

REACH:

Summary of Status & Implementation Issues

Presented by:

June C. Bolstridge

GAIA Corporation

8630 Fenton Street, Suite 226

Silver Spring, MD 20910-3813 USA

301-608-9469 gaiaco@earthlink.net

REACH: Registration, Evaluation, Authorization & Restriction of Chemicals

□ **Summary of Status**

- Requirements
- Timeframes & deadlines
- Industry actions

□ **Implementation Issues & Resources**

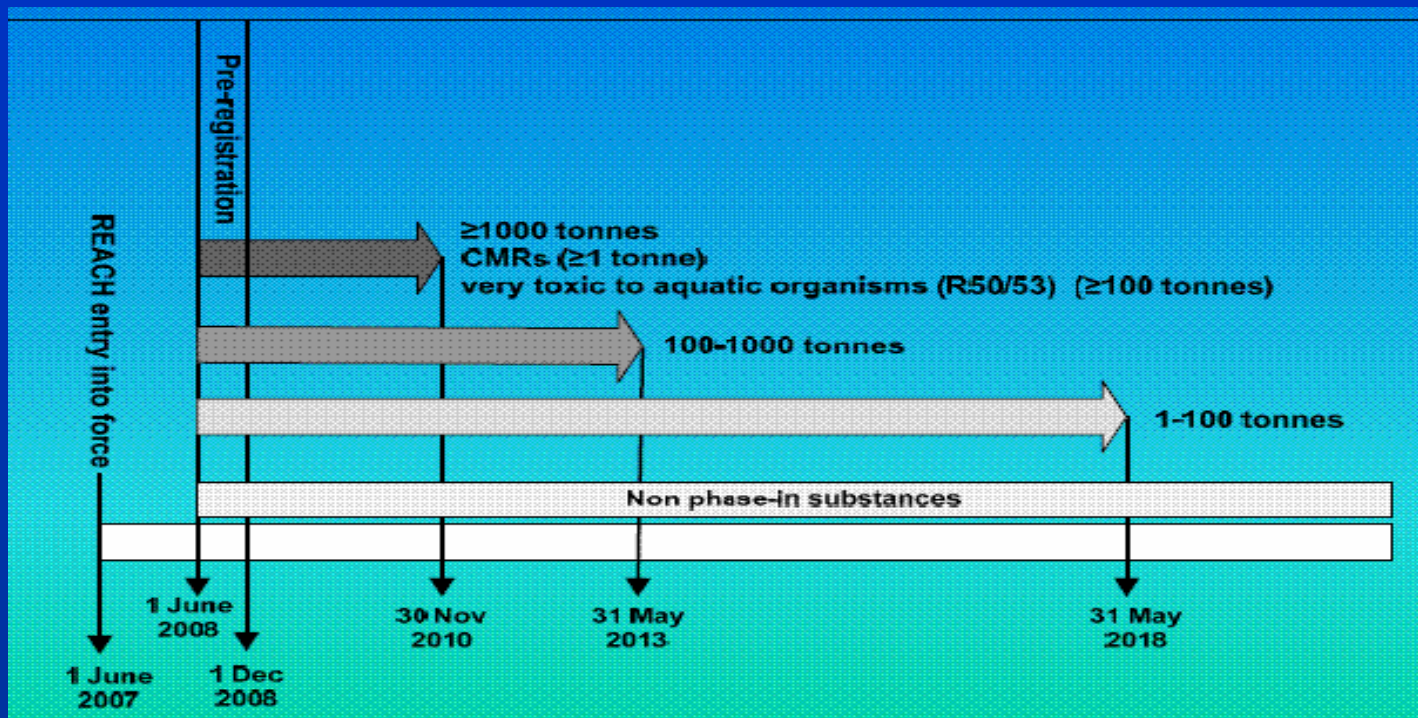
1. REACH regulated substances
2. Exempted substances
3. Articles
4. Supply chain
5. Communication (internal & external)
6. REACH-IT (data and information tools)

