

The background of the slide features a photograph of a modern building with a curved facade and large windows. Several yellow stars are scattered across the image, some appearing to be on the building's facade and others floating in the sky. The word "REACH" is written in large, white, bold, sans-serif capital letters across the top of the image.

REACH

GlobalChem

The Pre-Registration Window: Ready or Not, It's (Almost) Here

Robert Matthews
McKenna Long & Aldridge LLP

March 17-19, 2008
Baltimore, MD

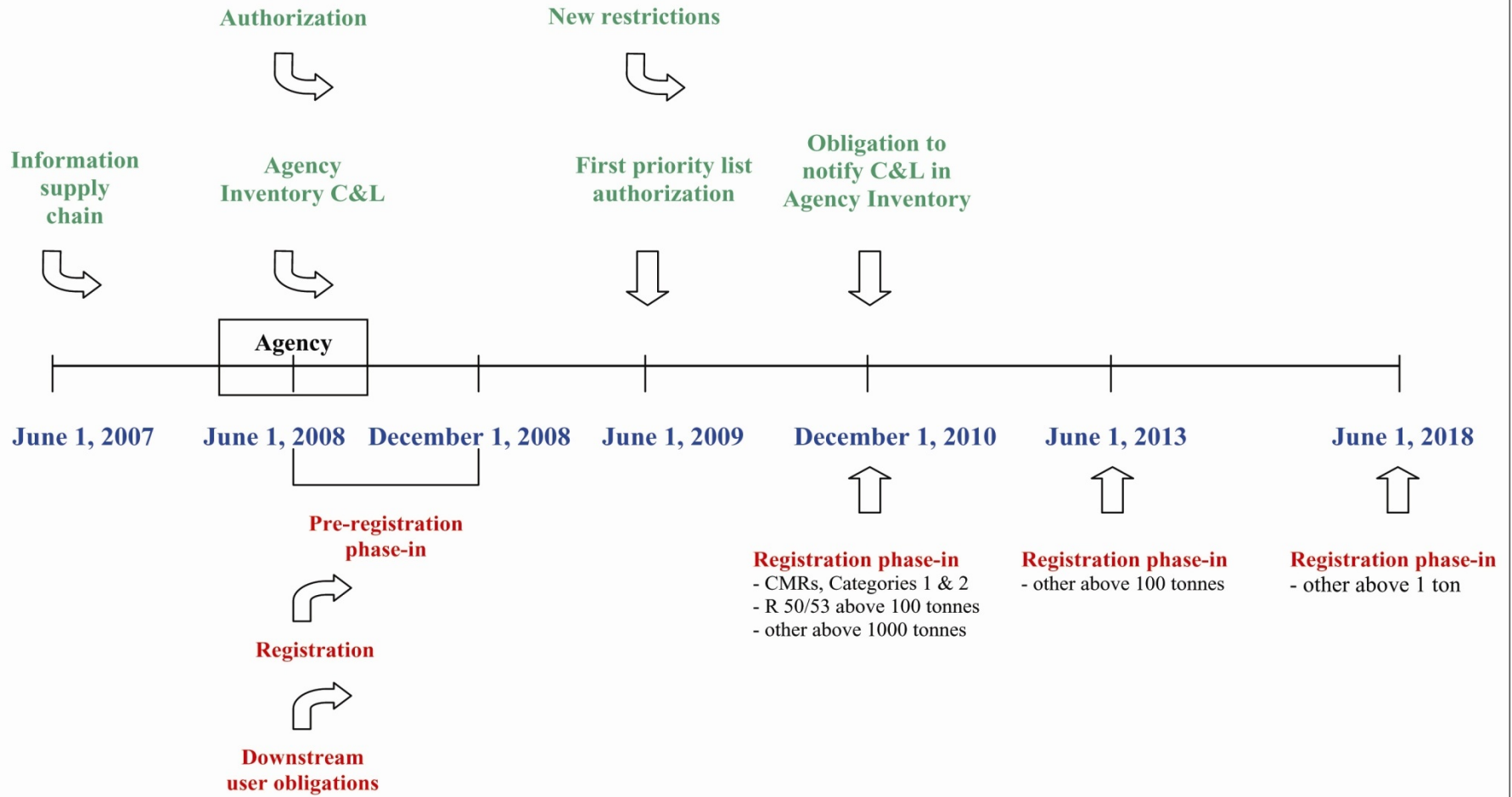
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REACH Realities

- 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

REACH TIMELINES



- Substances subject to registration
- All substances

Key Pre-Registration/Registration Concerns

1. Magnitude of efforts and costs
2. Substitution
3. Due diligence issues
4. Possible supply chain disruption/loss of market access

Key Pre-Registration/Registration Concerns (cont'd)

1. Magnitude of efforts and costs

- Supply chain – multiple suppliers (in some industries number in the 100's)
- Substances – dozens, hundreds, even 1000's in some industries
- Fees - \$10,000's (per substance)
- Testing - \$100,000's (per substance)

Key Pre-Registration/Registration Concerns (cont'd)

2. Substitution

- Substances of very high concern (SVHCs)
- Authorization annex
- Candidate list
- Deselection
- Reformulation

A shared problem?

