help with Chemical Safety Reports that will need to be prepared and filed during Registration for substances imported at 10 metric tons/year or more.
  - Work with suppliers and customers on use and exposure scenarios (ESs).
  - Otherwise, customers must do risk assessments for "non-identified uses" and notify separately.
- Data: Data Compensation Rules Apply.
- Composition Formulas or Assurance Letters

DOWNSTREAM USER NEEDS

- Downstream user:
  - any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities
  - A distributor or a consumer is not a downstream user.
- Manufacturer/Importer Registration to cover all identified uses unless use is too risky.
- Identified uses communicated to downstream users via Safety Data Sheets.
- Downstream user can identify a use or choose to keep confidential.
- Downstream user must:
  - Implement supplier's proposed risk management plan for identified uses;
  - Perform Chemical Safety Assessment on unidentified use; and
  - Notify Chemical Agency of unidentified uses > 1 ton/yr.

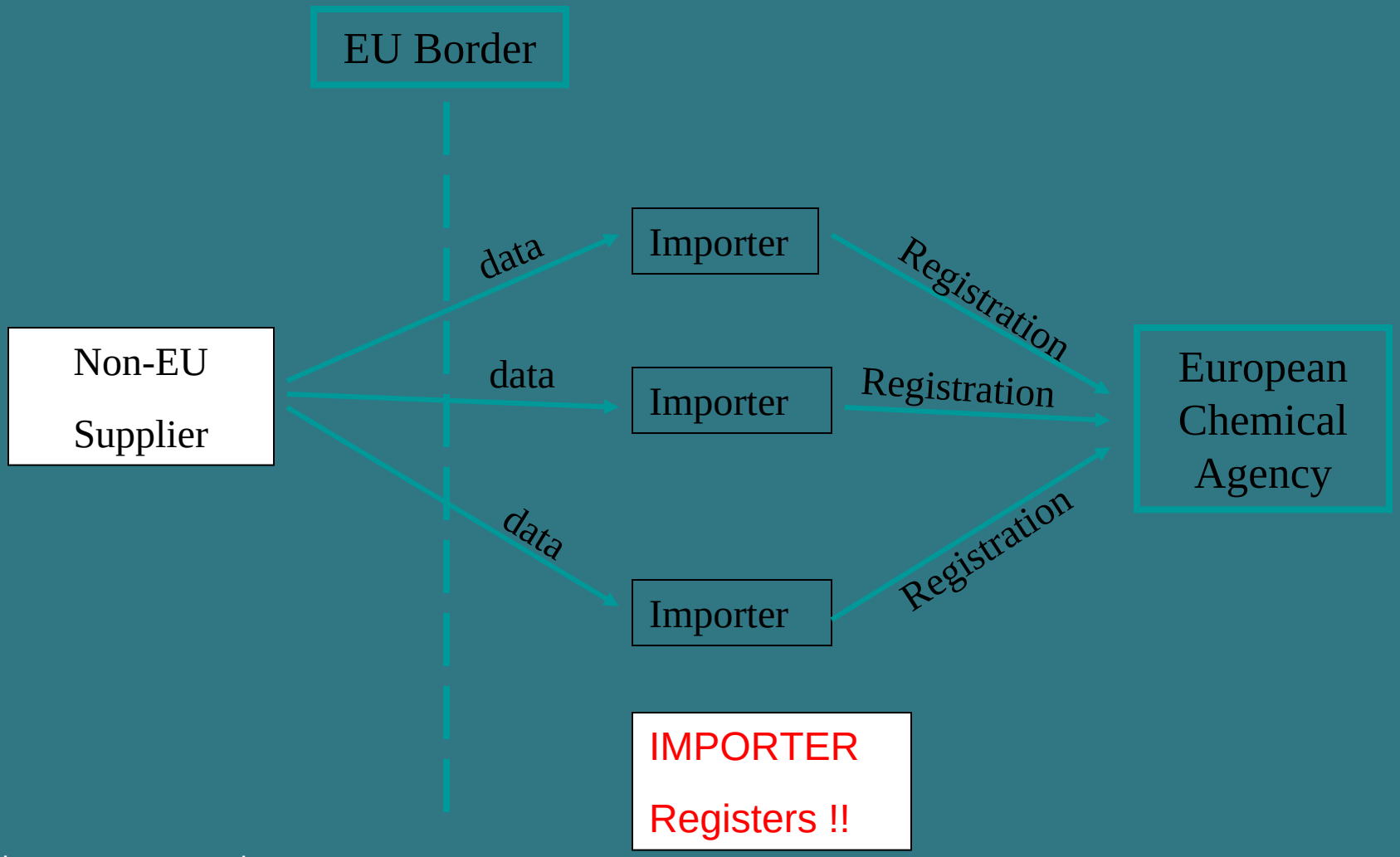
Data Sharing

- Facilitated through the “Substance Information Exchange Forum” or SIEF.
- Art. 29 and 30:
  - SIEF may consist of potential registrants and data holders.
  - “any person” with data relevant to a phase-in substance can lodge a request with the agency to participate.
  - Data holders may be manufactures, importers, downstream users, and third parties such as trade associations, agencies, and NGOs.