REACH: Registration, Evaluation, Authorization & Restriction of Chemicals

- **Registration - substances made or imported:**
 - 1,000 tons/year -- within 3 years (2010)
 - 100 tons/year -- within 6 years (2013)
 - 1 ton/year -- within 11 years (2018)
- **Evaluation of some substances**
 - Data validation & testing
- **Authorize substances of very high concern:**
 - Carcinogen, mutagen, reproductive toxic (CMR) 1 & 2
 - PBT & vPvB
 - Endocrine disrupters
- **Restrict manufacture or use to limit risk**

REACH Deadlines Cover 10 Years

- Pre-registration of phase-in substances (30 Nov. 2008)



Registration Deadline	June 2008 – Nov. 2010	Nov. 2010 – May 2013	June 2013 - 2018
Tonnes/year	1,000 or more	100 to 1,000	1 to 100

REACH Registration Formats: Dossiers & Chemical Safety Reports (CSRs)

- **Technical dossier** (1 tonne or more)
 - Properties, uses, classification, & safe use
 - Quantity determines if more testing required
- **Chemical safety report** (10 tonnes or more)
 - Hazard classification ■
 - Status as a PBT or vPvB chemical
 - Exposure scenarios -- own & downstream uses
-- include risk mgmt. measures & conditions
- **Less data required on isolated intermediates**
 - Hazard classification & risk mgmt. measures
 - Available information on properties

[Expecting 30,000 to 100,000 registrations]

REACH Requirements: Industry Actions for Compliance

- ❑ **Submit pre-registration for substances**
- ❑ **Revise safety data sheets on products**
- ❑ **Share and provide chemical data**
 - Participate in SIEFs
 - Provide information to downstream users
- ❑ **Submit information to Agency**
 - Registration of substances:
 - Technical dossier
 - Chemical safety report (>10 tonnes per year)
 - Exposure scenarios (PBT & vPvB)
 - Notify for articles if exposure to humans or environment occurs during use or disposal

Issue #1. REACH Regulated Substances

(One REACH registration per substance)

- **European Chemical Substance Info. System (ESIS)** Version 5.0 (July 2007) <http://ecb.jrc.it/esis/>
 - **Existing chemicals** (EU Inventory of Existing Commercial Substances (EINECS); before 1981)
 - **Notified substance** (EU List of Notified Chemical Substances (ELINCS); considered registered for REACH)

- **Identifying substance for REACH (RIP 3.8):**
 - **Well-defined composition** (include all grades)
 - 1 constituent > 80% = names substance
 - Multi-constituent: components at 10 to 80%
 - All additives; impurities >1% or affecting class
 - **Natural materials, articles, & preparations**
 - Cannot be registered (not chemically modified)
 - But substances contained require registration

Issue #2. Exempted Substances (EC to review within 12 months of REACH EIF)

- **Articles** with no human or env. exposure in use or disposal
- Covered by other legislation:
 - **Food or feeding stuffs**
 - **Medical products for humans & veterinary use**
 - **Radioactive materials**
 - **Materials under customs supervision** (not used)
- Not substances, preparations, or articles:
 - **Non-isolated intermediates**
 - **Wastes**
 - **Minerals; ore; ore concentrate; cement clinker**
- Present low risk:
 - **Water**
 - **Cellulose pulp**
 - **Polymers** [residual monomer >2% is not exempt]

Issue #3. Articles (RIP 3.8 Guidance Document)

- ❑ **Article:** object, whose specially produced shape, surface, or design is more important to end use functions than substances it contains
- ❑ **Register substances in articles when:**
 - Substance is intended to be released under normal or reasonably foreseeable use, and
 - Total substance in articles >1 ton/yr/producer
- ❑ **Notify for substance of very high concern if:**
 - Present in articles >0.1% by weight
 - Total substance in articles >1 ton/yr/producer
 - Unless exposure to humans & environment can be excluded during normal or reasonably foreseeable use conditions, including disposal

Issue #4. Identify the Supply Chain (for Each Substance)

□ Determine role in supply chain:

- Set by interactions with substance & EU boundary
- One company may have multiple roles
 - Only some roles must report or provide information
 - Downstream user may receive/create info.; request studies



