

The word "REACH" is written in large, white, bold, sans-serif capital letters across the top of the slide. The background is a dark blue-tinted photograph of a modern building with large windows and several yellow stars scattered across the scene.

REACH

Automotive Specialty Products Alliance

Current Implementation Issues

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STAY AHEAD OF THE CURVE

REACH Myths

- REACH is a chemical industry issue
- REACH is an EU-based company problem
- **REACH impacts U.S. exporters, but not their suppliers**
- REACH is an ES&H issue
- U.S.-based components of multi-national corporations face the same challenges as their EU colleagues
- U.S.-based components of multi-national corporations can rely on their EU colleagues for REACH training, planning, compliance

REACH Realities

- REACH poses **business risk** to any company doing business in the EU (and likely others)
- **Business continuity** can be adversely impacted by REACH; **supply chains** can be disrupted; you can lose **market access** in the EU
- **Suppliers that are not willing/able to provide information to U.S. exporters risk losing their customers**
- Companies that understand the **business implications and impacts** of REACH, and develop **strategic action plans**, will gain a **competitive edge** over those that do not



CURRENT REACH PRESSURE POINTS

- **Phase-in substances/pre-registration**
- **Supply chain/due diligence**
- **SVHCs**

First Critical REACH Milestone

- **Pre-Registration**

- Essentially a ‘grandfathering’ provision for chemicals already on the market in the EU (“**phase-in substances**”)
- Significantly defers deadline for full registration
- Data requirements limited; procedures simple
- **BUT: must pre-register between June 1 and December 1 2008**

Phase-In Substances

- A substance is a phase-in substance if it meets one of the following criteria:
 - **EINECS** listed or
 - Over 15 years preceding the entry into force of REACH, manufactured in the EU but not marketed by manufacturer/importer or
 - “No longer polymers”

Phase-In Substances (*cont'd*)

- **Deferred Registration for Phase-In Substances:**
 - December 2010:
 - CMRs Category 1 and 2
 - R 50/53 (very toxic to aquatic organisms) >100 tonnes/year and
 - >1000 tonnes per year
 - June 2013: >100 tonnes/year
 - June 2018: >1 tonne/year

Phase-In Substances (*cont'd*)

- To secure phase-in status, M/I must first **pre-register** the substance
- Timing of pre-registration – 6 month window
 - **1 June '08 – 1 December '08**
- Failure to pre-register results in loss of phase-in status
 - M/I of phase-in substance must begin full registration process 12 months after EIF (June '08)
 - ***See Guidance on Registration: as of 1 June '08, M/I must cease operations; may restart only after dossier submitted and deemed complete***

Phase-In Substances (*cont'd*)

- Data Requirements (the easy button)
 - Name of substance, plus EINECS/CAS numbers
 - Identification of registrant
 - Registration deadline (tonnage band)

Phase-In Substances/Pre-registration

Anticipating Future EU Business Growth

- Currently < 1 tonne, or even at 0
- But plan to increase sales into the EU in the foreseeable future
- **Options**
 - Pre-register now
 - Defer pre-registration

Anticipating Future EU Business Growth (cont'd)

- **Option #1 – Pre-register now**
 - Based on “intent” to cross 1 tonne threshold prior to June 2018
 - No proof of “intent” required
 - No obligation to Register if you never cross 1 tonne threshold

Anticipating Future EU Business Growth (cont'd)

- **Option #2 – Pre-register when growth plan is realized**
 - Late market entrants can obtain phase-in status if they submit required information
 - Within 6 months after crossing 1 tonne threshold
 - No later than 12 months before applicable registration deadline (3.5, 6, or 11 years)

Supply Chain/Due Diligence

- **Communications with Suppliers**
 - General awareness of REACH
 - Substance identification (CBI issues?)
 - Declaration of intent regarding registration
 - Contract provisions
 - Presence of SVHCs
- **Performance specifications**
 - Changes in substances/concentrations

Supply Chain/Due Diligence (cont'd)

Due diligence issues, i.e., how to:

- Obtain accurate/complete information from multiple suppliers regarding hundreds (+/-) of substances
- Verify accuracy/completeness of information received from suppliers
- Account for unannounced changes in supplier formulations
- Manage risk of inaccurate/incomplete information from suppliers

Supply Chain/Due Diligence (cont'd)

Contract Issues - Current contract language; review:

- Substance identification
- Pre-registration/registration commitment?
- Notice provisions
 - Commitments
 - Changes in substance identification
- Materiality
- Consequences – business disruption

Supply Chain/Due Diligence (cont'd)

If supply chain communications fail, what can/must you do to identify/quantify substances?