Key Pre-Registration/Registration Concerns (cont'd)

3. 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

Key Pre-Registration/Registration Concerns (cont'd)

4. Supply chain disruption/loss of market access

- E.g., supplier failure/refusal to provide necessary information
- 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

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Key Pre-Registration/Registration Issues

1. Phase-in Substances
2. Only Representatives
3. Monomers in Polymers
4. Substances in Articles
5. SVHCs

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

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Phase-In Substances/Pre-registration

- 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/Pre-registration (cont'd)

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

Phase-In Substances/Pre-registration (cont'd)

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

Phase-In Substances/Pre-registration (cont'd)

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
 - Commission does not support

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Phase-In Substances/Pre-registration (cont'd)

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)

Only Representative

- Only representative – an EU legal entity - can be appointed as the Registrant by non-EU
 - Manufacturer of substances
 - Formulator of preparations
 - Producer of articles
- Only representative takes on Registration and other REACH responsibilities

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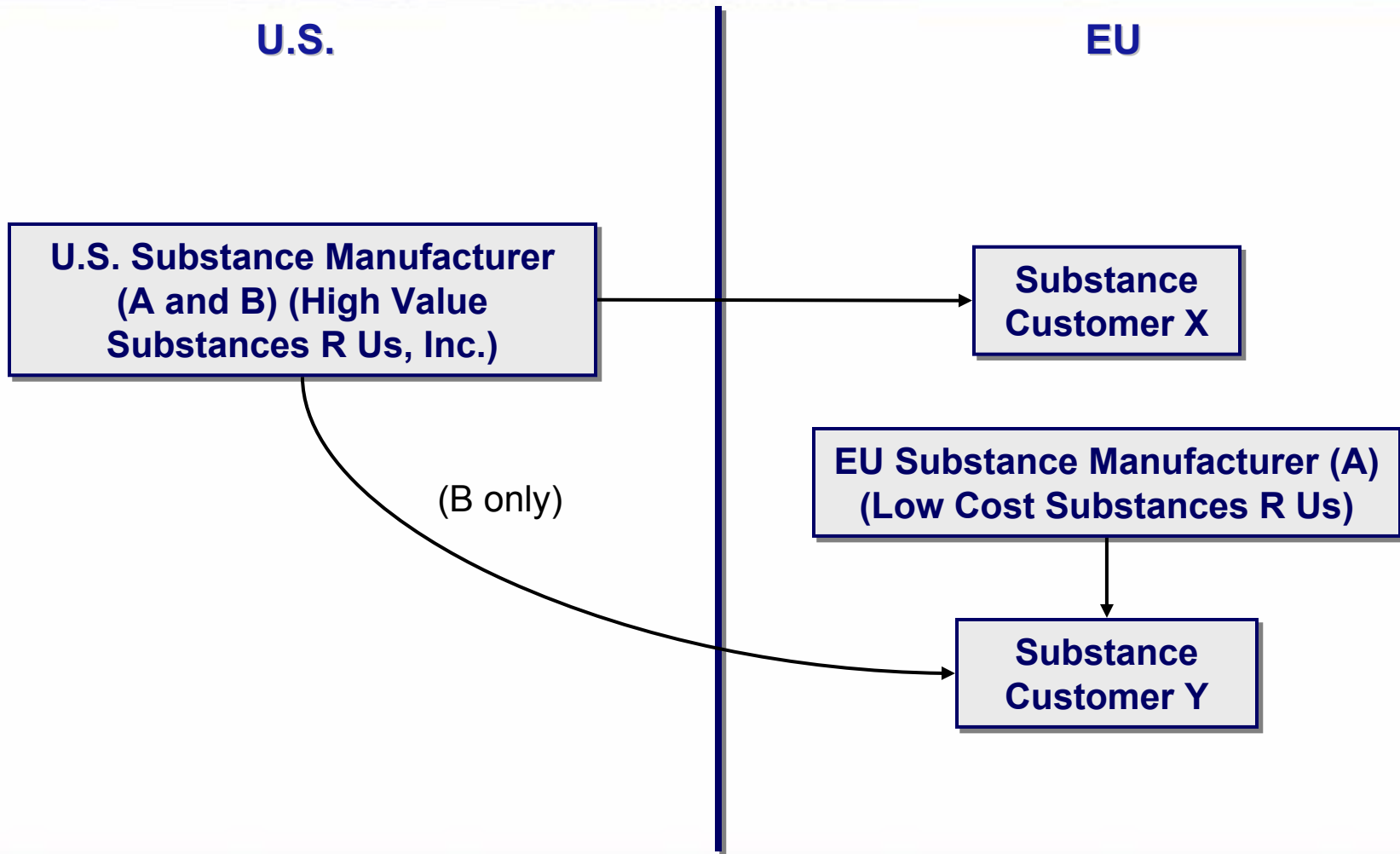
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Only Representative *(cont'd)*