Manufacturer

European Union

Issue #4. Identify the Supply Chain (for Each Substance)

□ Determine role in supply chain:

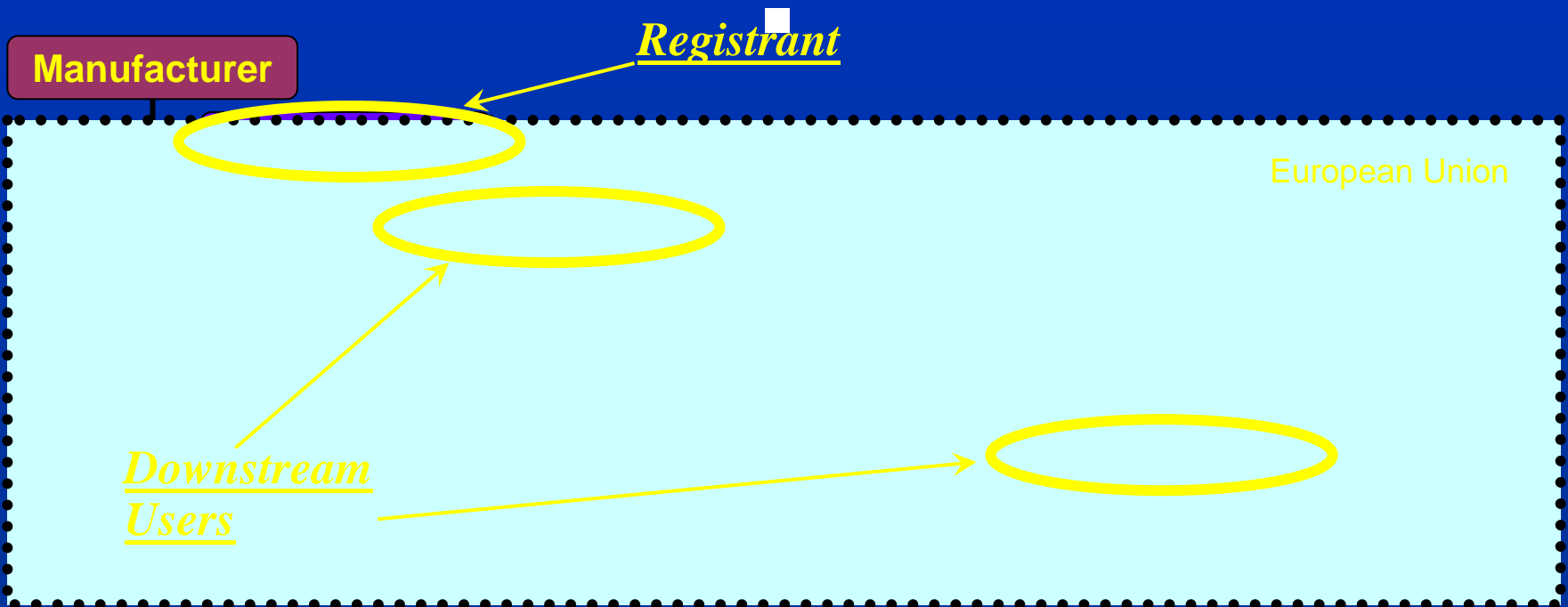
- Set by interactions with substance & EU boundary
- One company may have multiple roles
 - Only some roles must report or provide information
 - Downstream user may receive/create info.; request studies