- Review publicly available information
- Rely on “branch knowledge”
- Conduct chemical analysis

Article Importers/SVHCs

- Request supplier confirm presence/absence of SVHCs in the article
- If supplier unable to do so
 - Request supplier to forward request up its supply chain
 - Request supplier provide you with upstream supplier contacts

Supply Chain/Due Diligence (cont'd)

Supply chain disruption/loss of market access

- E.g., supplier failure/refusal to provide necessary information to customer/exporter
- Exporter unable to register all substances
- Options
 - A. Change suppliers
 - B. Substitute the substance/preparation
 - C. Move (more) production from U.S. to EU

A shared problem that needs shared solutions

Supply Chain/Due Diligence (cont'd)

Geography Lesson

- **U.S. company ships preparations to its EU facility, where final article is assembled**
- **Substances in preparations received from U.S. suppliers**
 - Who will register?
 - CBI issues (supplier provides preparation)?
- **If, instead, U.S. company moves entire production either to U.S. (ships final article to EU) or to EU (no shipment of preparation from U.S. to EU)**
 - Problem solved?

Substances of Very High Concern (SVHCs)

- Registration (30,000 substances)
- Evaluation
- **Authorization (1,500 substances)**
- Restrictions

Authorization

- Category 1 and 2 Carcinogens (C)
- Category 1 and 2 Mutagens (M)
- Category 1 and 2 Reproductive Toxicants (R)
- Persistent, Bioaccumulative, Toxic (PBT)
- Very Persistent, Very Bioaccumulative (vPvB)
- Substances with **Equivalent Concerns**
 - e.g., **Endocrine Disruptors**

Authorization (cont'd)

Substances placed on Annex XIV

- If on Annex XIV, substance may **not** be placed **on the market** after “**sunset date**”
- By a manufacturer, importer or downstream user
- **Unless** specific use authorization provided
 - Application \geq 18 months before sunset date

Authorization (cont'd)

The Candidate List

- Purpose is to identify substances “for **eventual inclusion** in Annex XIV”
- Substances **meeting the criteria** for authorization
- Based on review of Annex XV dossier
- **Likely publication: late '08 → '09**

Authorization (cont'd)

Candidate List Impacts – Deselection?

- Listing of 1500+ substances beginning in late '08 → '09
- Annex XIV listing of some substances may be 1 to 5 decades later
- In the interim
 - Customer deselection
 - For consumer products – self deselection?

Authorization (cont'd)

Substances placed on Annex XIV

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Authorization (cont'd)

Applications for Specific Use Authorization (Article 62)

- Must include
 - Specific uses, including in preparations and articles
 - Chemical Safety Report
 - Analysis of **alternatives**
 - **R&D** information
 - If suitable alternative is available - a **substitution plan**

Authorization (cont'd)

Granting of Authorizations (Article 60)

- Authorization shall be granted if
 - Risks to human health and/or the environment are adequately controlled
 - Taking into account discharges, emissions and losses, including risks from diffuse or dispersive uses

OR

Authorization (*cont'd*)

Granting of Authorizations (*cont'd*)

- If risks cannot be adequately controlled, authorization may still be granted

IF

- Socio-economic benefits outweigh the risks

AND

- There are **no suitable alternative** substances or technologies
- Makes application of the "**substitution principle**" mandatory

Authorization (*cont'd*)

Granting of Authorizations (*cont'd*)

- Only for the person(s) to whom authorization granted
- Only for uses authorized
- Conditions on use
- Time limits

These all create limitations/restrictions

Authorization (cont'd)

Substitution

- If judgment is made that risks are not adequately controlled, submission of **substitution plan** becomes mandatory
- NGOs
 - Can “point out there are **substitutes** available”



CURRENT REACH CONTROVERSIES

- **Only Representatives**
- **Monomers in Polymers**
- **Substances in Articles**

