



REACH

ACC Small Business Council

Regulatory Requirements and Business Implications

Robert Matthews

McKenna Long & Aldridge LLP

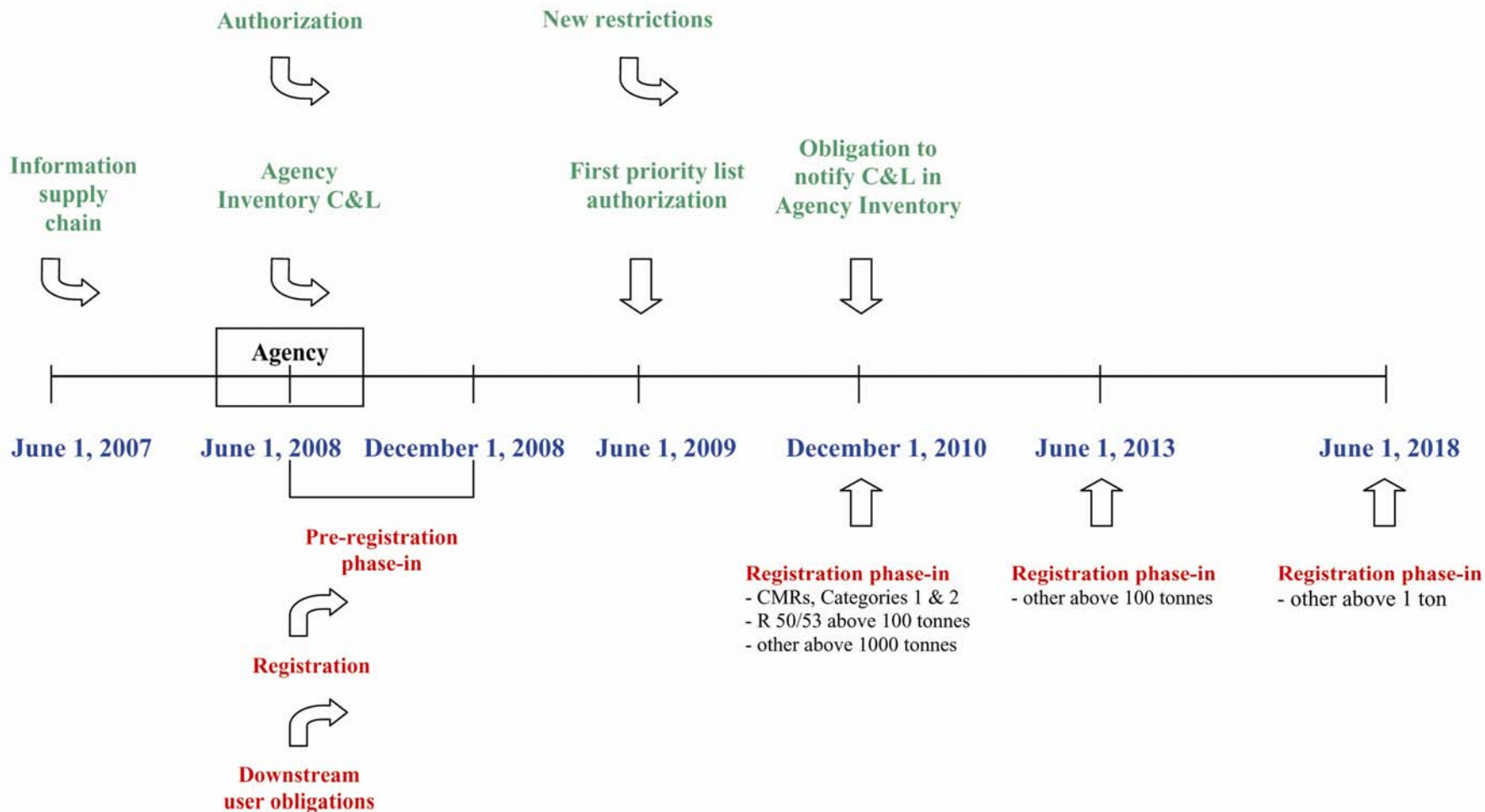
June 25, 2007

REACH Webinar – Session One

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STAY AHEAD OF THE CURVE

REACH TIMELINES



- Substances subject to registration
- All substances

REACH

- **Legal Profile**

- REACH is a Regulation, not a Directive
- Under EU law, that means it is fully harmonized
 - No need for Member State transposition
 - No room for Member State discretion
- Two exceptions
 - Enforcement
 - Defense exemption
- Significant Member State role
 - As the Competent Authority
 - Evaluation, Authorization, Restrictions process and decisions

REACH Myths

- REACH is a chemical industry issue
- REACH is an EU-based company problem
- 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 or you can lose **market access** in the EU
- 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 Business Implications And Impacts

Beyond ES&H

- Supply chain
- Customers
- Market Strategies
- CBI
- Investments/R&D
- Reformulation
- Substitution

REACH Impacts on U.S.-Based Companies

Operations in the EU

- Manufacture (substance, alone or in a preparation)
- Downstream user

Operations Outside the EU

- Substances or preparations exported to the EU
- Monomers in polymers exported to the EU
- Substances in articles exported to the EU
- “Blacklisted” substances
 - whether or not actually exported to the EU



Scope of Legislation

Major Requirements

- Registration (Title II)
- Evaluation (Title VI)
- Authorization (Title VII)
- Restrictions (Title VIII)

Other Significant REACH Concepts

- Data Sharing (Title III)
- Information in the Supply Chain (Title IV)
- Downstream Users (Title V)
- European Chemicals Agency (Title X)
- Classification & Labelling (Title XI)

General Obligations

- Register
 - Obligation of each manufacturer/importer
 - Substances, on their own or in preparations
 - 1 tonne threshold (per manufacturer/importer)
- Provide data
- No registration/data, no market

Exemptions and Exclusions

- Exclusions from REACH
 - Radioactives within Directive 96/29
 - Non-isolated intermediates
 - Waste as defined in Directive 2006/12
 - Defense (to be determined by Member States)
 - GMOs

Exemptions and Exclusions (*cont'd*)

Exemptions from Registration

- Substances notified under existing “new” substances legislation
- Below 1 tonne per year per manufacturer/importer
- Substances in medicinal products*
- Substances in food or feed incl. additives, flavorings*
- Annex IV substances**
- Annex V substances**

* Also exempt from downstream user requirements, evaluation and authorization

** Also exempt from downstream user requirements and evaluation

Exemptions and Exclusions (*cont'd*)

Exemptions from Registration

- Recovered substances similar to registered substances
- Polymers***
- PPORD for 5 years, but subject to notification
- Actives (and co-formulants) under Directive 91/414 and actives under Directive 98/8 if listed
- Reduced registration for on-site isolated or transported isolated intermediates

*** Also exempt from evaluation



Pre-Registration and Registration Issues

Registration

- Prohibition
 - Substances may not be manufactured or imported unless registered
 - and pre-registered for phase-in substances
 - Presumptive approval of registration completeness, unless contrary indication by Agency
 - Within 3 weeks of submission for non-phase-in substance
 - Within 3 months of submission of phase-in substance

Phase-In Substances

- Over 15 years preceding the entry into force of REACH:
 - EINECS listed or
 - 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

Pre-Registration

- Applies to phase-in substances
- Timing – 6 month window
 - Start date – 12 months after EIF
 - End date – 18 months after EIF
 - 1 June '08 – 1 December '08
- Failure to pre-register results in loss of phase-in status
 - Must begin full registration process 12 months after EIF (June '08)

Pre-Registration (cont'd)

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

Pre-Registration (cont'd)

Additional Rules

- Agency to publish list of pre-registered substances
 - By name and by EINECS and CAS numbers
- Downstream user of a substance not on the list may notify the Agency
 - Agency to publish DU name
 - With DU's permission, Agency seeks to identify new supplier

Pre-Registration (cont'd)

Additional Rules (cont'd)

- 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)

Pre-Registration (cont'd)

Once pre-registration requirements fulfilled, no further registration obligations for

- 3.5 years
- 6 years
- 11 years

BUT

- Possible testing complications; and
- Beware the SVHCs

Registration

Thresholds

- **Manufacturer of Substance**
 - 1 Tonne
- **Importer of Substance**
 - Alone or in a preparation
 - 1 Tonne
- **Manufacturer or Importer of Article**
 - 1 Tonne of Substance in Article

One Substance, One Registration (OSOR)

- Manufacturers/Importers registering the same substance at the same time (within the same tonnage band) must register jointly
- Information to be submitted jointly (by lead registrant)
 - Classification & labeling
 - Study summaries & robust study summaries (per specific tonnage band)
 - Testing proposal

OSOR (cont'd)

- Information that may be submitted jointly
 - Guidance on safe use
 - Chemical safety report
- Information to be submitted individually
 - Identity of registrant & substance
 - Information on uses & exposure

OSOR (cont'd)

- Companies may opt out of joint registration if:
 - Joint submission is disproportionately costly
 - Disclosure of commercially sensitive information is likely to cause substantial commercial detriment
 - There is disagreement with the lead registrant on the selection of information
- Justification would only be assessed during 'dossier' evaluation