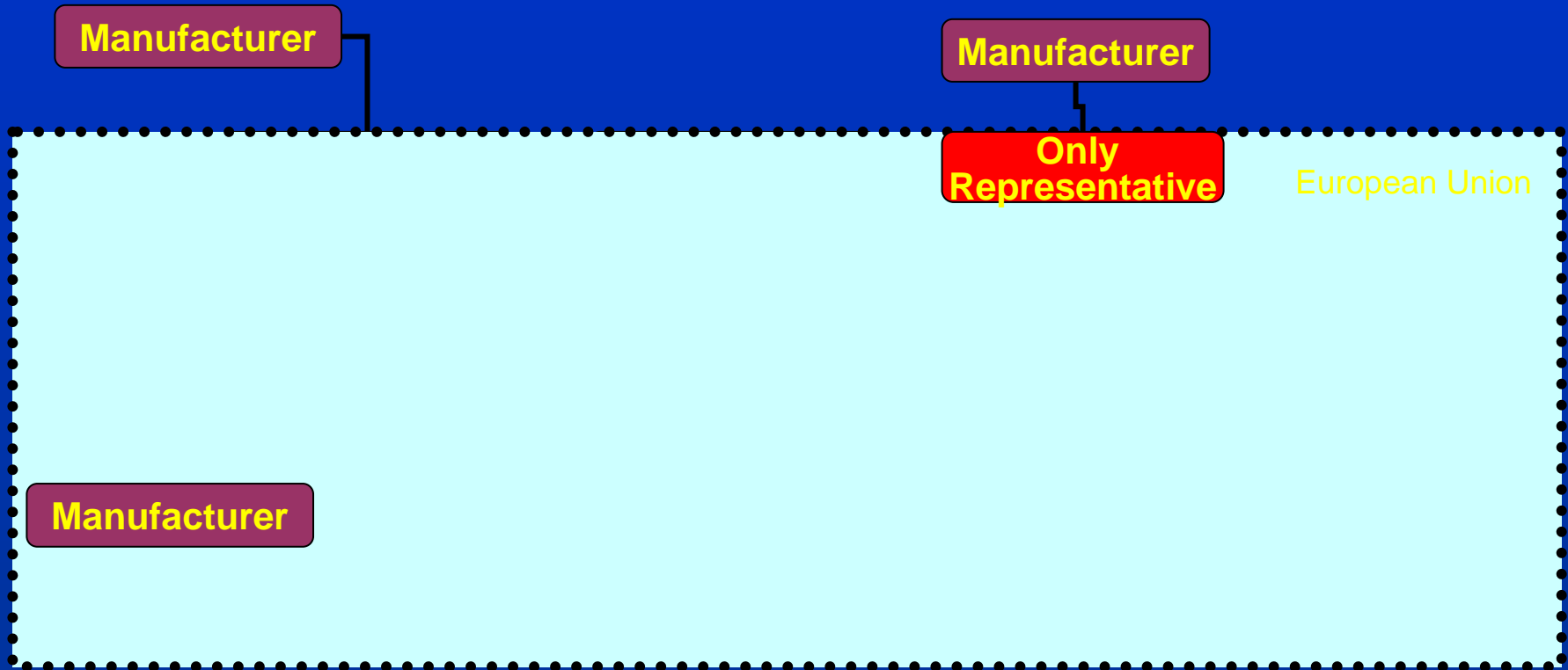
Issue #4. Identify the Supply Chain (for Each Substance)

□ Determine role in supply chain:

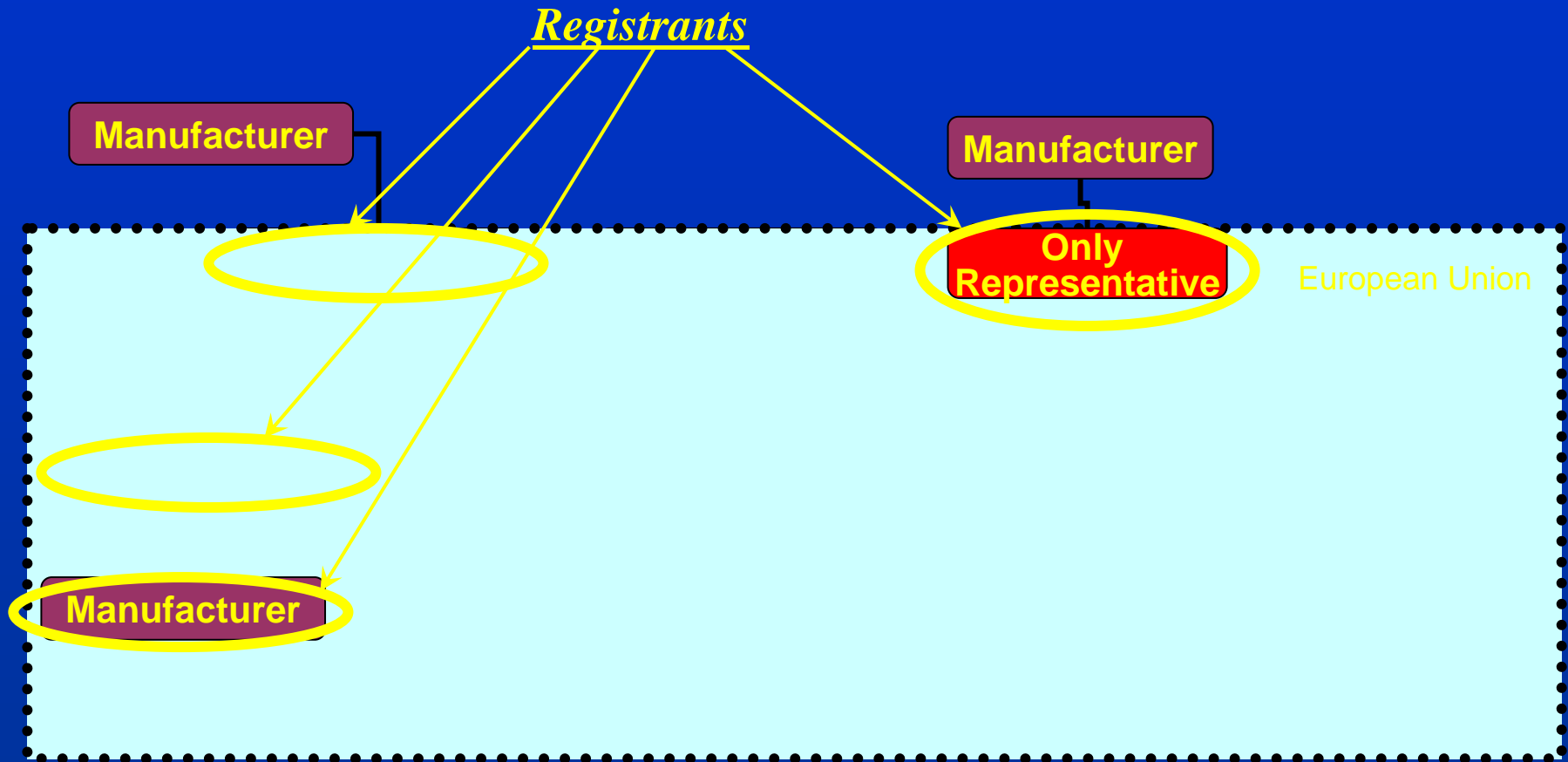
- Set by interactions with substance & EU boundary
- One company may have multiple roles
 - Only some roles must report or provide information
 - Downstream user may receive/create info.; request studies