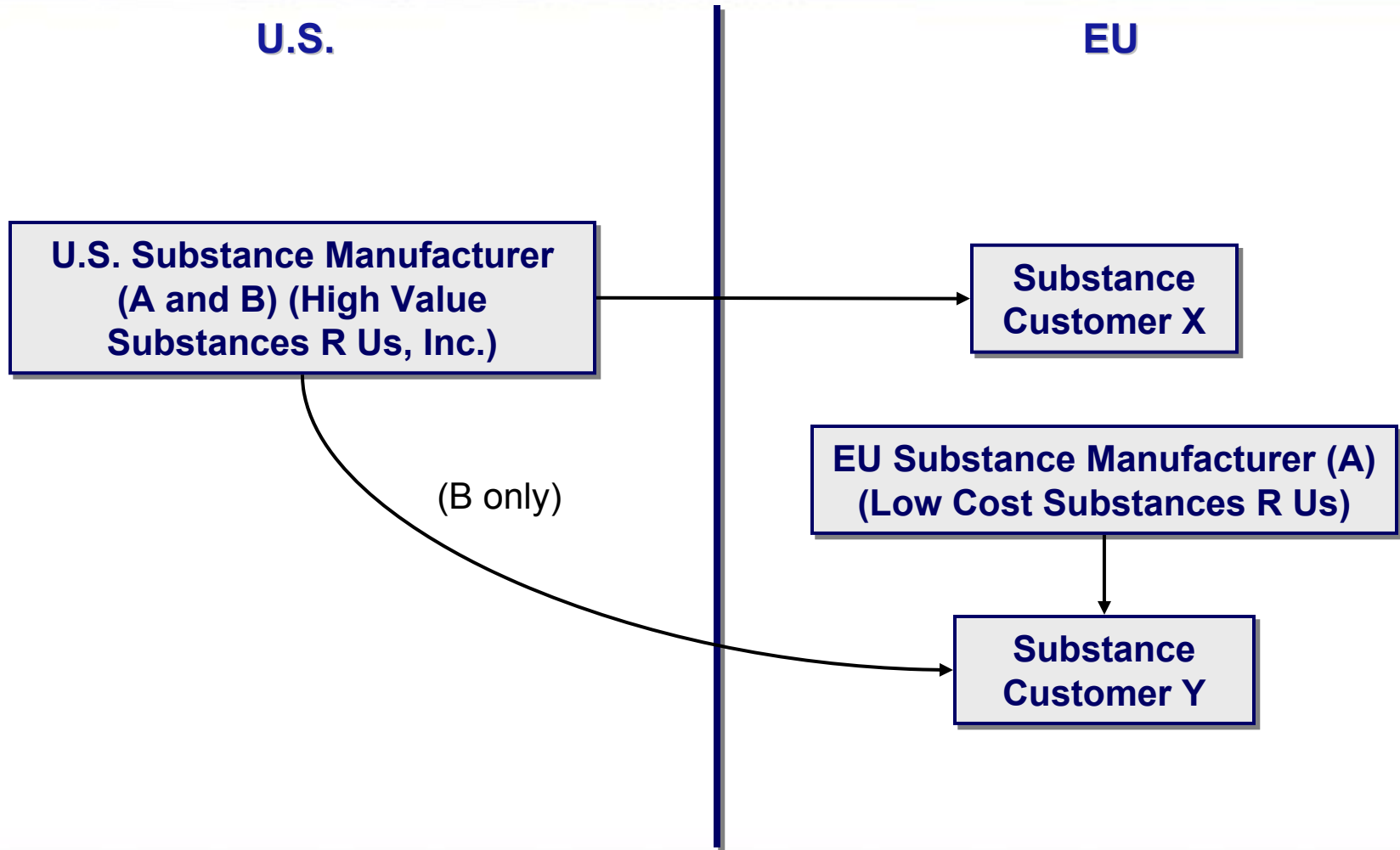
Only Representative

- Only representative can be appointed importer by non-EU
 - Manufacturer of substances
 - Formulator of preparations
 - Producer of articles
- Only representative takes on Registration and other REACH responsibilities

Why use an only representative?

- Solve customer as importer problem
- Solve confidential business information (CBI) problem, i.e., avoid disclosure of proprietary information by
 - Exporter to its EU customer
 - Supplier to the exporter (its customer)