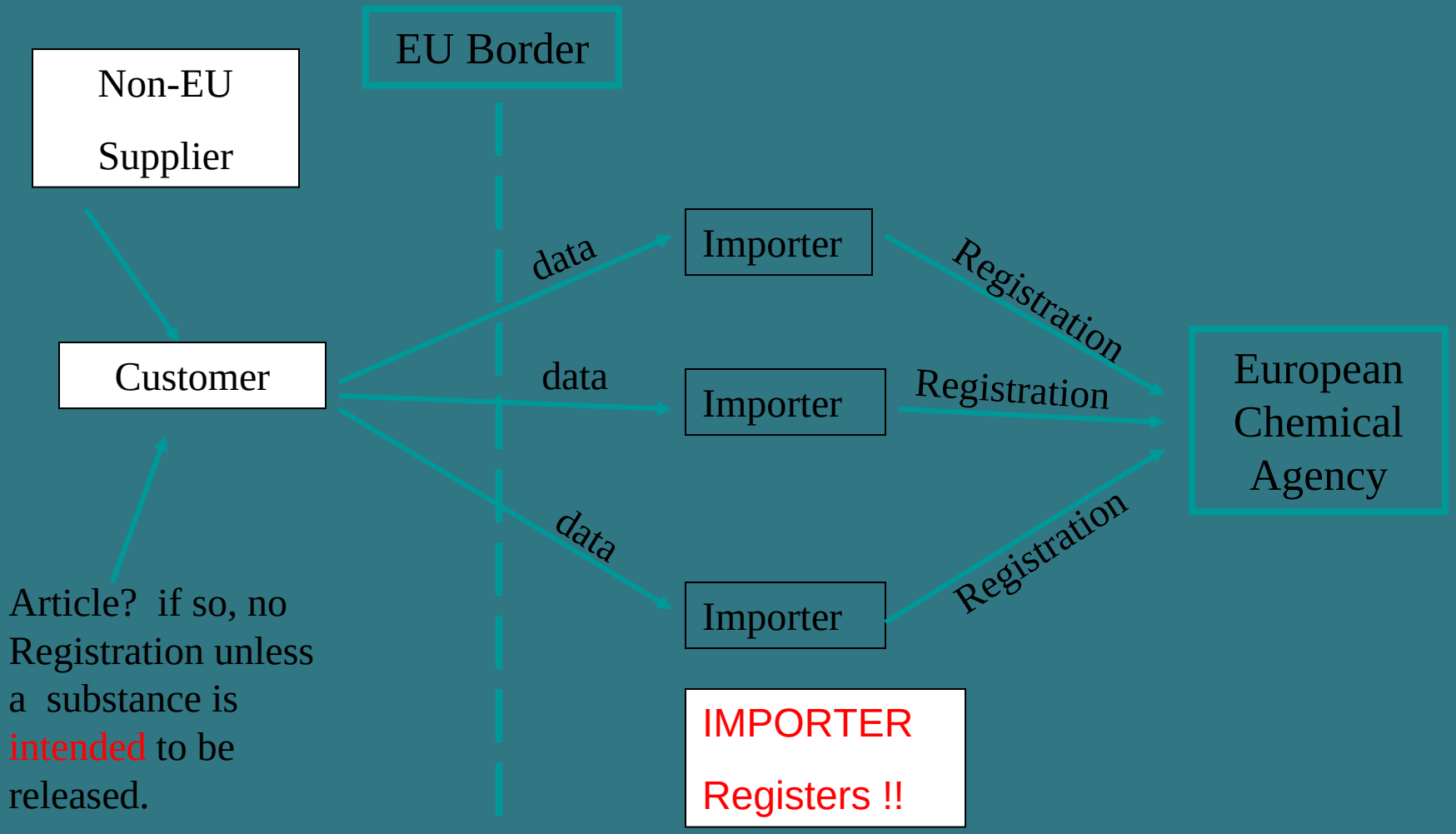
Data Compensation

- Compulsory sharing of existing vertebrate animal testing.
- Study owner to provide proof of cost.
- Obligation to make every effort to ensure fair and transparent sharing.
- If no agreement, then equal sharing.