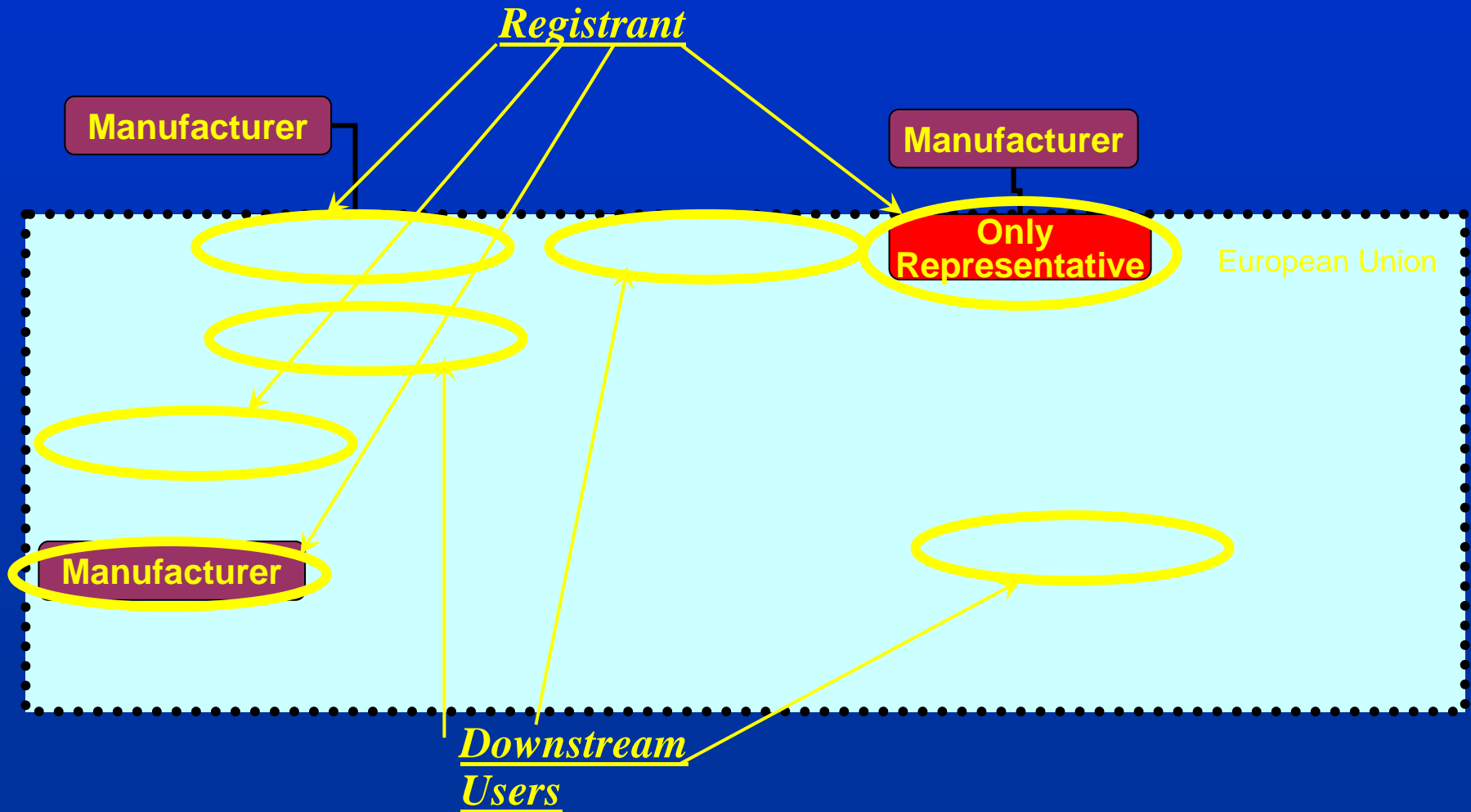
Issue #4. Identify the Supply Chain (for Each Substance)



Issue #4. Identify the Supply Chain (for Each Substance)



Issue #4. Identify the Supply Chain (for Each Substance)



Issue #5. Communication

(Internal & External)