Only Representative/Substances



Only Representative/Substances

The simpler case - problems confronting U.S. exporter

1. Customer as Importer

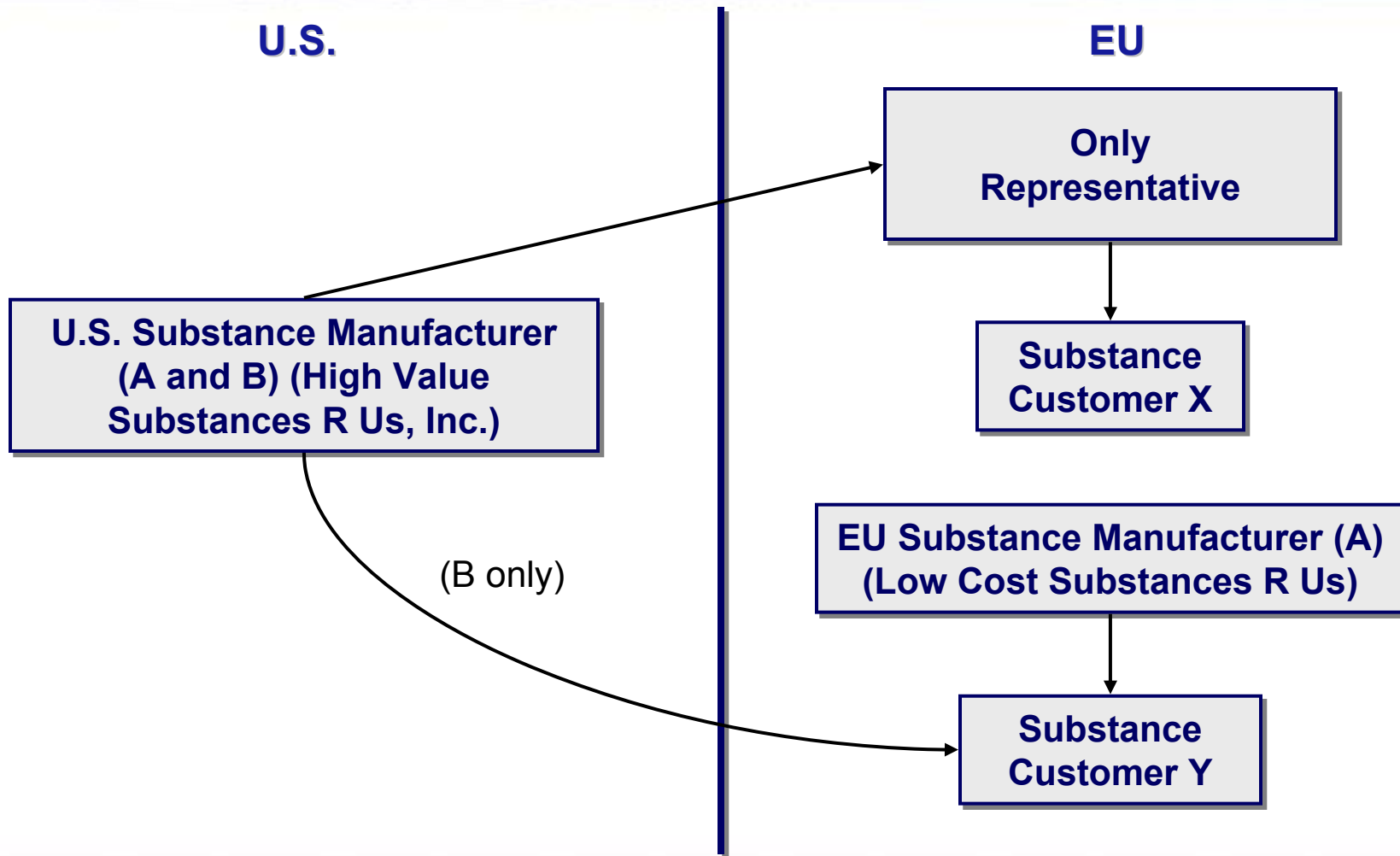
- Customer in EU must register substances A & B