Only Representative

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

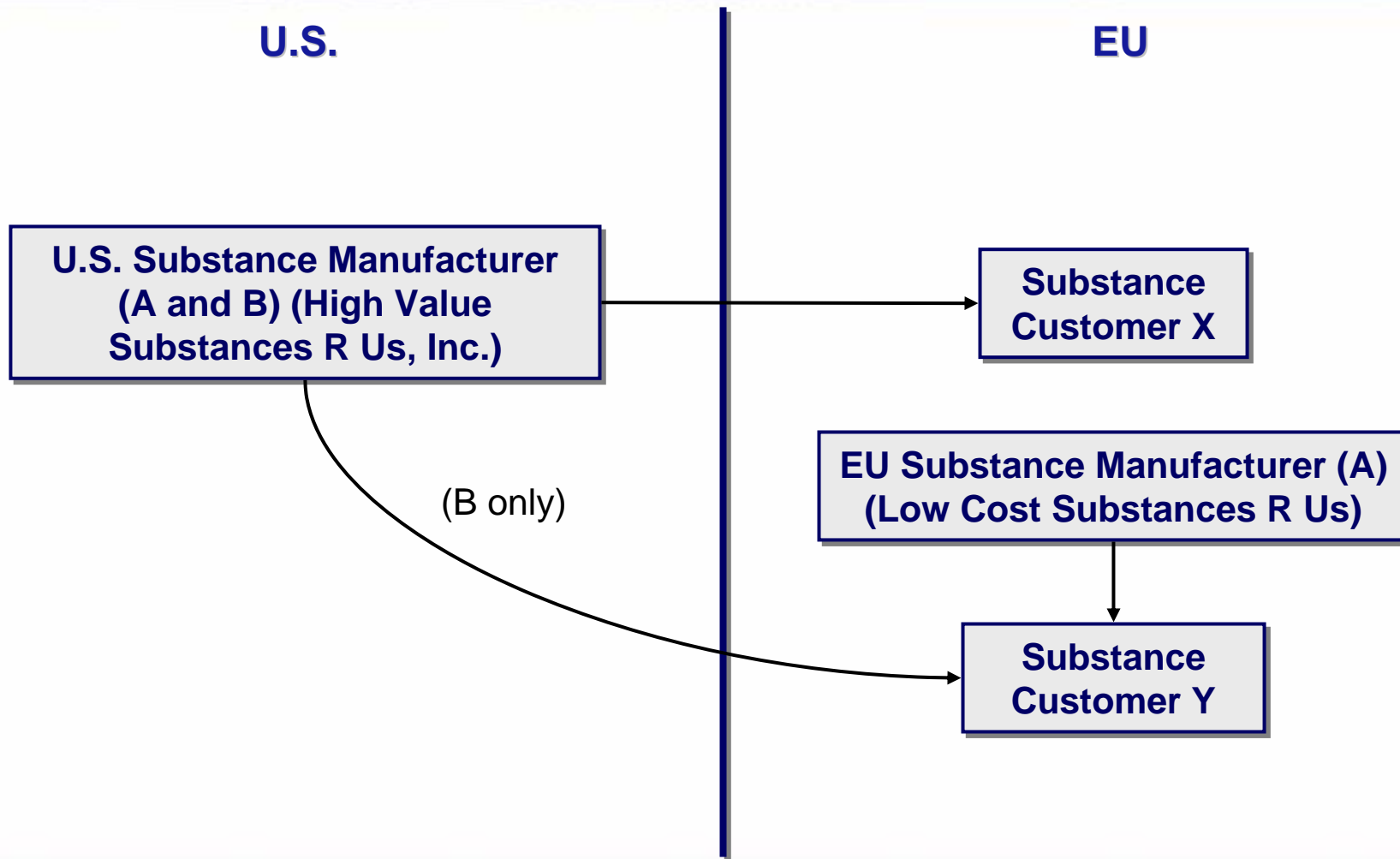
Only Representative (cont'd)

Why use an only representative?

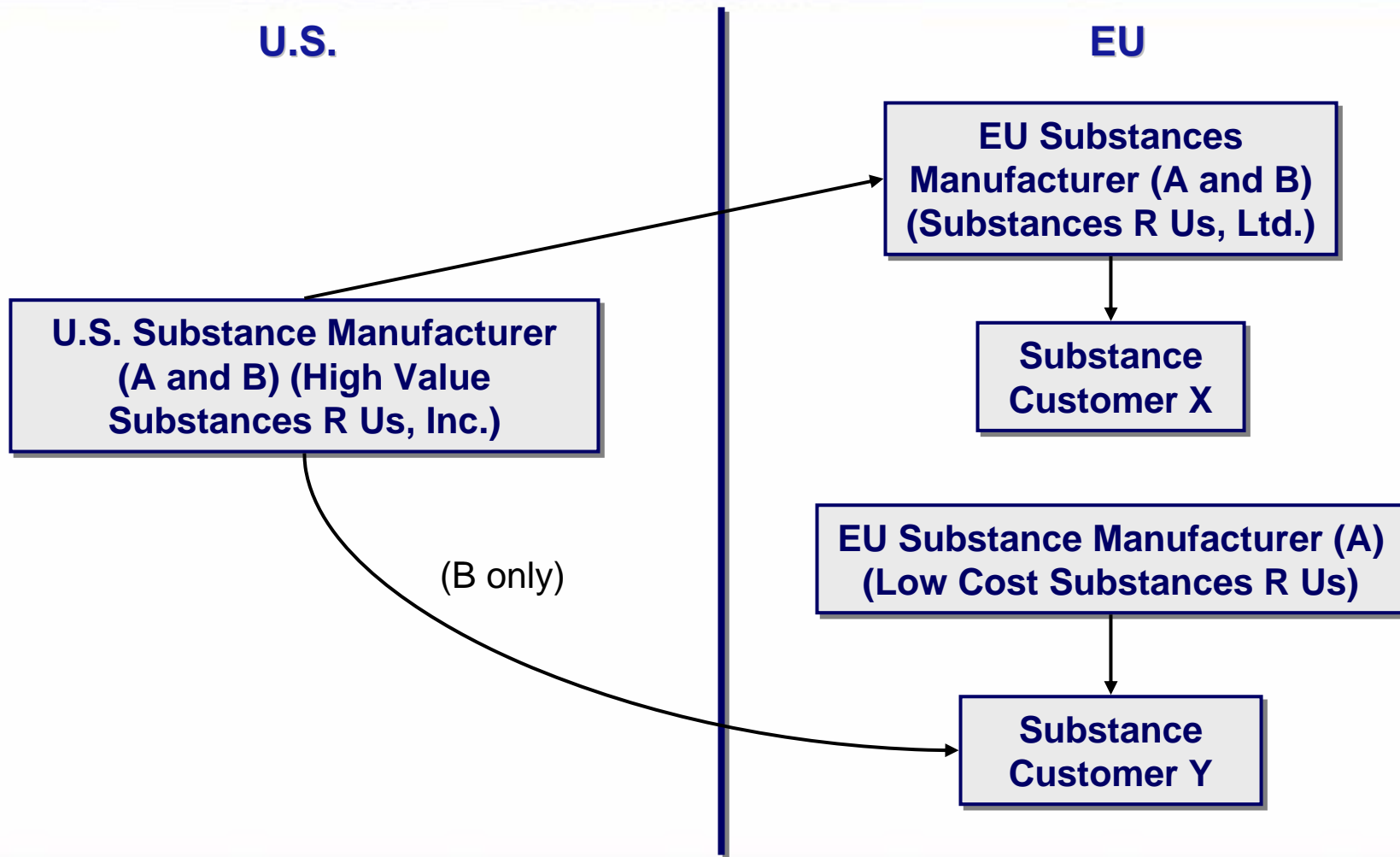
- Solve customer as importer problem
- Solve CBI problem

(See Substance and Preparation scenarios
in following slides)