Position in Supply Chain



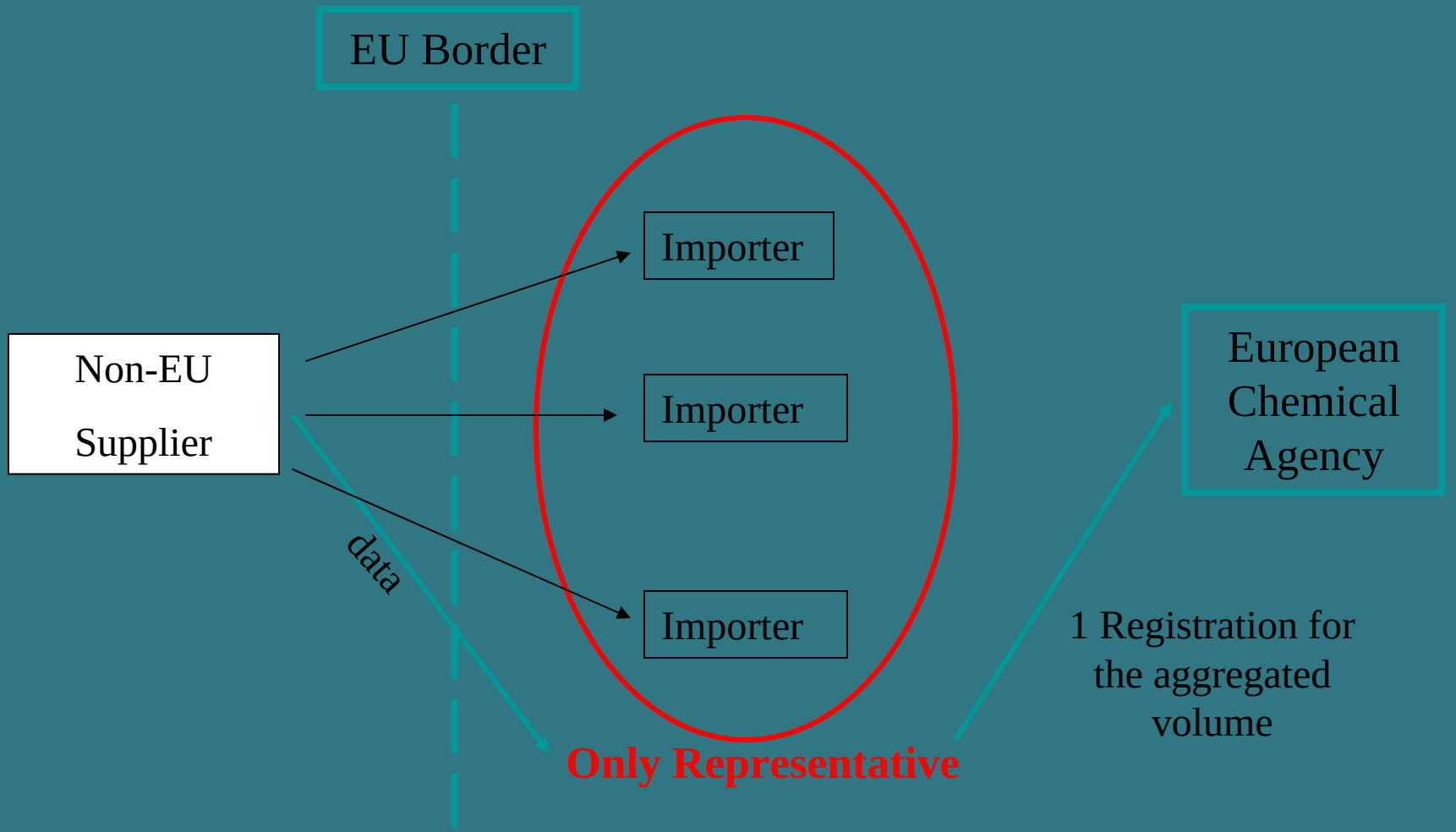
More Likely for Non-EU Supplier



WHO CAN PRE-REGISTER

- EU manufacturers and importers of phase-in substances.
- Importers of phase-in substances.
- Only-representatives of non-EU manufacturers.
- Non-EU manufacturers include:
  - Those that manufacture a substance on its own, in preparations or in articles that is imported into the EU.
  - Formulate a preparation that is imported into the EU.
  - Produce an article containing substances intended to be released that is imported by an EU importer.
- Non-EU manufacturers cannot pre-register directly.

WITH ONLY REPRESENTATIVE



ONLY REPRESENTATIVE (OR)

- REACH establishes the Only Representative (OR) mechanism in Article 8 as:
- Non-EU substance manufacturer or mixture/ article producer may appoint a natural or legal person established in the EU to fulfill, as his OR, the REACH obligations of importers.
- The OR must comply with all importer obligations, have sufficient background in practical handling of substances and information related to them, and keep available and up-to-date information on quantities imported and customers sold to, as well as updated safety data sheets.
- Non-EU manufacturer must inform the Importer(s) (“direct and indirect” customers) of the appointment. These importers shall be regarded as downstream users for the purposes of REACH.

PREREGISTRATION 6/08-12/08

WHAT WILL THIS ACCOMPLISH?

- A structure and a predictable timeframe for registration of existing substances to take place.
- Allows potential registrants to identify each other and organize themselves in a way that facilitates the registration of their products.
- Limited information submission required.
- RIP 3.10 Identification and Naming of Substances.

PRE-REGISTRATION EXAMPLE – Polymeric Coatings

- The monomers in the polymers are subject to Registration.
- Most, but not all, additives are subject to Registration (*i.e.*, no, if a stabilizer).
- There is no possibility of registering the polymer instead of the monomers.