2. CBI

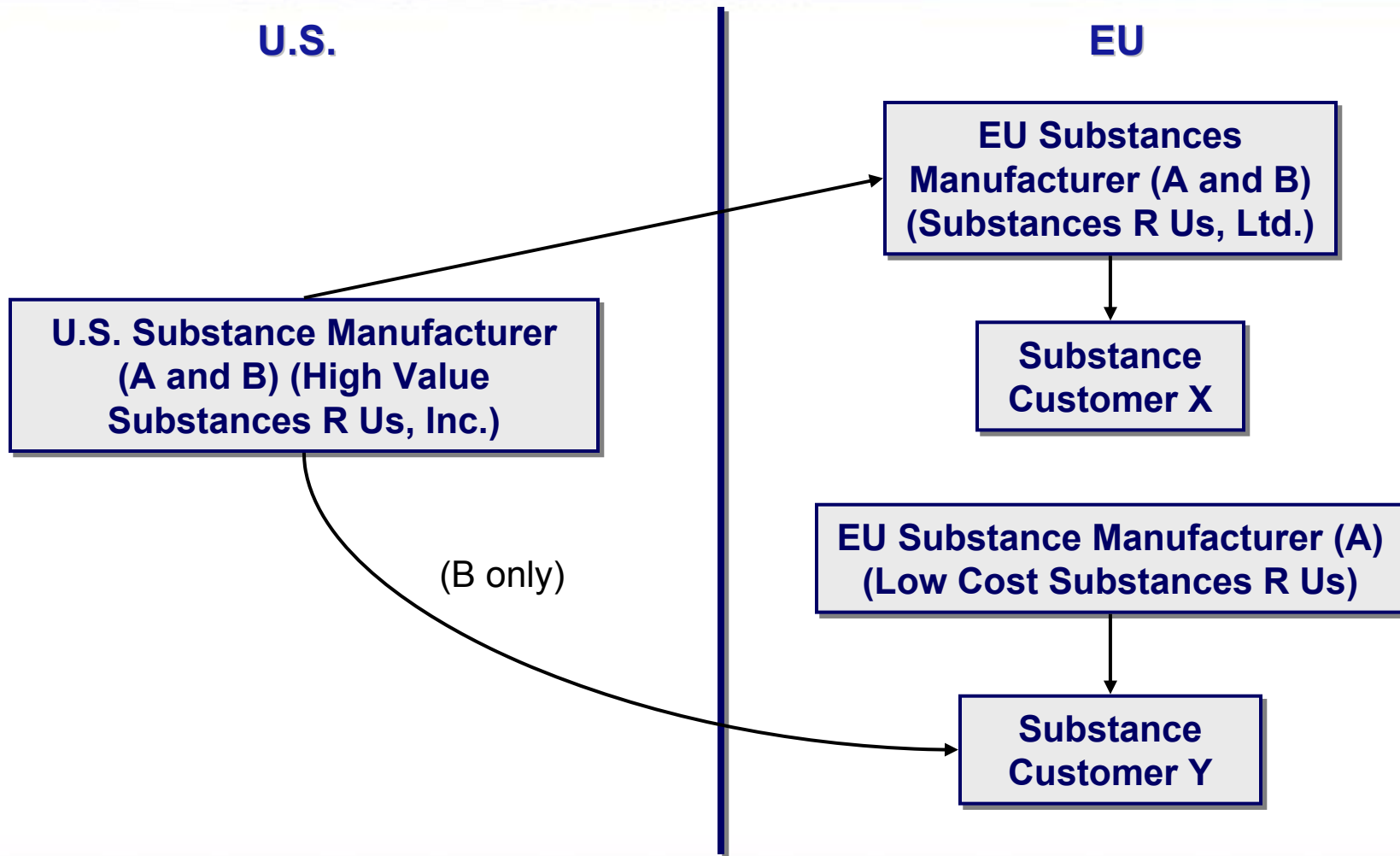
- In order for EU customer to register, it must know exactly what is in the materials it receives
- Exporter must disclose proprietary formula