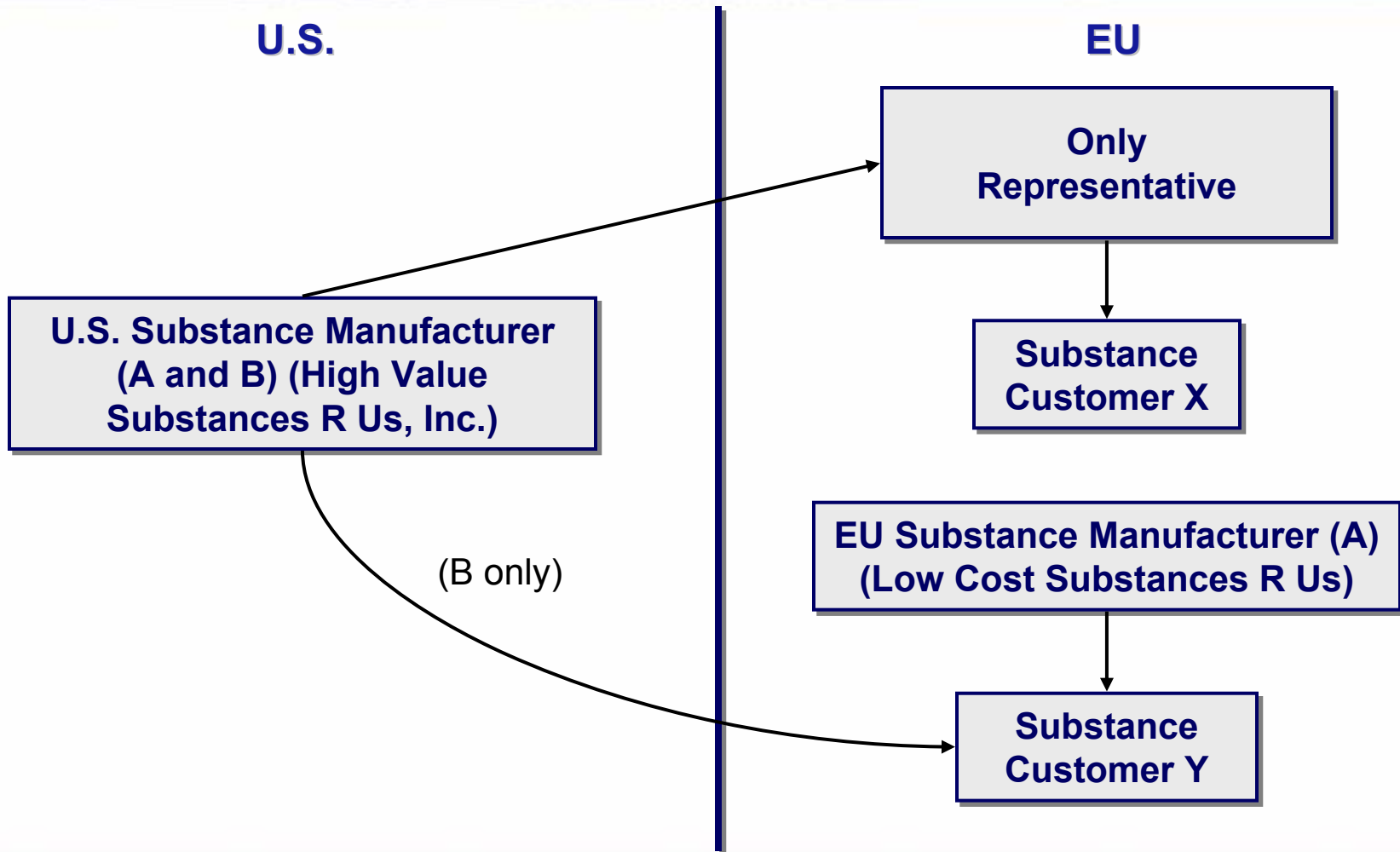
Why use an only representative?