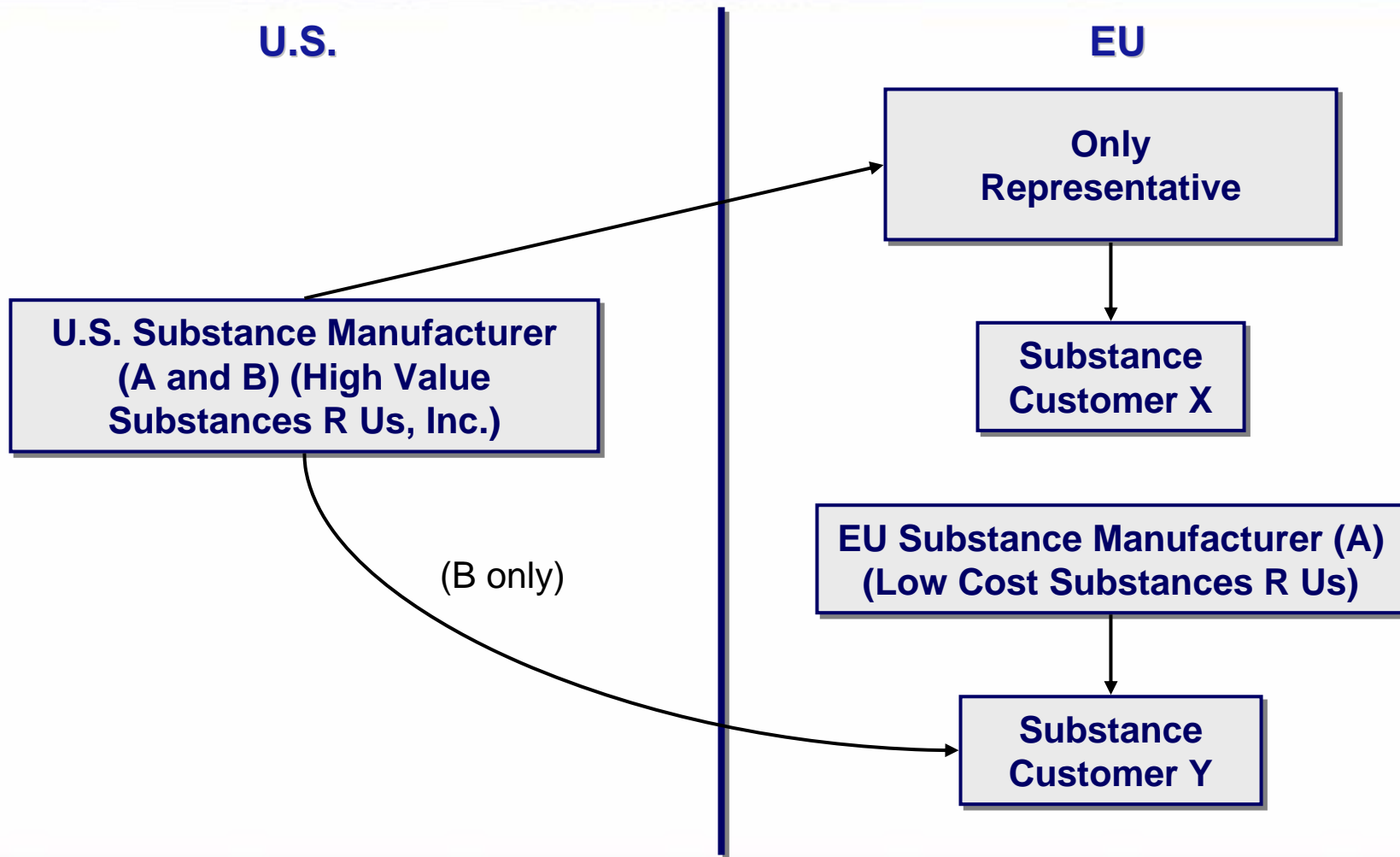
Substances



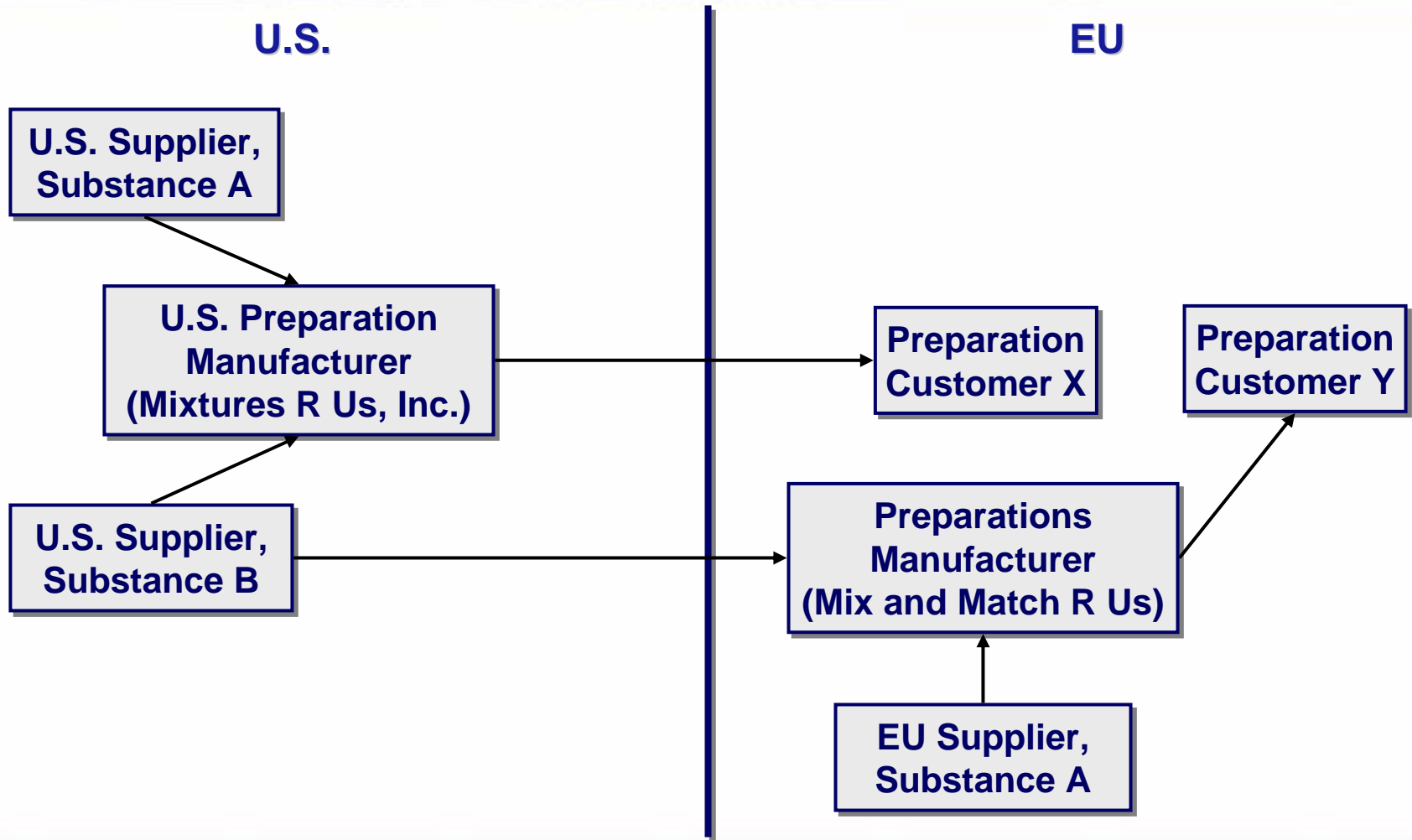
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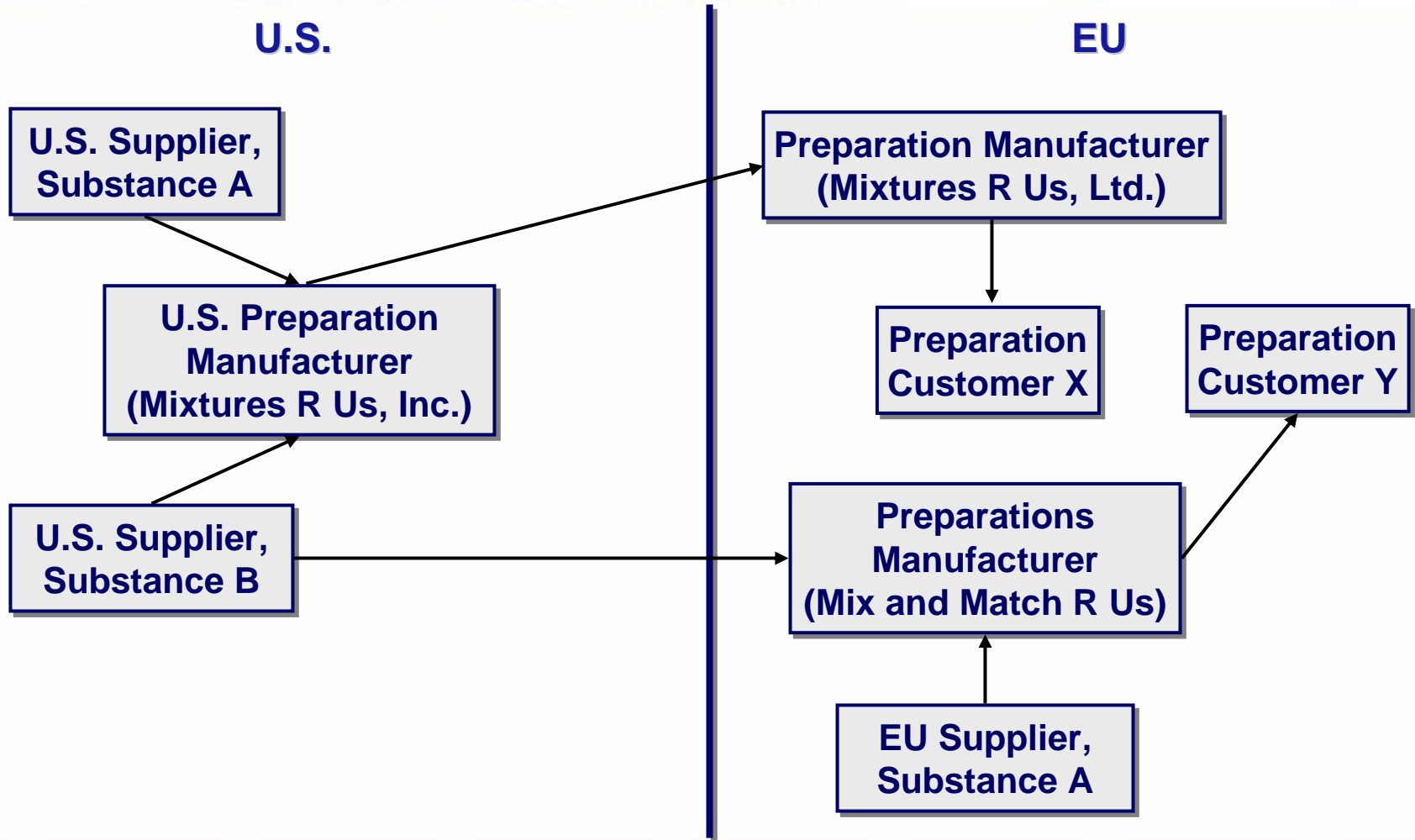
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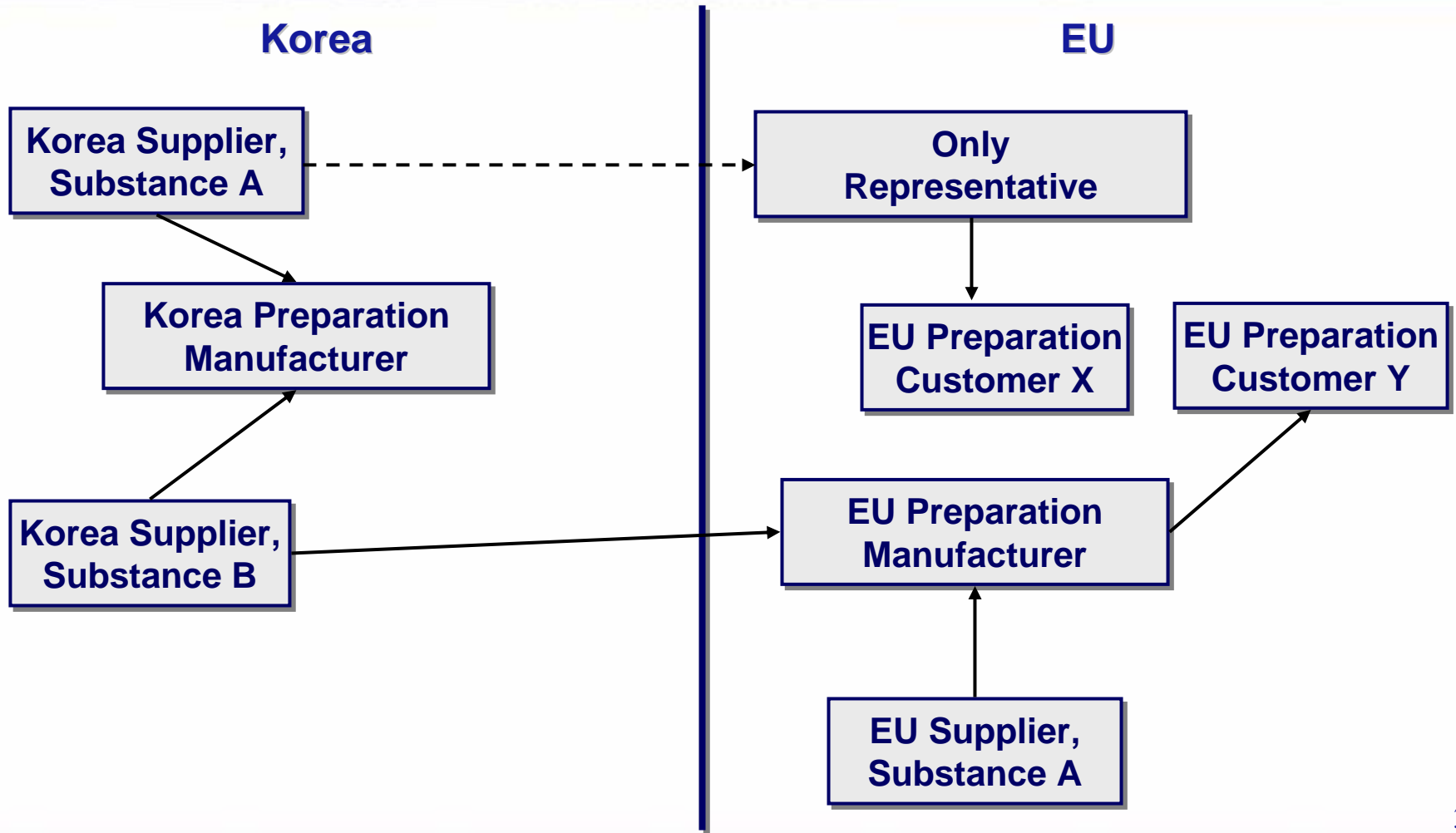
Preparations