- Polymer producers/importers may rely upon the registration of the monomers by their suppliers.

PRE-REGISTRATION EXAMPLE – Polymeric Coatings

- Must pre-register the monomers, etc. if above 1 metric ton and 2%. For EU Importer of Polymer, registration is required if:
  - Monomer not already registered by your supplier (Monomers are not likely to have been already registered during the pre-registration phase).
  - the polymer consists of 2% w/w or more of the monomer or the substance in the form of monomeric units and chemically bound substance.
  - the total quantity of the monomer or the substance used (and not removed) is ≥ 1 metric ton/year.

PRE-REGISTRATION EXAMPLE
Polymeric Coatings - Additives

- REACH Definition of a Substance:

  "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

- Anti-oxidants and heat and/or light stabilizers that preserve the stability of a polymer, are regarded as a constituent of the polymer and therefore do not need to be registered.
- Other additives, such as pigments, anti-stats, nucleating agents etc., must be treated as a preparation, composed of the mixture of the polymer substance and the additive substances. These components are subject to a general obligation to register under REACH in quantities of at least 1 metric ton per year.

PRE-REGISTRATION EXAMPLE
Polymeric Coatings

- Most importers of polymeric formulations will need to pre-register the monomers and other reactants in the polymers that meet the 2% and 1 metric ton rules because it is not likely that many monomers or other reactants will have "already been registered" by an actor up the supply chain during the pre-registration period from 1 June 2008 to 1 Dec 2008.
- Registrations can only be submitted after 1 June 2008, and REACH provides that downstream customers are relieved from the need to independently register monomers or other reactants, when the ingredient has "already been registered" by an upstream supplier.

ARTICLES

- FIBERS
- COMPOSITES
- FILMS
- SHEET

➢ Traditional status should be carefully reviewed for continued compliance with REACH.