- Solve customer as importer problem
- Solve CBI problem

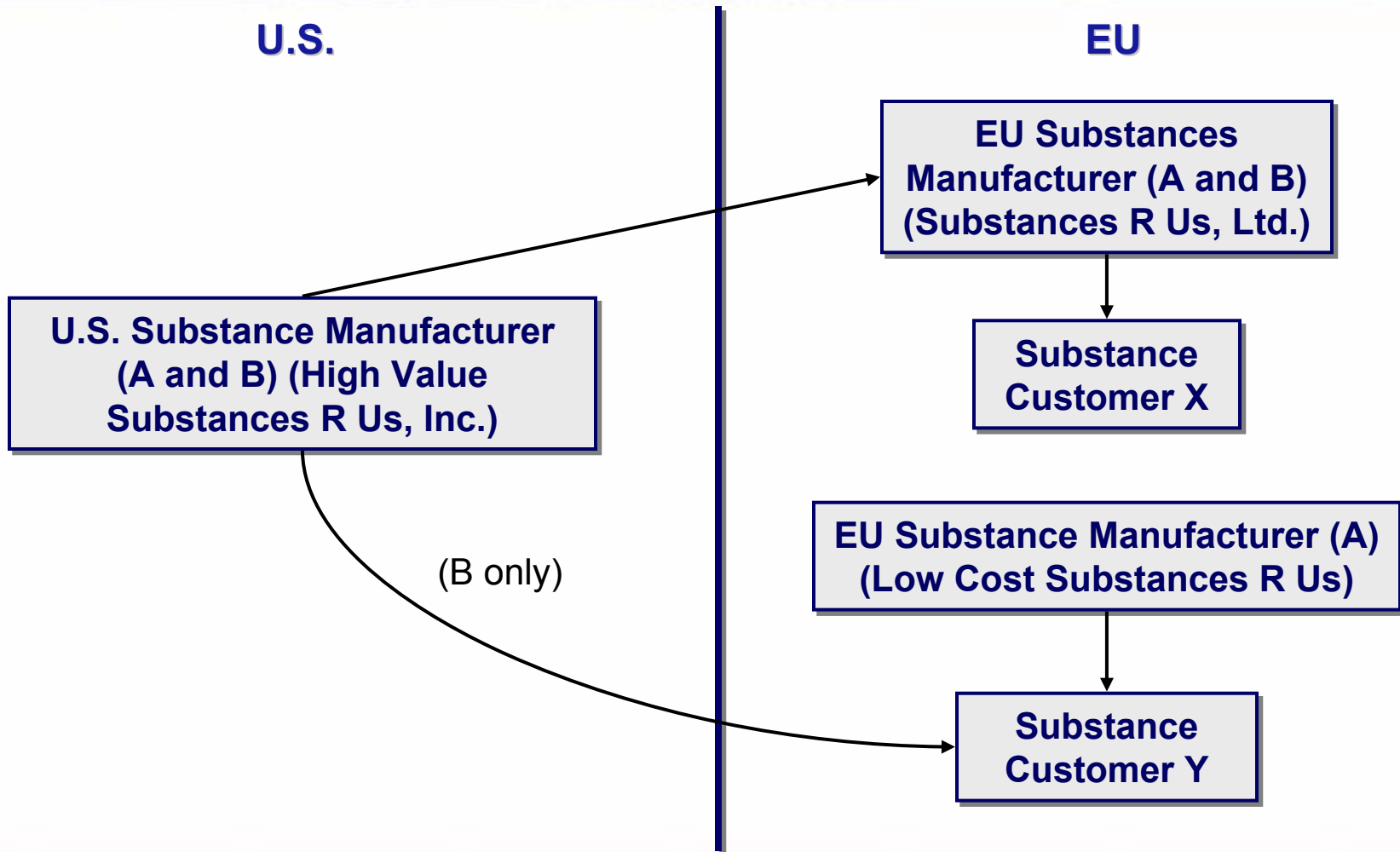
Only Representative/Substances



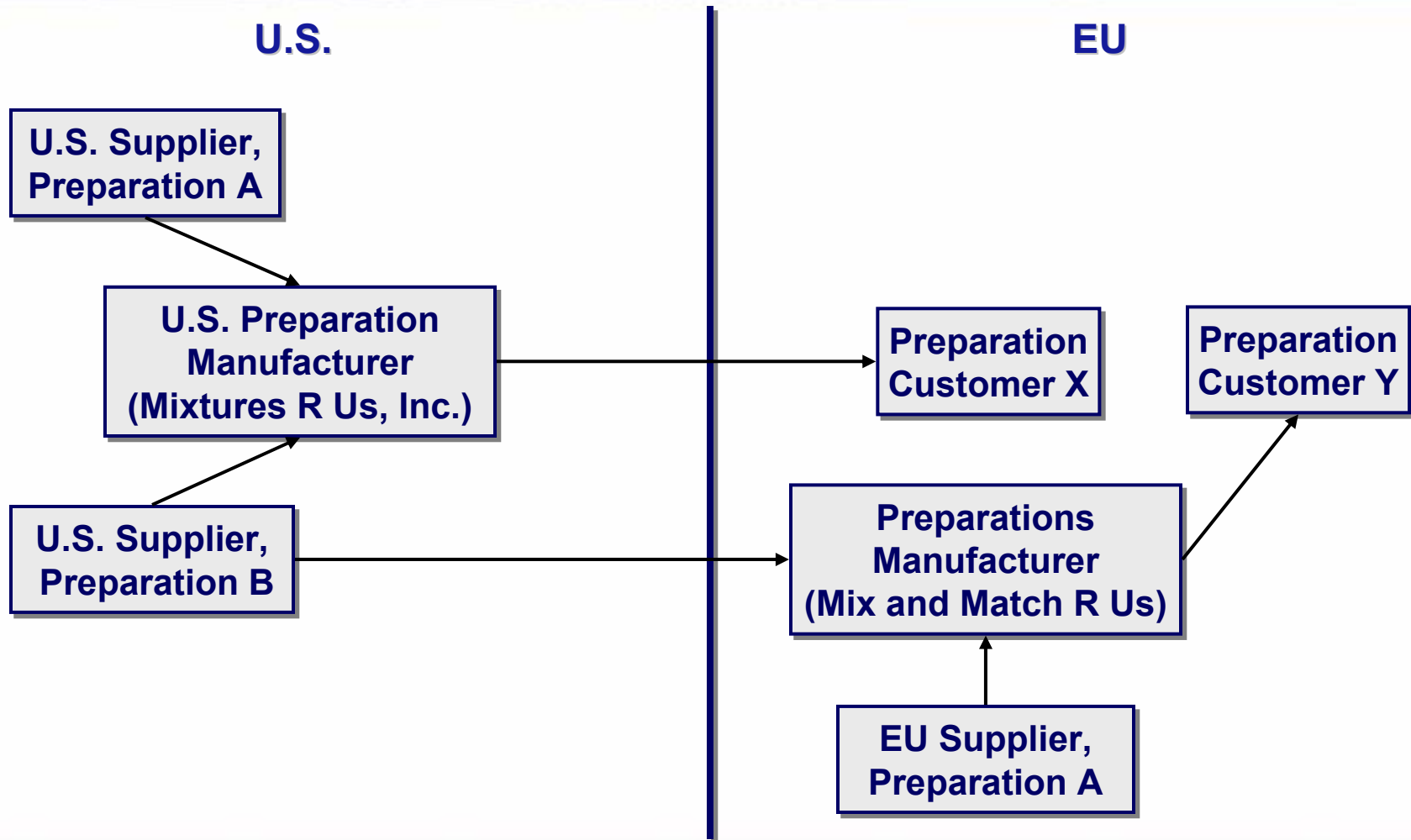
Only Representative/Substances



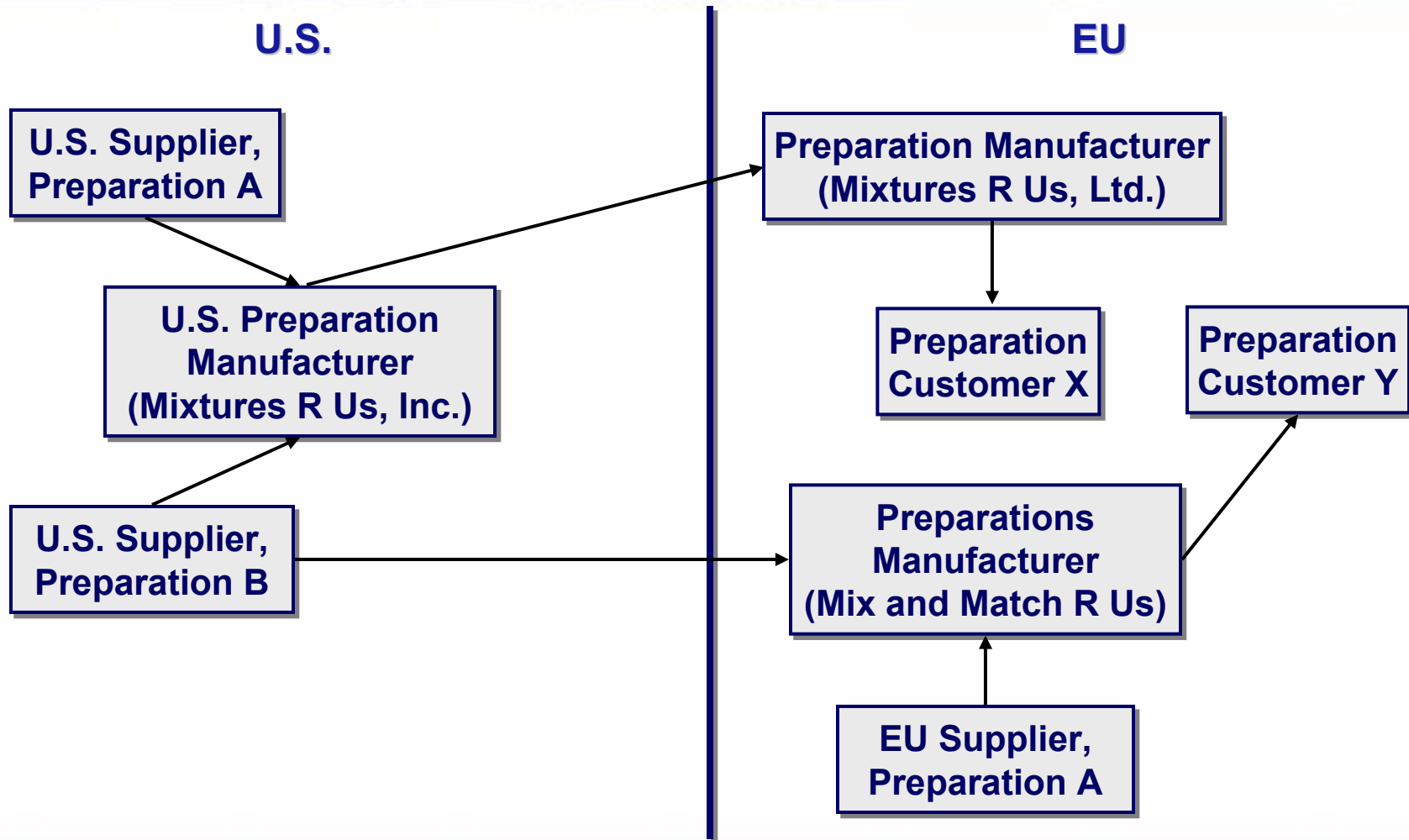
Only Representative/Substances



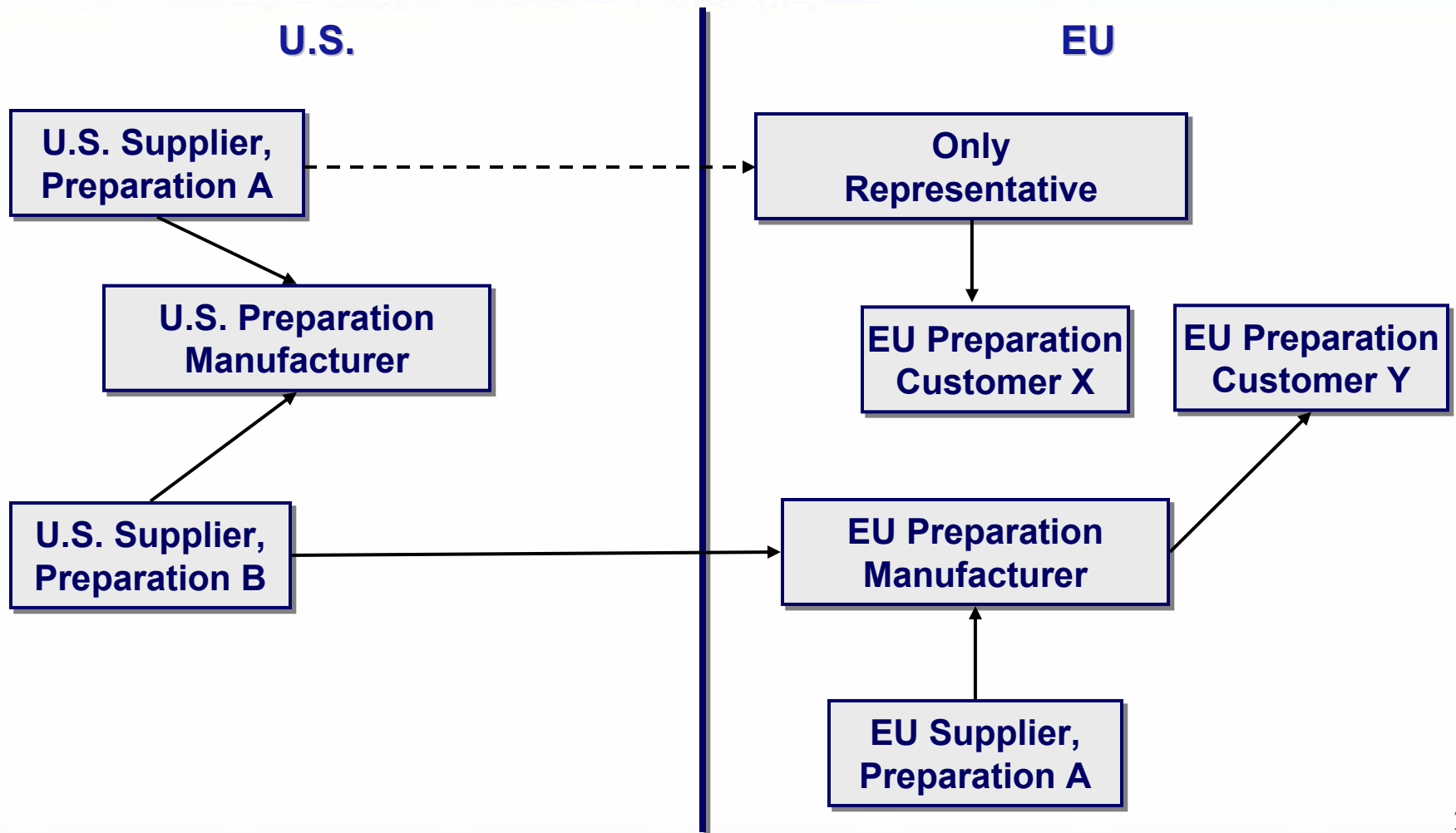
Only Representative/Preparations



Only Representative/Preparations



Only Representative/Preparations



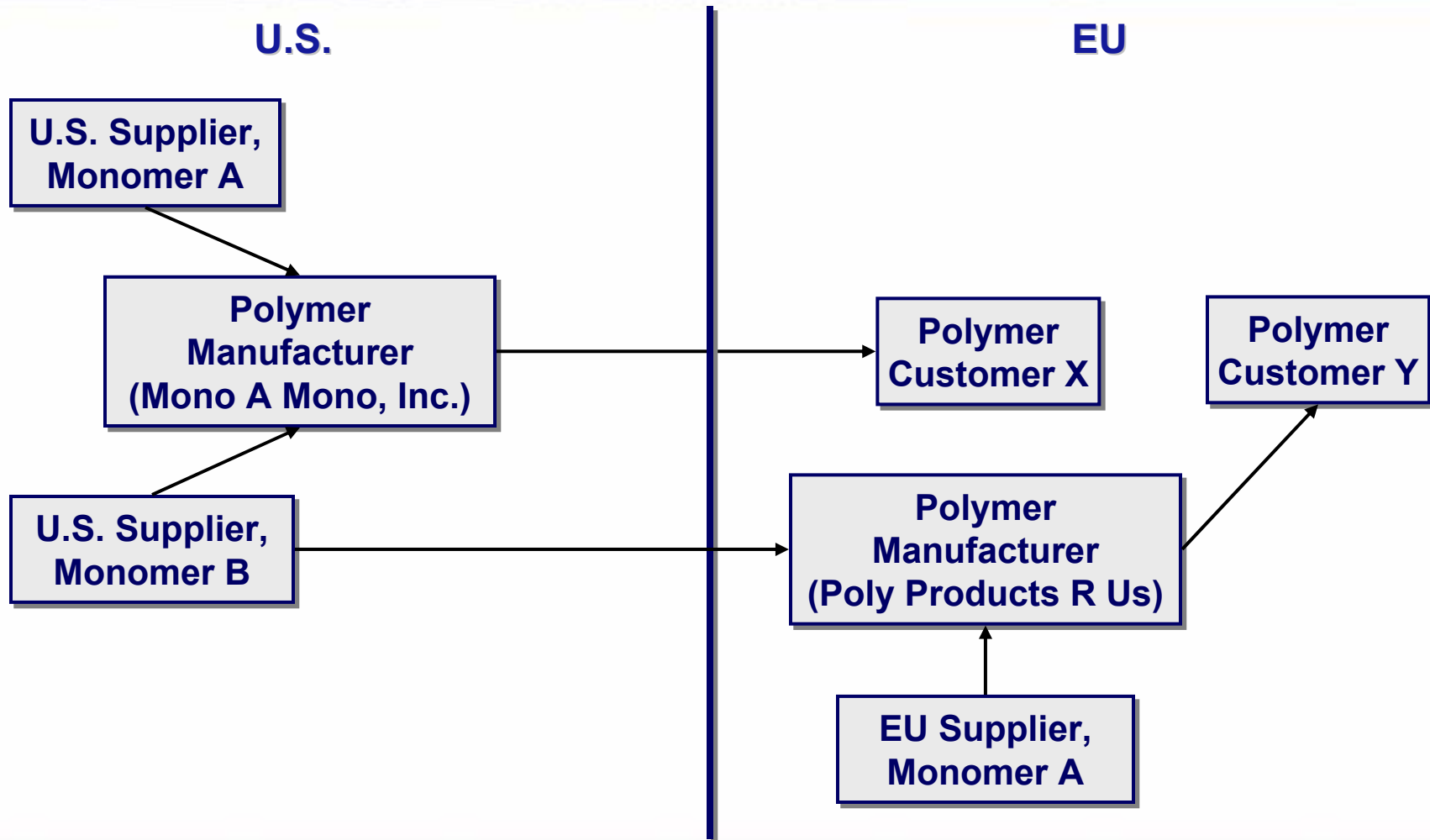
Only Representative – Other Issues

- Scenarios – use of one only representative to register common substance exported by
 - one U.S. company to multiple EU customers
 - multiple non-EU legal entities to separate EU customers
 - single U.S. company with multiple U.S. customers each of whom exports substance to its own EU customer
- Question – must the only representative submit a single registration (and aggregate the volumes)?

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



Monomers in Polymers (U.S. Exporter)

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