Preparations



Preparations (cont'd)



Preparations

U.S. vs. EU Preparation Manufacturer

- EU-based manufacturer purchases substance from its supplier
 - Supplier registers substance
- U.S.-based manufacturer purchases substance from its supplier
 - Supplier not in EU
 - Substance introduced into EU by preparation manufacturer
 - Customer of preparation manufacturer must register the substance

Only Representative vs. Current Sole Representative

- Only representative has additional obligations
 - Must have ‘sufficient background in the practical handling of substances and the information related to them’
 - Must keep available information on quantities and customers
 - Must keep the information on the supply of the latest up-dated Safety Data Sheet

Only Representative vs. Current Sole Representative *(cont'd)*

- When imports are covered by an only representative, importers are considered downstream users
 - They must assess information received
 - They must assess risk management measures
 - They may need to recommend risk management measures further down the supply chain

Only Representative – Other Issues

- When an only representative represents several non-EU companies, are the tonnages aggregated and, if so, how are the registration responsibilities allocated among non-EU companies?
- Free riding possible if the only representative represents several non-EU companies within the same tonnage band
- Liability for non-compliance with obligations (data sharing, up-dates)

Special Rules

- Intermediates
- Monomers in Polymers
- Substances in Articles

Intermediates

- Definition of “intermediates” (Article 3)
- Non-isolated intermediates are excluded from REACH
- Reduced registration requirements for “on-site isolated intermediates”
 - Only to the extent that submission is possible without additional animal testing
 - Identity of the manufacturer
 - Identify of the intermediate
 - Classification
 - Any available existing information on physico-chemical, human health or environmental properties
 - No chemical safety assessment

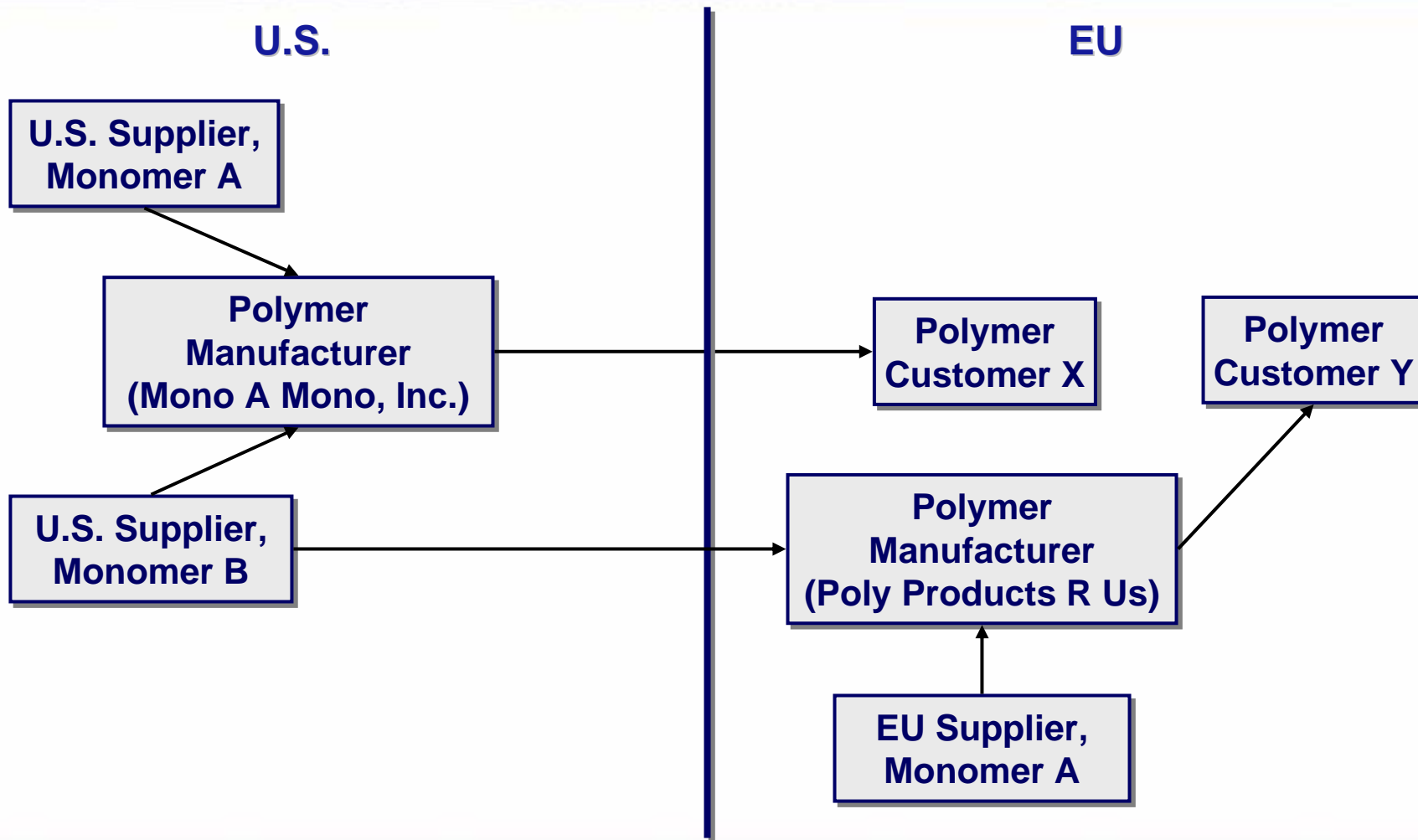
Intermediates (cont'd)

- Reduced registration for *isolated intermediates transported*
 - Same as for on-site isolated intermediates
 - Annex VII information if transported in Q of more than 1000 Tons per year
 - No chemical safety assessment
- BUT only if subject to strict contractual control, and
 - Substance is rigorously contained
 - Potential emissions/exposure minimized
 - Training, maintenance, handling procedures followed and documented

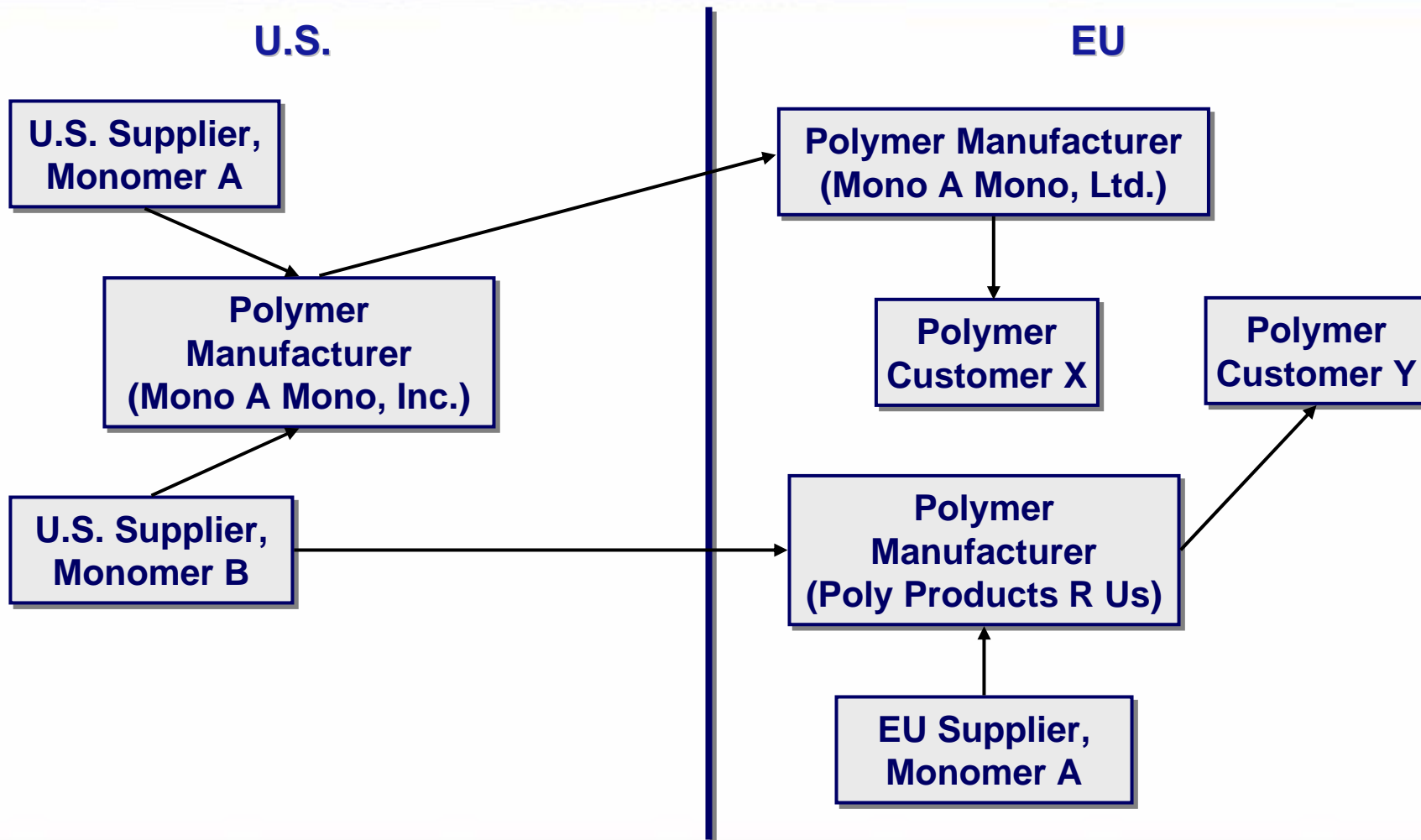
Monomers in Polymers

- 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.