Solution – the Only Representative

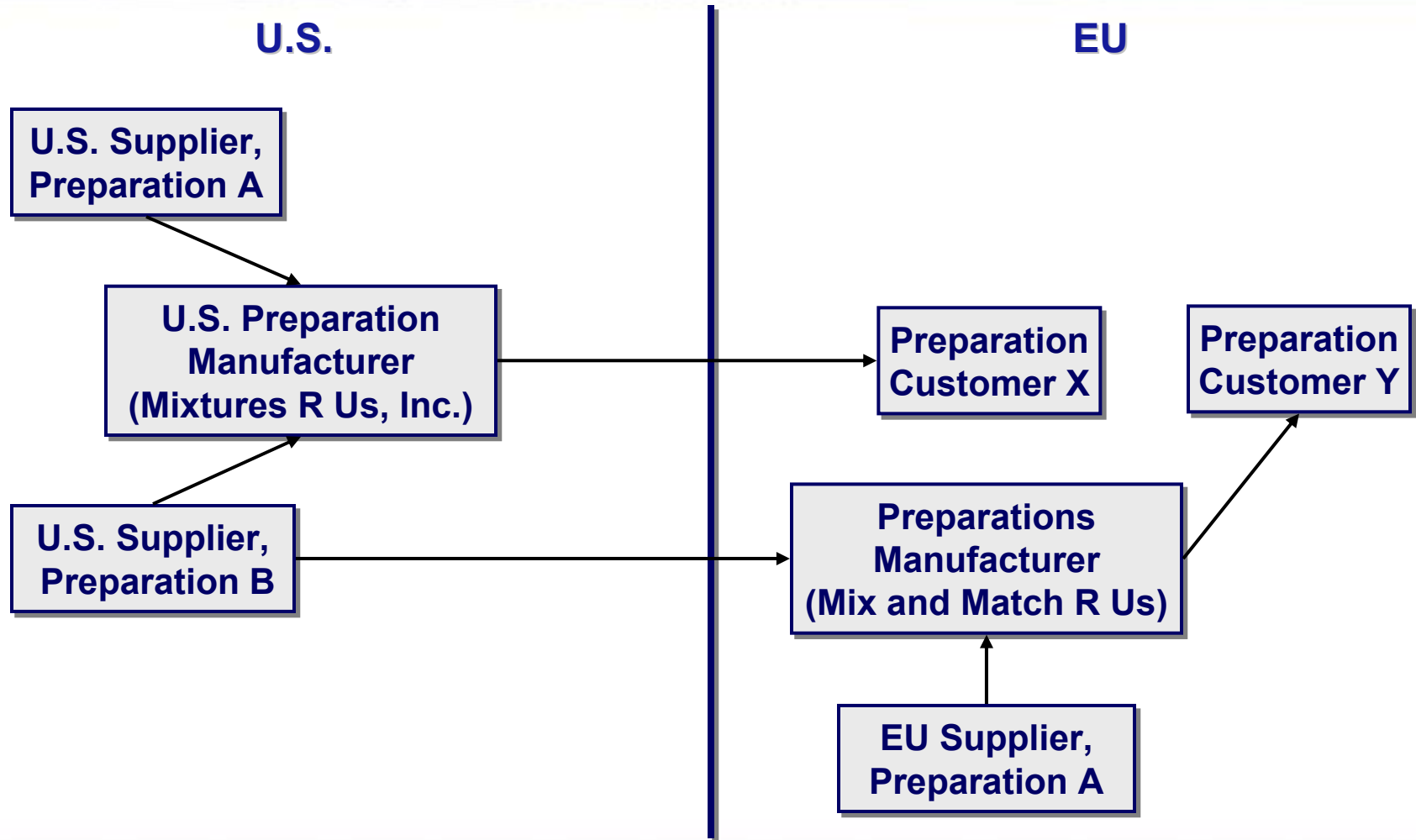
Only Representative/Substances



Only Representative/Substances



Only Representative/Preparations



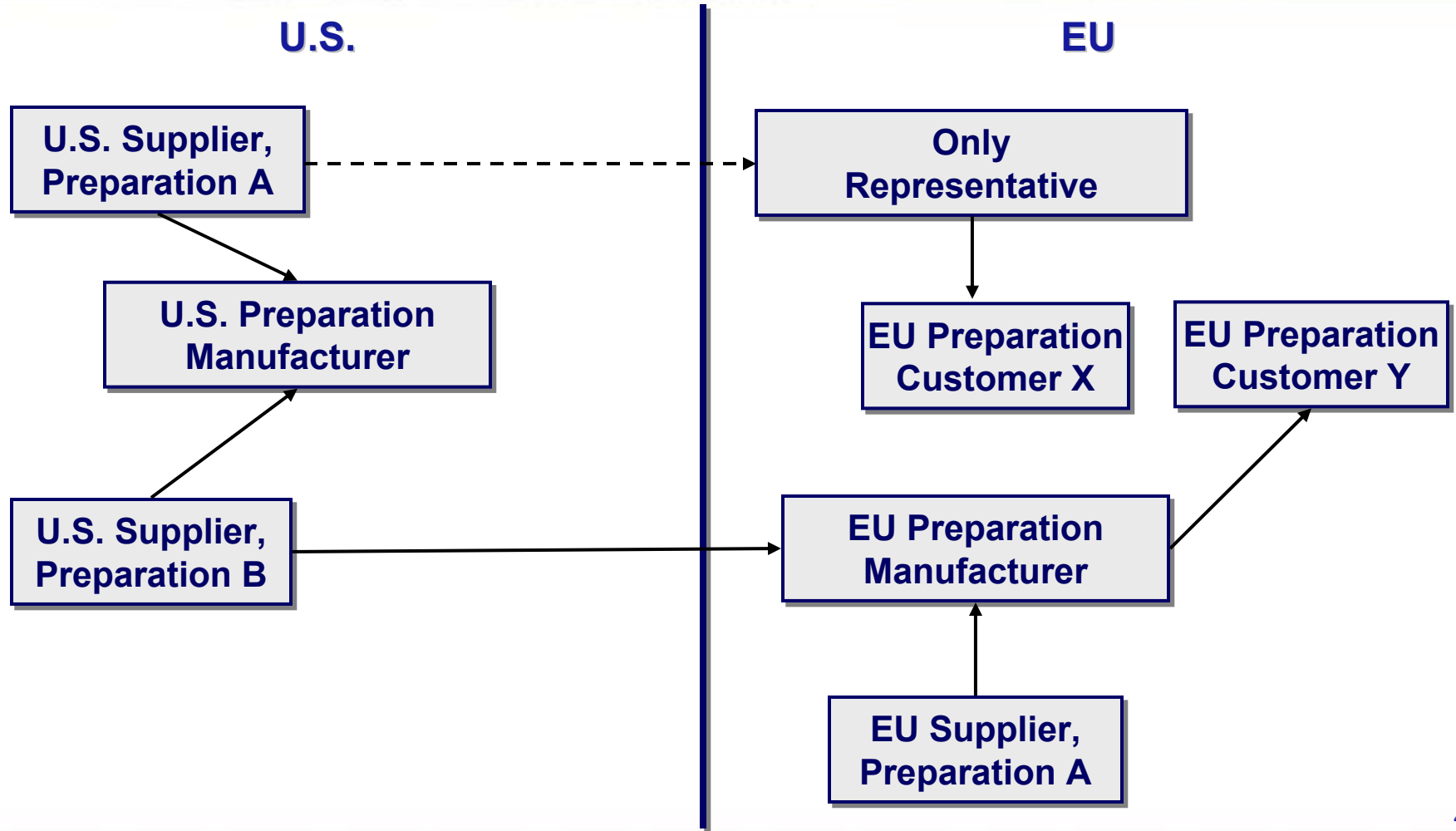
Only Representative/Preparations

The more complex case - problems confronting U.S. exporter and its suppliers

1. Customer as Importer (same as above)
2. CBI
 - Suppliers assert formula is proprietary; will not disclose to their customer (the exporter)
 - Exporter cannot arrange for registration

Solution – the Only Representative?

Only Representative/Preparations



Only Representative/Preparations

Solutions to upstream supplier/CBI problem:

1. Customer and supplier enter into confidential disclosure agreement
2. Supplier retains only representative (as above)
3. Customer finds another supplier
4. ?

Monomers in Polymers

- Polymers are exempt from registration, but
- Monomers and other substances contained therein must be registered if
 - Present at 2% or more in the form of monomeric units and chemically bound substances; and
 - The total quantity per year is 1 tonne or above.

Monomers in Polymers (cont'd)

Exemption – Registration not required if the monomer has “already been registered by an actor up the supply chain”

- EU supplier can include use by its EU customer (polymer manufacturer) – customer exempt
- US supplier not a registrant
 - US customer (polymer manufacturer) can not be exempt

Monomers in Polymers

Litigation Status – October 11, 2007 Ruling

- Standing affirmed in UK Court
- Challenge to Article 6.3
 - An actor “up the supply chain” means an actor “in the present supply chain”
 - Scientific and legal validity of the monomer registration requirement – “a serious issue”
 - Issue to be referred to European Court of Justice (ECJ)
 - Timing – ECJ decision not likely before pre-registration window closes