□ **Within organization**

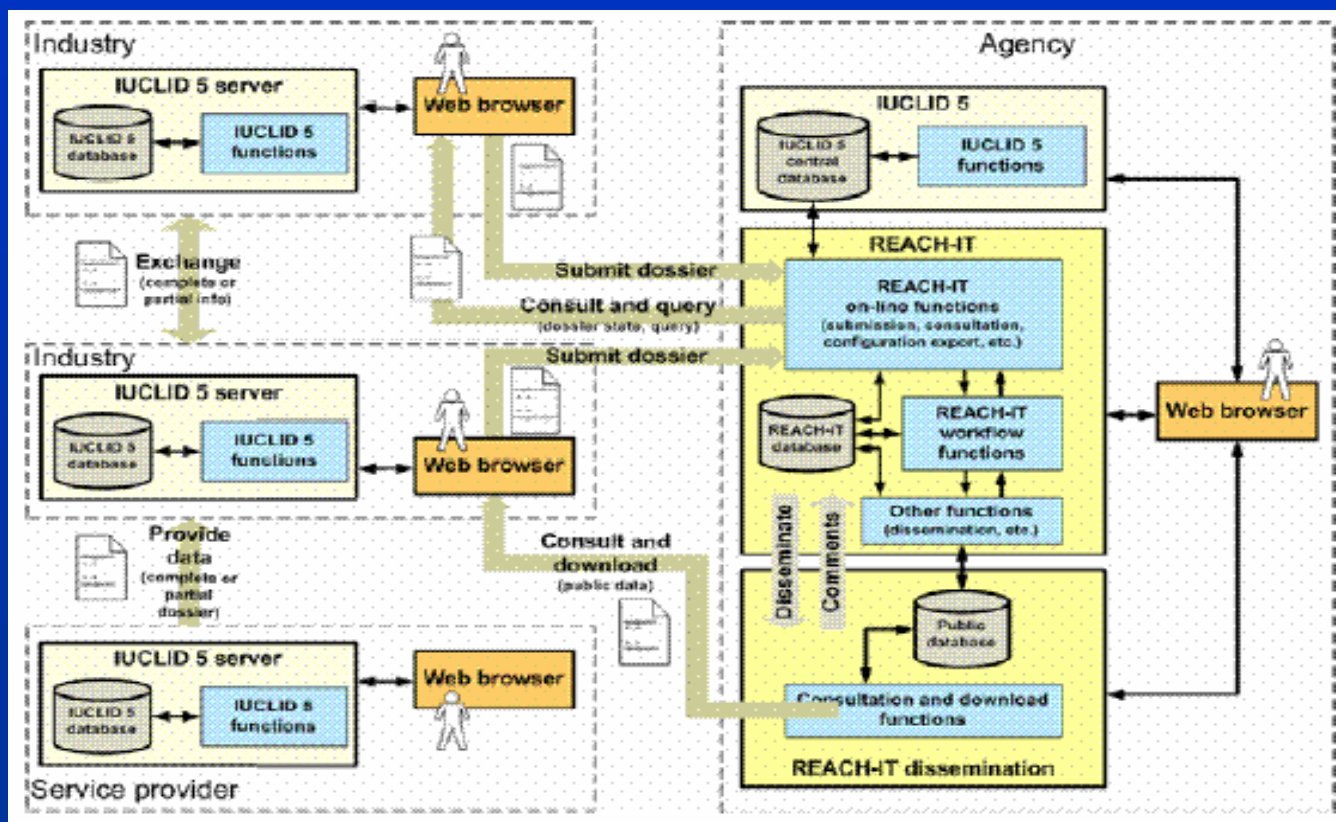
- **Management support & commitment**
- **REACH coordinator** – responsible for all activities
- **Information exchange between departments:**
 - Marketing; sales; purchasing; customer service
 - Health & safety; environmental; legal
 - Production; research & development
- **Confidential, proprietary, & owned data**

□ **External strategy, resources, & capabilities**

- **Substance Information Exchange Forum (SIEF)**
 - consistency and cooperation with other registrants
- **Translate to 22 EU languages & jargon of industry**

Issue #6. REACH-IT Data & Info. Tools (for Dossier & CSR Submittals)

- ❑ **IUCLID 5 (International Uniform Chemicals Information Database)** – formats for dossier & chemical safety reports (revised 12 June 2007) <http://ecb.jrc.it/iuclid5/>



http://ecb.jrc.it/DOCUMENTS/REACH-IT_AND_INFORMATICS/IUCLID5/BETATEST/PRESENTATIONS_BETATEST_21-23_06_06/21and22_03_betaTestVersion.pdf

Additional Resources for Meeting the REACH Requirements

- **REACH Implementation Projects (RIPs):**
 - RIP 1: “REACH in Brief” and Q&A (July 2007)
 - RIP 3: Industry guidance on REACH
 - Guidance for Identification and Naming Substances (June 2007)
 - Technical Guidance for Industry on Preparing Safety Data Sheets (July 2007)
 - Guidance on Pre-Registration and Data Sharing (draft July 2007)
 - Guidance for Downstream Users (Sept. 2007)
- **Inventory of Quantitative Structural Activity Relationship (QSAR) Models** – by European Chemicals Bureau to identify available models
http://ecb.jrc.it/QSAR/qsar_tools/qsar_tools_qrf.php