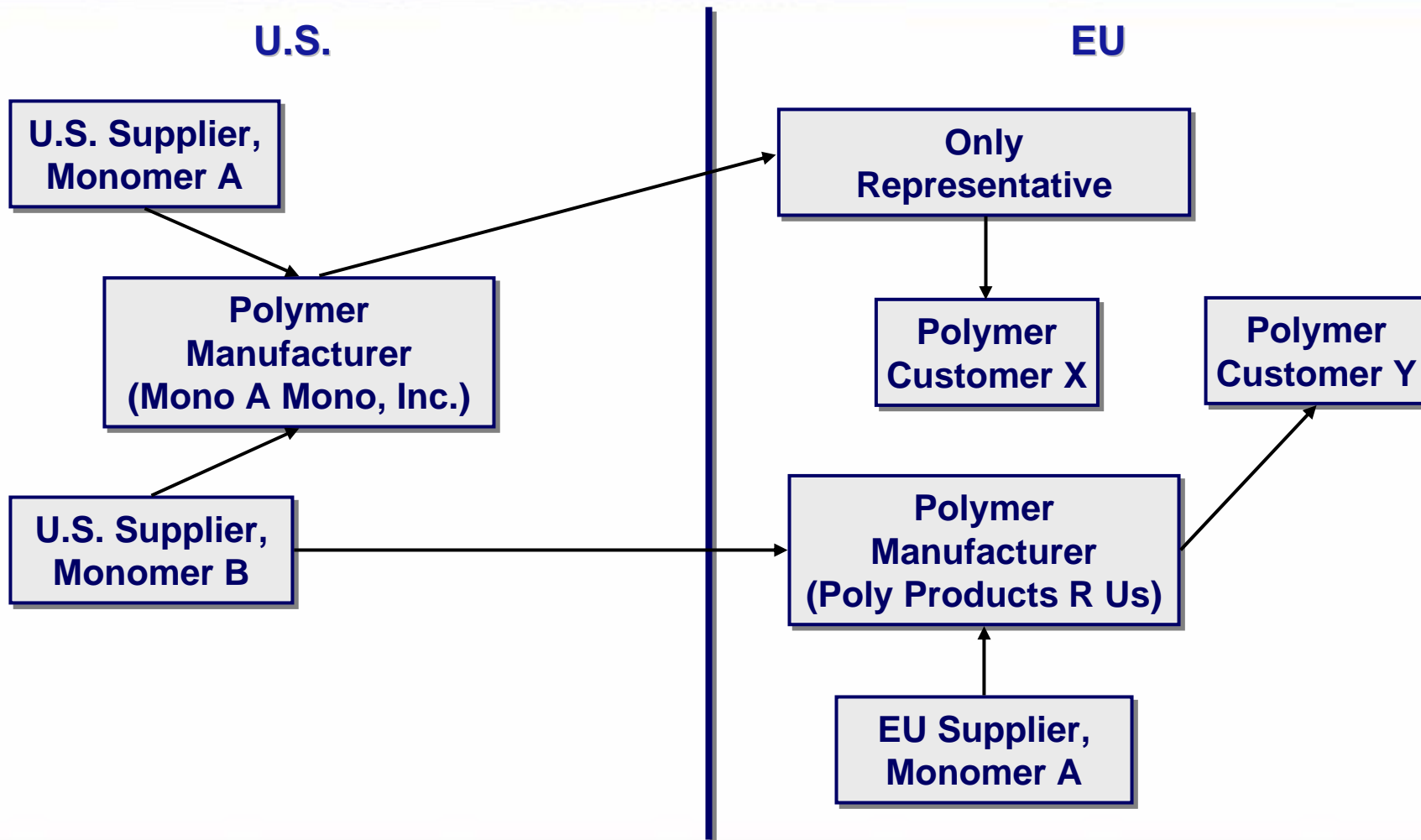
Monomers in Polymers



Monomers in Polymers



Monomers in Polymers



Monomers in Polymers

U.S. vs. EU Polymer Manufacturer

- EU-based manufacturer purchases monomers from its supplier
 - Supplier registers monomer
- U.S.-based manufacturer purchases monomers from its supplier
 - Supplier not in EU
 - Monomer introduced into EU by polymer manufacturer
 - Customer of polymer manufacturer must register the monomers
 - Even though fully polymerized

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

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 - Issues

- What is an article?
 - Definition
 - Intentional releases
 - Normal/reasonably foreseeable
- RIP 3.8
 - “Agreed Cases”
 - “Borderline Cases”

Substances in Articles – Exemptions

- Exemptions from registration and notification
 - If the substance has already been registered ‘for that use’ (by anybody)
- Exemptions from registration
 - As applicable to all other substances
- Exemptions from notification
 - If notifier can exclude substance exposure to humans and the environment during the normal or reasonably foreseeable conditions of use (including disposal)

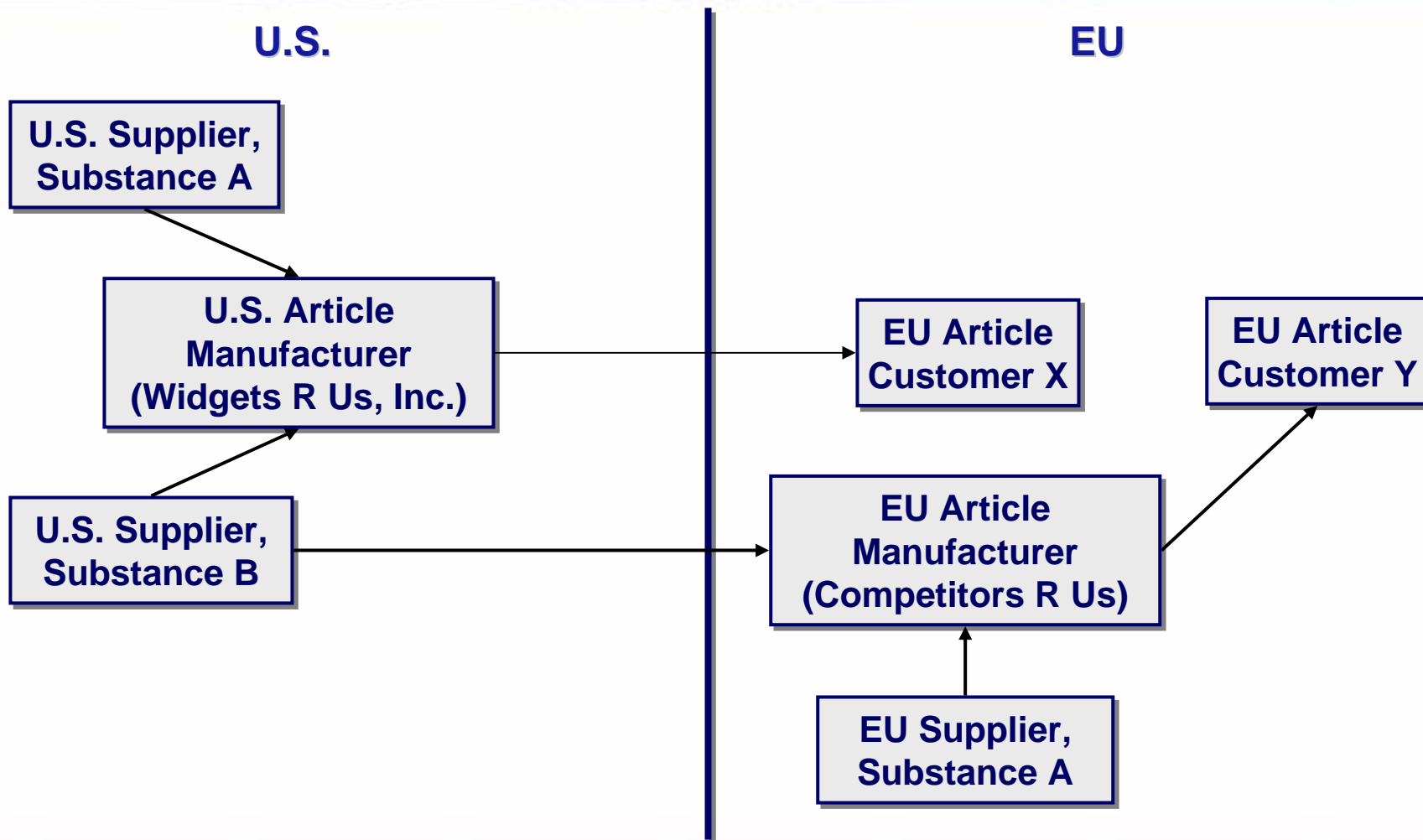
Substances in Articles – Timing

- The same registration deadlines as for all other substances
 - 3.5, 6 and 11 years for “phase-in”
 - 1 year for non “phase-in”
- Notification applies as of 48 months after entry into force (June 2011) and 6 months after new substances are included in the ‘candidate list’
 - Most CMRs and R50/53 above 100 tonnes will be registered by December 2010, hence no notification if registration covers use in article