Substances in Articles

- Substances intended to be released under normal or reasonably foreseeable conditions of use must be **registered** if above 1 tonne per year
- Substances contained in articles above 0.1% w/w must be **notified** if they are included in candidate list and if above 1 tonne per year

Substances in Articles (*cont'd*)

Exemptions

- Neither Registration nor Notification required if a substance has “already been registered for that use”
 - Customer of US article manufacturer not exempt
 - Unless another EU M/I of same substance registers (for that use)
- If notifier can exclude substance exposure to humans and the environment during the normal or reasonably foreseeable conditions of use (including disposal)

Substances in Articles (*cont'd*)

Three Threshold Issues

1. For article definition purposes, when during the manufacturing process does a substance/preparation become an article?
2. For substance registration purposes, is a substance contained in an article properly characterized as separate from, or integral to, the article?
3. If it is a substance in an article, when is a release considered intentional?

Threshold Issue - Transition from Substance/Preparation to Article

- Main Principle - If raw material does not yet have end use function (processing step required to give it shape that would render it useful for a final purpose)
 - Starting material is a substance/preparation
 - The result of the processing would become an article
- A material has an end use function where it can be directly applied to carry out a function without further processing
 - It is an article
 - Even if further processing could take place

Threshold Issues for Registration/ Notification - Is it a Substance/Preparation (S/P) in a container or carrier or a Substance in an article?