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

Articles Issues *(cont'd)*

Threshold Issues for Registration/ Notification

- Substance/preparation (S/P) in a container or carrier vs. 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 – Intentional release (Article 7.1)
 - Notify – Candidate list substance present above a concentration of 0.1% w/w (Article 7.2)

Articles Issues *(cont'd)*

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

Articles Issues (cont'd)

Substance in an Article

- Substance is an **integral** part of the article
- But **physical characteristics** of the object, i.e., shape, surface or design, are **more relevant** to function than chemical content
- If function determined **both** by chemical composition and physical characteristics, the **object is a carrier** and S/P must be registered

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Articles Issues *(cont'd)*

Substance/preparation in an Article *(cont'd)*

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

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 (*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 – 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
 - Exemptions (< 1 tonne, exposures excluded, already registered for that use) do not apply

Substances of Very High Concern (SVHCs)

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**

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SVHCs/Authorization

SVHCs will be:

- Identified
- Listed on Annex XIV
- Subject to Authorization
- Small volume SVHCs (i.e., < 1 Tonne/Year)
 - May be placed on Annex XIV
 - Small volumes uses must then be authorized

SVHCs/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**
- NGO Declaration
 - Will attempt to drive the process

SVHCs/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?

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SVHCs/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



How Do I Manage My REACH Liabilities?

Compliance and Business Considerations

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REACH Liabilities – Where Are You in the Supply Chain?

- EU Customer/Importer
 - Must register each substance