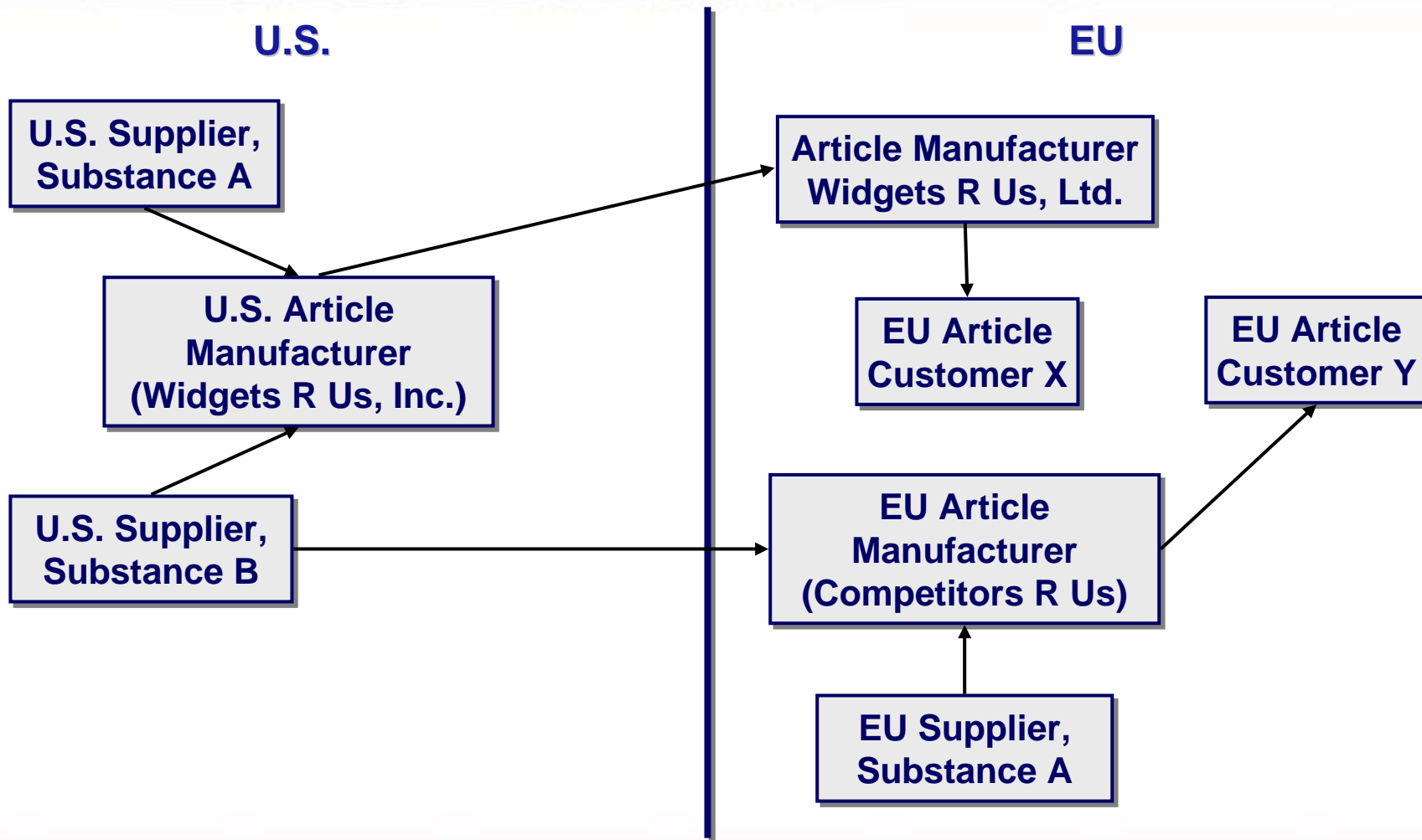
Substances in Articles – Information in the Supply Chain

- Suppliers of articles containing SVHCs (listed in “candidate” lists) must provide sufficient information allowing safe use of the article (including, at a minimum, name of the substance)
 - to recipients of articles
 - to consumers
- Information must be provided within 45 days of receipt of request

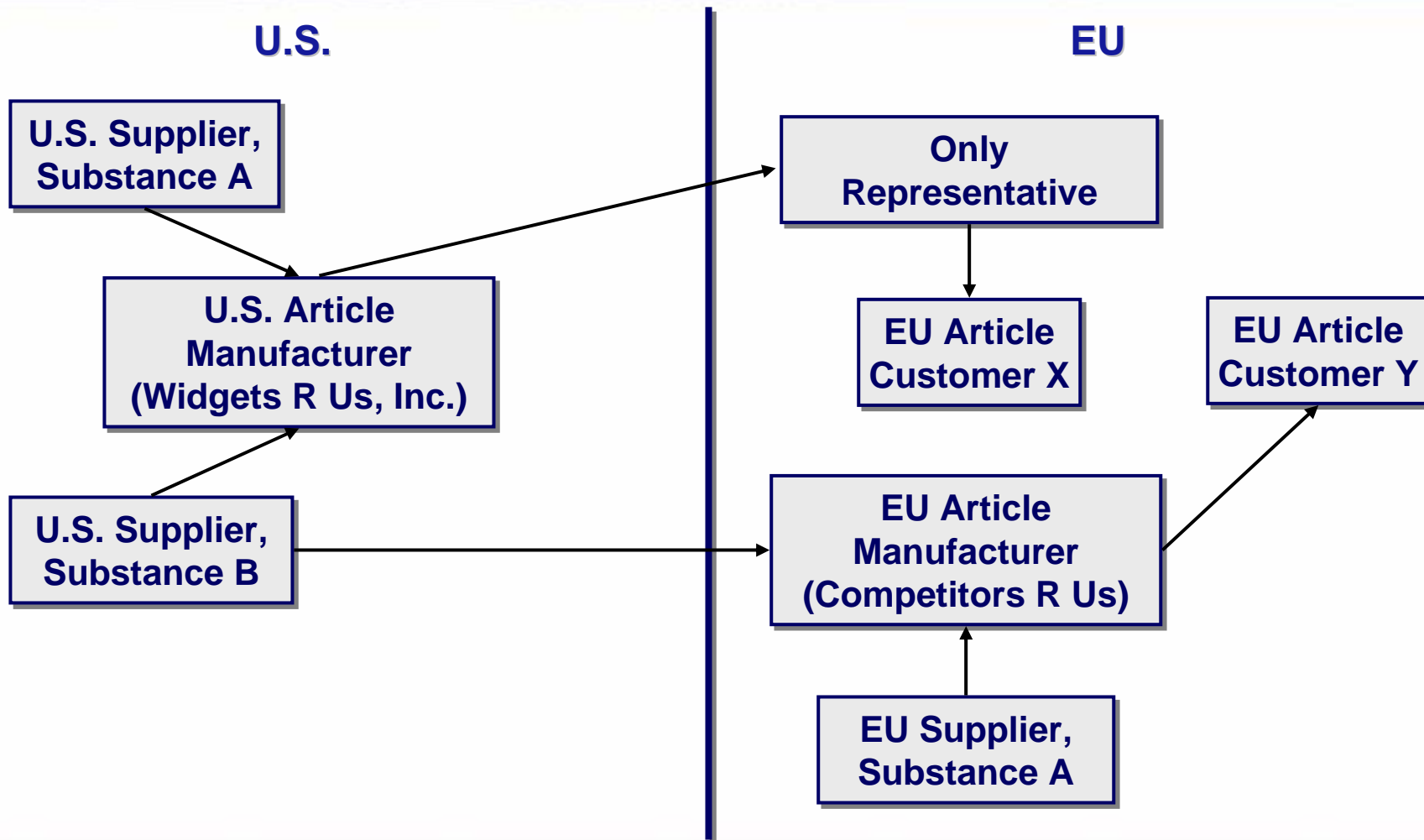
Substances in Articles



Substances in Articles



Substances in Articles



Substances in Articles

U.S. vs. EU Article Manufacturer

- EU-based manufacturer purchases substance from its supplier
 - Supplier registers substance
- U.S.-based manufacturer purchases substance from its supplier
 - Supplier not in EU
 - Substance introduced into EU by article manufacturer
 - Customer of article manufacturer must register the substance

Substances in Articles (*cont'd*)

Exemption – Neither Registration nor Notification required if a substance has “already been registered for that use”

- EU supplier can include use by its EU customer (article manufacturer) – customer exempt
- US supplier not a registrant
 - US customer (article manufacturer) can not be exempt
 - Unless another EU M/I of same substance registers (for that use)



Registration Dossier

A Registration Dossier

Contains:

- A technical dossier, and
- A chemical safety report (CSR)
 - If triggered

The Technical Dossier

- Identity of manufacturer/importer
- Identity of the substance
- Information on manufacture and use
- C & L
- Guidance on safe use
- Exposure information (if applicable)
- Study summaries for data requirements
- Proposals for testing

The Technical Dossier: data

Data requirements are related to tonnages manufactured/imported:

<u>Tonnage</u>	<u>Requirements listed</u>
≥ 1 tonne	Annex VII
≥ 10 tonnes	Annex VII and VIII
≥ 100 tonnes	Annex VII to IX
≥ 1000 tonnes	Annex VII to X

Chemical Safety Report (CSR)

- Required for all substances > 10 tonnes/p.a.
- Purpose is to describe how chemicals are used in a safe manner
- European Commission aims to make the creation process transparent and straightforward, particularly exposure estimates
- The template and precise format has not yet been fully established/released

Chemical Safety Assessment

Obligation of manufacturers, importers and downstream users to perform a *Chemical Safety Assessment (CSA)*

- 10 tonnes threshold
- May cover substances on their own, in preparations, or in groups

Chemical Safety Assessment (*cont'd*)

- Hazard assessment
 - Environmental hazard assessment
 - Human health hazard assessment
 - Physicochemical hazard
- Specific section on PBT, vPvB (or of similar concern)
- If substance is classified as dangerous or is a PBT, vPvB, then
 - Exposure assessment
 - Risk assessment

Chemical Safety Assessment (Annex I)

- Only for registered substances in Q of 10 tonnes or more
 - Technical dossier and other available information
 - If further information involving testing on vertebrate animals is necessary, proposal for testing strategy must be submitted
- All “identified” uses
- All stages of the life-cycle of the substance, including the waste phase
- Not required for substances present in preparation below specified concentration limits
- May be conducted per preparation (Annex Ib)

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Chemical Safety Assessment (*cont'd*)

- If supplier does not include a customer's use in its CSA, the DU can either switch to another supplier who has identified that use, or must conduct its own CSA
- But either way, CSA must cover exposure scenario for all uses and recommend measures to “adequately control the risks”



Substances of Very High Concern (SVHCs)

REACH

The top of the slide features a blue background with a photograph of a modern building's glass facade. Three yellow stars are overlaid on the image, positioned above the word 'REACH'.