INVENTORYING EXEMPTIONS – Articles

- REACH requires the registration of substances as such, in preparations and sometimes when present in articles.
- An article is "an object composed of substance(s) and/or preparation(s) which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does.
- Register substances intended to be released from articles during normal or reasonably foreseeable conditions of use, if substance:
  - > 1 metric ton/year per article type per Manufacturer/Importer
  - Not registered further up the supply chain, or
  - no exposure during normal or reasonably foreseeable conditions of use, including disposal

INVENTORYING EXEMPTIONS – Articles

- Ex.: Coating on a hammer – no Registration.
- Next step: Notification?
  - Yes if listed on the "candidate list" for Authorization;
  - > 1 metric ton per Manufacturer/Importer; and
  - In a concentration > 0.1% weight/weight.
- Except if the substance has already been registered for that use by an actor up the supply chain or there will be no exposure during normal or reasonably foreseeable conditions of use, including disposal.
- Notification is only required after 1 June 2011
- Notification can trigger Registration.

A FEW WORDS ON AUTHORIZATION

- Most high tonnage chemicals have at least SIDs level data.
- Data requirements for low volume substances are modest.
- Several years to fill data gaps in the case of animal studies for higher tonnage chemicals.
- The heart of REACH is in dealing with SVHCs.

SVHCS ARE -

- CMRs
  - Cat 1 and 2 Carcinogens
  - Cat 1 and 2 Mutagens
  - Cat 1 and 2 Reproductive toxins
- PBT or vPvB
  - Persistent, bioaccumulative and toxic or very persistent and very bioaccumulative substances
- Have “equivalent effects”
  - Scientific evidence of probable serious effects to human health or the environment, e.g. endocrine disruption

WHEN IS AN SVHC IDENTIFIED?

- **Registration and Evaluation**
  - During review of Registration Dossier, Classification & Labeling & the CSR.
  - Substance Evaluation by the Agency or Member States (MS) could lead to advancement to SVHC status.
- **Authorization**
  - Separate track under REACH: first, a Candidate list (2009); and then, listing in Annex XIV (2011). Only authorized uses are allowed and a substitution plan must be developed.
- **Restriction**
  - Bans or Restrictions for cases where benefits do not outweigh risk and Community-wide regulation is needed. Could apply both to SVHCs and non-SVHCs.

Evaluation phase becomes more important with SVHCs

- Priority based on Risk.
  - Criteria:
    1) hazard information, for instance structural similarity with known substances of concern or with substances which are P and B;
    2) high exposure information;
    3) mega-tonnage.