- U.S. Exporter
 - Downstream liabilities
 - EU Customer = Importer = Registrant
 - Unless exporter retains only representative
 - Either way, exporter will need to provide information
 - Upstream liabilities
 - Must rely on supplier for information
 - Risk of inaccurate/incomplete information

REACH Liabilities – Where Are You in the Supply Chain? (cont'd)

- U.S. Supplier
 - U.S. customer = exporter
 - Supplier must help customer meet its information requirements
 - Challenges
 - Protecting proprietary formulations
 - Tier 1 supplier relies on Tier 2 supplier for information; Tier 2 relies on Tier 3; → →→

REACH Liabilities/Preparing for REACH

Individual Company Efforts

- Step 1 – Secure Management Buy-In
- Step 2 – Conduct Training
- Step 3 – Conduct Inventory Review
- Step 4 – Conduct Supplier/Customer Review
- Step 5 – Develop Strategic Action Plan (at company, division, product and/or substance level)

REACH Liabilities/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

REACH Liabilities/Supply Chain Considerations

Due Diligence Issues

- Communications with Suppliers
 - First letter: general description of REACH
 - Second letter: provide supplier with specific (industry) list of substances
 - Third letter: request supplier provide identity of all substances
- Performance specifications
 - Changes in substances/concentrations

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REACH Liabilities/Supply Chain Considerations (cont'd)

Contract Issues

- Current contract language – review
- Substance identification – certification of completeness?
- Pre-registration/registration commitment?
- Notice provisions
 - Commitments
 - Changes in substance identification
- Materiality
- Consequences – business disruption

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REACH Liabilities/Supply Chain Considerations (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

REACH Liabilities/Supply Chain Considerations (cont'd)

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

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Contact Information

THANK YOU

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