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

Substances of Very High Concern (SVHCs)

See Authorization, Article 57

- 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

SVHCs (cont'd)

See also Classification and Labeling,

- Article 115
- C&L to continue under REACH
- For Dangerous Substances on Annex I of 67/548/EEC, and for
 - CMRs, Categories 1, 2 and 3
 - Respiratory sensitizers
 - Other effects (case-by-case)

REACH “Frontloads” SVHCs

- Article 23(1)(a) – Phase-In Substances
 - First tier (3.5 years) – CMR Cat. 1 and 2
- Article 40(1) – Dossier Evaluation
 - Priority substances: PBT, vPvB, sensitizers, CMR
- Article 44(1)(a) – Substance Evaluation
 - Priority substances: Persistent, Bioaccumulative

REACH “Frontloads” SVHCs (Cont'd)

- Article 58(3) – Recommendations of Priority Substances for Authorization Annex (XIV)
 - PBT or vPvB substances
- Article 68(2) – Restrictions
 - CMR Cat. 1 and 2 substances used by consumers

SVHCs (cont'd)

See also

- Article 7(2) – Notification of substances in articles
 - Producers and importers must notify Agency if substance has been identified on Authorization candidate list (Article 59(1))
 - Beginning June 1, 2011, within 6 months following inclusion on candidate list

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

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

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)

Annex XIV Listing Decision

- Exemptions
 - Authorization listing can include exemptions
 - Commission anticipates issuing exemptions covering “uses or categories of uses”

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*)

- Authorization may not be granted based on determination that risks are adequately controlled for:
 - CMR Category 1 and 2 and substances with effects of equivalent concern for which a threshold of effect for humans can not be established (Annex I, point 6.4)
 - PBTs
 - vPvBs
 - Possible future addition of endocrine disruptors

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

AND

Authorization *(cont'd)*

Granting of Authorizations *(cont'd)*

- “Notwithstanding any conditions of an authorization, the holder shall ensure that the exposure is reduced to as low as is technically and practically possible.”

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”

SVHC Candidates, Early Indications?

- Annex I of 67/548 (dangerous substances Directive) [CMR = yes, PBT =no]
- ECB (4/14/02 Rev. 1) screening study of PBT/vPvB [IUCLID screen of 2682 substances]
 - 93 substances identified as potential PBT/vPvB
- US EPA PBT programme
 - 12 (groups) substances identified
- Japan programme for PBT

Restrictions

Substances on Annex XVII are subject to Restrictions

- If on Annex XVII, substance may not be manufactured, placed on the market or used unless specific conditions met
- Substances subject to Annex XVII inclusion
 - Substances posing an unacceptable risk to human health or the environment and
 - Not adequately controlled and
 - Risk needs to be addressed at Community level

Restrictions (cont'd)

Substances Identified for Restrictions

- CMRs Category 1 or 2 for which consumer uses are proposed
 - Listing process managed by Commission, not Agency
- Substances which the Commission considers meet the risk criteria

Session Two (July 18, 2007); Preview

- Evaluation
- Downstream Users
- SIEFs
- Consortia
- Preparing for REACH



REACH

ACC Small Business Council

Regulatory Requirements and Business Implications

Robert Matthews

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July 18, 2007

REACH Webinar – Session Two

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STAY AHEAD OF THE CURVE

Session One

- Scope
- Pre-Registration
 - Phase-In Substances
- Registration
 - OSOR
 - Only Representative
 - Intermediates, Monomers/Polymers, Substances/Articles
 - Dossier
- SVHCs

Session Two

- SIEFs
- Data Sharing/Consortia
- Downstream Users
- Evaluation
- European Chemicals Agency
- Preparing for REACH

REACH Structural Issues

- Precautionary Principle
- Burden on Industry to Prove Substance is Safe
- No Data/No Market
- Substitution Principle
- No Vertebrate Animal Testing

REACH Regulatory Issues

- Registration
 - Pre-Registration for Existing Substances
- Testing Requirements
- Data Sharing/Consortia
- Substance Evaluation
- SVHC Listing

REACH Market Issues

- Trade – Advantage EU Suppliers?
- Supply Chain Relationships
- SVHC Listing – “Blacklists”
 - Customer Deselection
 - Self Deselection
- Business Winners and Losers



Substance Information Exchange Fora (SIEFs)

Concept

- All pre-registrants of the same substance become members of a Substance Information Exchange Forum for that substance

Goals

- Facilitate Registration
- Facilitate exchange of information
- Avoid duplication of studies
- Identify and agree on needs for further studies
- Resolve differences on classification and labelling

SIEF - Functioning

- Manufacturers and importers are encouraged to communicate their intentions to downstream users
 - intentions not to register should be communicated sufficiently in advance for the downstream user to find alternative sources of supply
- No legal consequences are apparent if information is not communicated

SIEF – Functioning (*cont'd*)

- By January 09, Agency to publish list of pre-registered substances on its website (no company names)
- Around the same time, Agency is expected to inform all pre-registrants of the same substance of the identity of the other companies

SIEF – Functioning (*cont'd*)

- Upon publication of list of pre-registered substances on Agency's website, other parties may become members of SIEF
 - Companies manufacturing/importing below 1 tonne
 - Downstream users
 - Third parties holding information on substances

SIEF – Functioning (*cont'd*)

- Each SIEF is operational until June 2018
 - Would cover evaluation of substances registered in 2010 (above 1,000 tonnes and SVHCs) and 2013 (above 100 tonnes), including joint generation of data during evaluation phase
 - May cover “authorization” discussions (defense of “candidate” or “priority” substances)

SIEF Data Sharing Rules

- Formally, the first step will be taken by the first SIEF participant who needs to conduct a study for its registration dossier
- In practice, companies are expected to start discussions when all or most of pre-registrants are known
 - possibly even before formal pre-registration

The REACH data sharing process

Phase 1: pre-registration

- Each legal entity submits a pre-registration for each substance (EINECS) (between 1/06/08 and 30/11/08)
- The first submission triggers the creation of a corresponding (pre)SIEF
- Later pre-registrants are directed to the same page and the identity of all potential registrants becomes visible to each other
- Once all participants agree on substance identity, SIEF is actually formed and data sharing can start

The REACH data sharing process (cont'd)

Phase 2: Data holders join in the SIEF

- When the pre-registration phase is closed, ECHA will publish the list (01/01/2009)
- Data holders can then make submissions to ECHA
- Data holders can be:
 - DSU
 - Academics, Gov. Agencies, NGO, etc.
 - PPP, BPD (mandatory data holders)
 - Early registrants (mandatory data holders)

The REACH data sharing process (cont'd)

Phase 3: Exchange of data within SIEF

- Mandatory within a SIEF
 - Missing vertebrate animal data must be queried
 - Testing VA cannot be undertaken without querying first
 - Other data may be queried
 - Answering queries is always obligatory
- Exchange of data is optional between different SIEFs (read across)
- Cost sharing
 - either agree on non discriminatory, fair and equitable cost sharing, or
 - equal sharing

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The REACH data sharing process (cont'd)

Phase 4: Joint submission of data

1. Lead registrant submits first
 - Designation of a lead registrant
 - Data set to be submitted (individual route vs collective route)
2. Possibilities to “*opt-out*”
 - Disproportionately costly
 - Lead to CBI disclosure
 - Disagreement with the Lead Registrant on data selection
3. Joint CSR: optional

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Consortia

Consortia

- Will be formed under REACH
 - Many now forming
- To address REACH data requirements, *e.g.*:
 - Articles 10, 11 and 19: joint submission of data by multiple registrants
 - Articles 25 to 30: data sharing and avoidance of duplication of testing

Advantages of Forming REACH Consortia

Optimize pre-registration

- Identify properly the substance in order to be allocated the right SIEF
- Ensure that data sharing is optimized through coordinated pre-registration with other M/I
- Prepare cross reading options

Advantages of Forming REACH Consortia (cont'd)

Reduce registration costs

- Compensate for existing studies
- Share testing costs
- Save effort by sharing tasks
- Share administrative costs, benefit from reduced registration fees

Advantages of Forming REACH Consortia (cont'd)

Technical and scientific advantages

- Optimize the quality of the registration dossier, thus avoiding non-justified threat on the substance
- Avoid inconsistencies in data submitted to the agency
- Agree on classification and labeling (mandatory)
- Maximize cross reading potential
- Allow extending co-operation on CSR if feasible and found appropriate by partners
- Improved risk assessment with enlarged data base on the substance

Advantages of Forming REACH Consortia (cont'd)

More advantages

- Strong and clear industry position vis-à-vis the Agency
- Avoid being selected as priority because of opt out
- Gain time by sharing workload



Practical Aspects of Consortium Formation and Management

Define the form of cooperation

Consortia do not necessarily strictly mirror SIEFs

- They can be formed before pre-registration
- They can cover more than one substances and consequently more than one SIEF
- They may not include all potential registrants
- There can be more than one consortia within one single SIEF (differences in substance identity, different uses, e.g.)

Consortium Formation

Horizontal or Vertical?

- SIEFs – formed out of registration of single substance by multiple companies across multiple industries
 - Horizontal consortia to address testing requirements
- Within horizontal SIEF/consortia, possible need to address specific industry issue, e.g.
 - Vertical industry consortia to address Authorization issues
 - Exemption
 - Socioeconomic benefit vs. risk

Consortium formation

- **Contract between interested parties (operating rules)**
- **Contractual freedom but there are limitations**
 - EU competition law
 - Confidentiality must be ensured
 - REACH Regulation provisions
- **Consortium usually created as a “task force”**
 - No legal personality
 - Flexible, limited in time and scope

Consortium operating rules - main provisions

- **Scope and purpose**

- Substance identity/ purity/ groups of substances => decisive who can become a member
- Purpose => Registration? Evaluation? Authorization? CSR? Other purposes?

- **Membership**

- Categories of members and conditions of admittance
 - Regular members
 - Associate members
 - Late members
- Transfer/ Withdrawal/ Exclusion => consequences

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Consortium operating rules - main provisions (cont'd)

Consortium organization

- Structure, composition, procedures for appointing:
 - Steering committee - Technical committee
 - Lead registrant(s) (rights and obligations, liability)
 - Secretariat
 - Day to day management
 - Neutral third party – trustee / facilitator
 - Archiving, management of access to the consortium data, etc.
 - Other bodies, e.g., ad hoc groups, contracting labs
- Decision-making process - Voting rules
- Representation
- Duration
- Consortium dissolution and wind up, survival clauses

Consortia Issues

- **Existing Data**
- **New Data**
- **Data Sharing**
- **Late membership/data compensation**

Existing Data

- Selection of 'best study' among existing data
- Third party consultant may facilitate process
- Compensation formula
- Ownership clause and citation rights

New Data

- Identify data gaps – consultant
- Selection of laboratory (GLP, etc.)
- Study protocols – use scenarios
- Data waivers/read-across rationale
- Co-funding and joint ownership

Consortia Issues (cont'd)

Data Sharing

- Ownership
 - existing data is not jointly owned
 - new data is jointly owned
- Use of existing and new data
 - EU or worldwide?
 - for REACH or other regulatory purposes?
 - by associate businesses, customers, downstream users?
 - by affiliates?