- If S/P in a container or carrier, must register each substance (> 1 tonne) – Article 6
- If substance in an article
 - Register only if there is an intentional release (Article 7.1)
 - Notify – Candidate list substance present above a concentration of 0.1% w/w (Article 7.2)

Substance/preparation in a container or carrier

- Examples from guidance
 - Toner Cartridge
 - Toner = S/P; Cartridge = Container
 - Cleaning Wipe
 - Cleaning material = S/P; Cloth wipe = Carrier
 - Printer ribbon

Substance in an Article *(cont'd)*

- Examples from guidance
 - Thermometer
 - Some adhesive tapes
 - Batteries

Articles – Intentional Release

When is a release considered intentional?

- A release is intended when it contributes to a quality or minor function of the article
 - “Added value” not directly connected to the end use function of the article
- Examples
 - Perfumed eraser (function is to erase; scent is added value)
 - Fade-out jeans (release of dyes during each washing is intended. Or is it?)
 - New car smell (when added in production process)

Articles – Intentional Release

- A release is not intended
 - During removal of impurities from a semi-finished or finished article during its production process
 - During use or maintenance activities that are meant to improve product quality or safety
 - Unavoidable side effect
- Examples
 - Size added to fabric to improve processability (released during further processing)
 - Clothes washing where chemical remnants from processing (e.g., dye) are released
 - Wear and tear/friction (break linings; tires)

Substances in Articles – Information in the Supply Chain (Article 33)

Suppliers of articles containing substances listed on the **candidate list** must provide sufficient information allowing safe use of the article (including, at a minimum, name of the substance)

- to recipients of articles
- to consumers
 - on request
 - within 45 days

Article 33 *(cont'd)*

- Article 33 obligations apply if the substance is present in article $> 0.1\%$ w/w
- For Article 33 purposes, there is
 - No tonnage threshold
 - No Article 7(3) exemption (exclude exposure)
 - No Article 7(6) exemption (already registered for that use)



Preparing for REACH

ASPA Spring Meeting
June 4, 2008

Preparing for REACH

Purpose

- Obtain an overview of which REACH obligations apply to your company
- Take strategic decisions about substances, products, suppliers and customers
- Allocate responsibilities and funds
- Incorporate “REACH think” into process/planning/decisions on R&D, alternatives, substitution

Step 1 – Secure Management Buy-In

- Engage corporate and division managers
- Involve purchasing, sales/marketing, R&D, legal
- Assign regulatory and business responsibilities
- Train

Step 2 – Conduct Training

- At corporate, division, product levels
- Across disciplines
 - **Management, e.g., business, product**
 - **Regulatory specialists**
 - **Supplier and customer relationship managers**
 - **R&D personnel**
 - **Counsel**

Step 3 – Conduct Inventory Review

- All substances, preparations, monomers in polymers, substances in articles
- Manufactured, imported (e.g., export by U.S. company to EU affiliate), purchased
- At legal entity level
- Each EU affiliate may be a separate legal entity
- Centralization advantages
 - classifications/SDS should be consistent;
 - strategic decisions about phase-out, reformulation and allocation of resources taken at corporate level

Step 4 – Conduct Supplier/Customer Review

Suppliers

- Location
- Willingness/ability to provide substance information
- Willingness/ability to assume Registration role
- Alternative suppliers
- Communications with suppliers (see below)
- Contract issues (see below)

Conduct Supplier/Customer Review (cont'd)

Customers (U.S.)

- Willingness/ability to assume Registration role
- Do they have alternative suppliers
- SVHC/deselection issues?
- Communications with customers
- Contract issues

Conduct Supplier/Customer Review (cont'd)

Customers (EU)

- Uses/exposures
- Willingness/ability to assume Registration role
- Do they have alternative (EU) suppliers
- SVHC/deselection issues?
- Communications with customers
- Contract issues

Step 5 – Develop Strategic Action Plan

- Identification of key EU products/substances
 - Active role in SIEFs/consortia (lead registrant?)
 - Registration by supplier? customer? affiliate? only representative?
- Supplier issues
 - Geography issues
 - What do I need to do to secure supply chain?
 - Will I need to streamline supply chain?

Develop Strategic Action Plan (cont'd)

- Customer issues
 - How will REACH impact current customer relationships?
 - U.S. customer (of U.S. supplier)
 - EU customer (of U.S. exporter)
 - New product/market challenges? opportunities?
- For each product/substance
 - How does REACH impact my current and future market strategies?
 - Are we in a position to create a REACH “win”?

Individual Company Efforts - Conclusion

Process – Training, Inventory, Evaluation of
Supply Chain, Planning

Endpoint – Develop REACH Strategic Action
Plan

- At company, division, product and/or substance level

Contact Information

THANK YOU

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