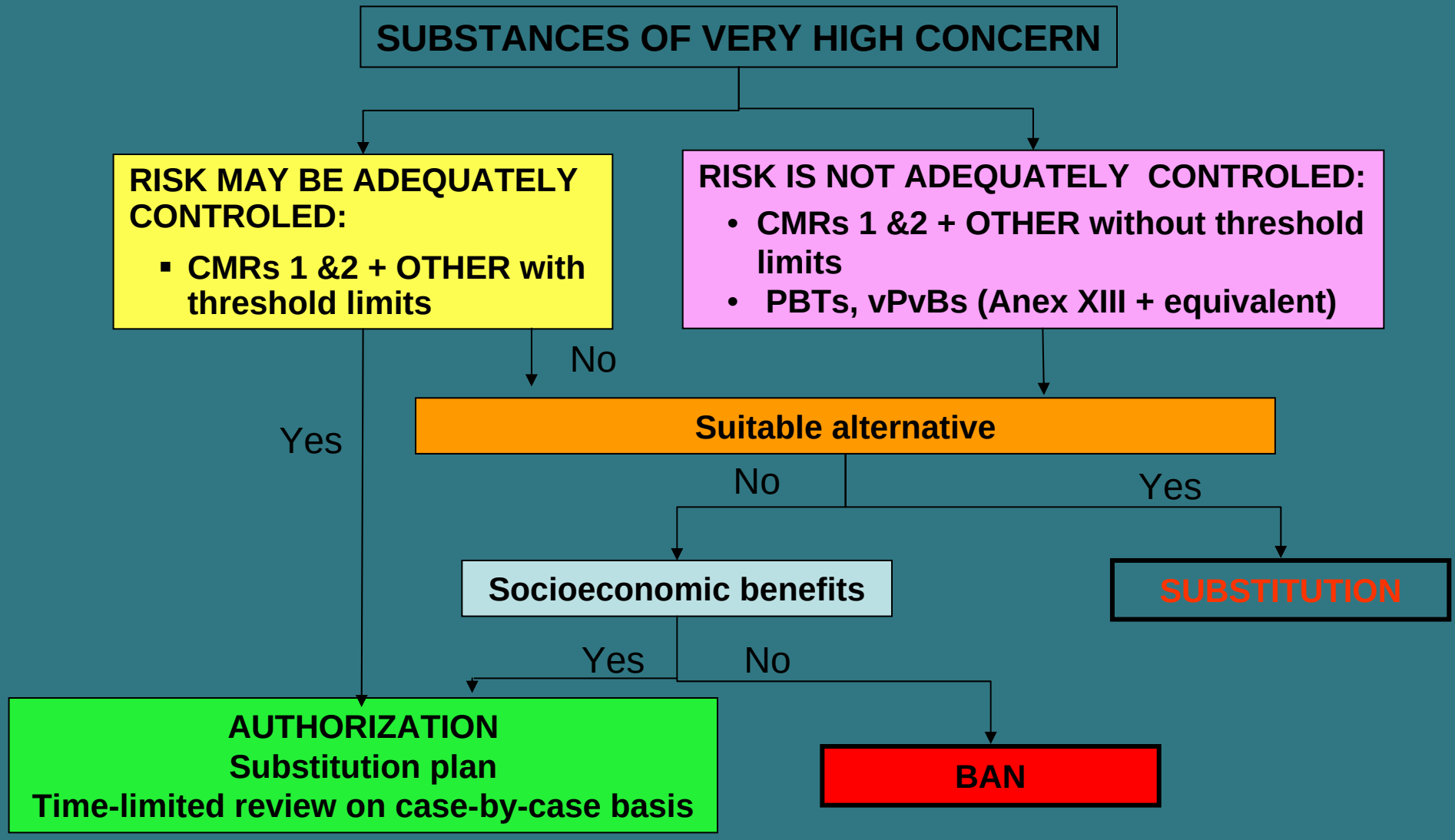
When is Authorization granted?

- An authorization is granted if the risk from the use of the substance is "adequately controlled." But,
- PBTs, vPvBs and those CMR substances for which a safe level cannot be defined, cannot be authorized based on adequate control of risk, however –
  - Authorization may be granted if the socioeconomic benefits outweigh the risks and there are no suitable alternative substances or processes.

AUTHORIZATION, CONT.

- Polymers are exempted from Registration and Evaluation.
  - POTENTIALLY subject to Authorization and to Restriction.
- Uses or categories of use may be exempt if there is already adequate protection to human health and the environment because of already existing Community regulations.
  - May provide an opportunity to opt out of the system for uses with low exposure potential, *i.e.* special forms of the substance, processing aids, *etc.*

When Will Authorization Be Granted?



MARSHALLING THE FACTS

- CONDUCT INTERNAL INVENTORY
  - Group where you can.
- ID YOUR EXEMPTIONS AND SVHC's
- MAP AND ENGAGE SUPPLY CHAIN
  - Parent or subsidiary presence in the EU?
- CALENDAR UPCOMING EVENTS
- MONITOR DEVELOPMENTS
- KEEP A "PUNCH LIST"

MARSHALLING THE FACTS, CONT.

- THE TIME TO MAKE THE CASE THAT A CHEMICAL DOES NOT PRESENT AN UNACCEPTABLE RISK IS AT REGISTRATION.
  - MARSHAL THE SCIENCE FROM THE REGISTRATION STAGE TO PROTECT AGAINST LISTING AS A SVHC
- DEVELOPING PRODUCT STEWARDSHIP PRACTICES TO DEMONSTRATE ADEQUATE CONTROL OF SVHCS.
- COMMUNICATE WITH CUSTOMERS.
- DEVELOP THE CASE AGAINST FORCED SUBSTITUTION.

LINKS

- European Chemicals Bureau – http://ec.europa.eu/echa/reach_en.html
- http://ecb.jrc.it/
- RIPS – http://ecb.jrc.it/reach/rip/
- REACH – http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_396200612 30en00010849.pdf

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Thank you!

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