Late membership/data compensation:

- entry fee (to cover set up and administrative costs)
- cost of the data ('actual' vs. 'current' cost)
- 'risk premium' to compensate founding members for higher risks in data development
- 'investment premium' to compensate founding members for lack of return on funds used for data development
- 'interest adjustment' on all payments

Current Consortia Considerations

- **Establish your company strategy for all substances in the portfolio**
 - Take the lead ?
 - Follower ?
 - Early register ?
 - etc.
- **Start preliminary discussion with competitors**
 - To study the feasibility of consortium and negotiate the basic principles and modalities of consortium agreement
 - Competition law and confidentiality concerns to be taken into consideration => consider signing a preliminary agreement and/or, preferably, use support of a neutral third party

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Current Consortia Considerations (cont'd)

- Consider using support from reputable service providers for consortia management
 - => this will include the setting up and managing of consortia
 - => technical and legal support
 - => “third party” facility to preserve confidentiality, archiving and management of application for registration and access to consortia data



Downstream Users (DSU)

Definition

- New concept
- Definition of “downstream user” and “use”: any person using a substance during his industrial or professional activities
- Includes EU manufacturers of preparations and EU manufacturers of articles
- Includes re-importers of substances
- Excludes distributors and consumers

DSU Obligations

General

- May make use known to supplier to make it an “identified” use (supplier must include it in registration and CSR)
- Perform chemical safety assessment only if use is not covered by the SDS supplied to him
- Communicate information through the supply chain (if substance/preparation is placed on the market)

DSU Obligations

Direct

- Identify, apply and where suitable recommend appropriate risk reduction measures identified in
 - Own CSA or
 - SDS supplied to him

DSU Obligations

Direct (cont'd)

- Prepare a CSR unless
 - No SDS is required or
 - His supplier need not complete a CSR or
 - He uses the substance within the conditions described in the exposure scenario communicated to him in the SDS or
 - He implements or recommends an exposure scenario that includes as a minimum the conditions described in the exposure scenario communicated to him

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DSU Obligations

Direct (cont'd)

- Keep CSR available and up to date
- Report information to the Agency if a SDS including an exposure scenario is communicated and his use is outside the exposure scenario (unless substance is used in yearly quantities of less than 1 tonne)
- Report if classification is different from supplier (unless substance is used in yearly quantities of less than 1 tonne)



Evaluation

Evaluation

Following Submission of Registration

- Dossier Evaluation
- Substance Evaluation

Dossier Evaluation

Examination of Testing Proposals

- By Agency
- Priorities:
 - Substances which have “or may have” the following properties
 - • PBT • Sensitising
 - • vPvB • CMR
 - Substances classified as dangerous under 67/548 above 100 tonnes “with uses resulting in widespread and diffuse exposure”

Dossier Evaluation *(cont'd)*

Examination of Testing Proposals *(cont'd)*

- Agency may
 - Approve testing proposal and establish deadline
 - Modify proposal
 - Add testing requirements
 - Reject proposal
- In case of several registrants, Agency designates one to take lead, if they cannot agree

Dossier Evaluation *(cont'd)*

Compliance Check

- By Agency
 - Determine adequacy of
 - Information in the registration technical dossier
 - Chemical Safety Assessment/Report
 - Explanation for opt out from OSOR
 - Agency can
 - Require additional information
 - Set deadlines

Dossier Evaluation *(cont'd)*

Follow Up

- Agency can “draft any appropriate decisions”
- Agency notifies Commission and Member States
- Agency can use the dossier evaluation information on a substance in prioritizing and establishing Community Rolling Action Plan

Dossier Evaluation *(cont'd)*

Follow Up *(cont'd)*

- Competent authorities can use the dossier evaluation information on a substance
 - To raise its priority for substance evaluation
 - To base its decision to prepare a dossier under Annex XV for a candidate list substance
 - To base its decision to prepare a dossier under Annex XV for a Restrictions list substance

Substance Evaluation

- Priority for substance evaluation to be determined by Agency
- Prioritization based on risk-based criteria
 - Hazard information, e.g., structural similarity to known substances of concern, or to substances which are persistent and may bio-accumulate, “suggesting” the substance may be P and B (but no mention of T)
 - Exposure information
 - Tonnage
 - Aggregation if multiple registrations

Substance Evaluation *(cont'd)*

Community Rolling Action Plan

- Compiled by Agency
- Based on risk-based criteria
- Covers 3 year period
- Specifies substances to be evaluated each year
- Submitted in draft to Member States
 - First draft by December 2011
 - Updates by February 28 each year
- Finalized by Member State Committee

Substance Evaluation *(cont'd)*

Performed by Member State Competent Authorities

- Member States volunteer to evaluate substances on Rolling Plan
- If two Member States volunteer for same substance
 - Member State Committee resolves, if unanimous
 - If not unanimous, Commission chooses Member State
- Member States can propose to add substance to Rolling Plan
 - Agency, with recommendation of Member State Committee, makes decision
- Member State can propose to require submission of additional information

Substance Evaluation *(cont'd)*

- **Timing**
 - To be completed within 12 months
- **Follow Up**
 - Member State can recommend use of its evaluation in Authorization, Restrictions and/or Harmonized Classification and Labelling decisions

Dossier and Substance Evaluation Decisions

- Agency notifies registrant of draft decision
- Registrant has 30 days to comment
- Agency forwards draft decision, with registrant comment, to Member States
- If no proposed amendment, Agency “shall take the decision”

Dossier and Substance Evaluation Decisions (cont'd)

- If Member State proposes amendment to the draft, issues goes to Member State Committee
 - Registrant given another 30 days to comment
- If Member State Committee unanimous, Agency adopts that decision
- If no unanimity, issue resolved by Commission

Registrant Right to Cease Manufacturing or Importing

- Registrant may notify Agency
 - Registered volume becomes zero
- Following receipt of draft evaluation decision, registrant can notify Agency
 - Registration no longer valid

Registrant Right to Cease Manufacturing or Importing (cont'd)

- No further information may then be required of the registrant **UNLESS**
 - Member State concludes, based on Annex XV dossier, that there is a potential long-term risk justifying need for more information, and/or
 - “Where the exposure to the substance . . . contributes significantly to that risk”



European Chemical Agency (ECHA)

- Responsible for managing the operation of REACH and coordinating scientific/technical resources
- Body of the Community
- Legal personality, legal capacity and legal standing in Court
- Seat in Helsinki (not Ispra)
- Not extended arm of European Chemical Bureau
- Independence, transparency

Tasks

- Provide scientific opinions
- Take certain decisions in the registration, evaluation and (possibly) authorization phase, data sharing and confidentiality
- Manage and update the C&L Inventory
- Coordination with other EU Scientific Committees

European Chemicals Agency (*cont'd*)

- Board of Appeal
- Limited jurisdiction
- Suspensory effect
- Decisions of Board of Appeal reviewable by European Court of Justice

Key Decisions Under REACH

By Agency; Appeal to New Board

- R&D Exemptions
- Registration/Completeness
- Data Sharing
- Dossier Evaluation
- Substance Evaluation (if Member State Committee acts unanimously)
- Authorization candidate listing (if Member State Committee acts unanimously)

Key Decisions Under REACH *(cont'd)*

By Commission; Appeal to Court of First Instance

- Use Authorization
- Substance Evaluation (if Member State Committee fails to act unanimously)

(Because these Decisions are company specific)

Key Decisions Under REACH *(cont'd)*

By Commission; Appeal Uncertain Because of Standing Issues

- Procedural rules for Registration/Notification of Articles
- Authorization candidate listing (if Member State Committee fails to act unanimously)
- Authorization Listing
 - Including granting (or denial) of generic use exemptions
- Restrictions Listing
- Classification & Labeling (67/548)



2007 - 2008

Preparing for REACH

2007 – 2008 Preparing for REACH

Individual Company Efforts

- Training
- Inventory
- Supply Chain/Customer Review
- Strategic Action Plan

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

First Step – Management Buy-In

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

Second Step – Conduct Inventory

- 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

Content of Inventory

- Substance identification
- Tonnage
- Whether produced, imported used, etc.
- REACH exemptions
- Classification

Content of Inventory *(cont'd)*

- Suppliers
- Customers/Applications and uses
- Contracts
- SVHCs (Authorization, Restrictions)
- Other important information (data requirements, etc.)

Third Step – Evaluate Inventory

- Take strategic decisions, including
 - Stop using/manufacturing/importing/supplying substance
 - Change, streamline suppliers and customers
 - Get to harmonized classification at industry level
 - Assemble data, create SIEFS and consortia
 - Identify your key substances
 - Take the lead?

SVHC Considerations

- From available data determine whether your substances are likely to be SVHC
- Relate potential SVHC to uses, exposures
- Prepare documentation on uses and risks, and if uncertain or currently likely to be unacceptable:
 - Implement improved RRMs
 - Acquire better data on exposure and hazard [basis for granting authorisation]
 - Ultimately, consider options for lower risk alternatives
- Look at RIP 4.3 on guidance for inclusion of substances in Annex XIV

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

2007 – 2008 Preparing for REACH

Potential Joint Industry Efforts

- Materials Declaration
- SVHCs/Product Defense
- RIPs/Guidance
- SIEFs/Consortia

Potential Joint Industry Efforts

Materials Declaration

- Options
 - Open-ended inventory/questionnaire
 - Targeted inventory/questionnaire
- Practical issues
- Legal consequences

Potential Joint Industry Efforts

(cont'd)

SVHCs/Product Defense

- Predicting the Candidate List
- Deselection?
 - Customer
 - Self
- Authorization
 - Exemption (generic)
 - Individual use authorization

Potential Joint Industry Efforts

(cont'd)

RIPs/Guidance

- Articles (3.8)
- CSR (uses and applications) (3.2)
- C & L under GHS (3.6)
- Identification and naming of substances (3.10)

Potential Joint Industry Efforts

(cont'd)

SIEFs/Consortia

- Substances (horizontal)
- Industry sector (vertical), e.g.:
 - SVHC/Product defense
 - Common/key substances
 - Authorization
 - Exemption
 - Use authorization (socioeconomic benefits; alternatives)

REACH Impacts in the U.S. – Some Damage Is Already Done

- Supply Chain Disruptions
- Testing of Substances
 - Costs
 - Results
- SVHC Listing – “Blacklists”
 - Customer Deselection
 - NGO Pressures