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September 18-20, 2011
Gaylord Opryland
Nashville, Tennessee

Executive Forum

Global Regulatory Requirements from a Product and Operating Perspective

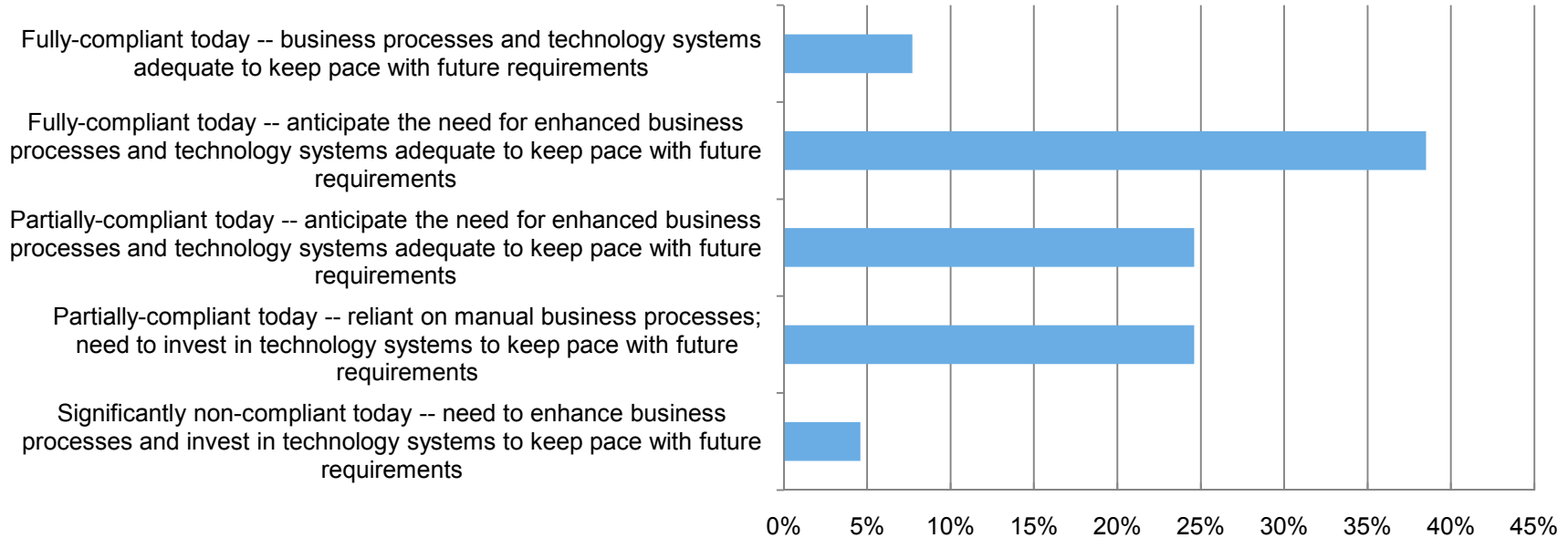
Chuck McCormick, Practice
Director
Global SAP Enterprise
Compliance & Sustainability

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First Look – 2011 Sustainability Survey

Industry Profile of Product Regulatory Preparedness

How would you rate the ability of your organization to achieve and maintain compliance with company-wide product stewardship requirements ?



Source: Preliminary results from 3rd Annual CSC/Chemical Week Survey



Panelists

- **Julia Tsvetkova** - Senior Product Management 3E
- **Frank Kochendoerfer** - SAP Chemical Industry Director
- **Tamie Webber**— Director, Product Management 3E

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The Global EH&S
Regulatory Landscape

Julia Tsvetkova
Senior Product Manager
3E Company

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Global EH&S Regulatory Landscape

- Increase in frequency and volume of regulatory changes
- Burden of assessing and complying with changes is increasing
- Fewer EH&S resources

Restricted Substances	Authorization/ Registration	Classification Labeling	Environment
<ul style="list-style-type: none">• RoHS• Phthalates• BPA	<ul style="list-style-type: none">• EU REACH• Japan CSCL (PAC)• Korea MOE	<ul style="list-style-type: none">• Classification• Labeling• Packaging	<ul style="list-style-type: none">• Carbon Reporting• Emissions• GHGs• Waste – ELV, WEEE

Restriction of Use of Certain Hazardous Substances in Electric and Electronic Equipment (RoHS)

- **EU Directive 2011/65/EU (RoHS Recast)**

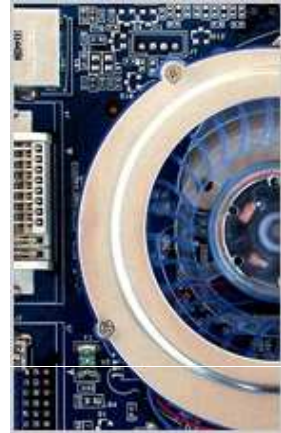
- Replaces original RoHS as of 2013
- Expands the original categories of EEE
- Exemptions and exclusions remain, with some new in place
- EU Declaration of Conformity
- Documentation retention (technical and declaration of conformity) for 10 years

- **Scope**

- Same list of substances and thresholds but the new directive opens room for expansion in line with REACH and regulations related to nanomaterials

- **RoHS in Asia and the Americas**

- Japan, Korea, India (January 1, 2012), Australia (Draft)
- US States (California, New Jersey)



EU REACH



- **Regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (1907/2006/EC)**

- First deadline was 30 November 2010:
 - Phase-in substances > 1,000 t/y
 - CMRs > 1 t/y
 - Substances very toxic to aquatic environment (R50/53) > 100 t/y
- Second deadline is 30 May 2013
 - Phase-in substances > 100 t/y
- Third deadline is 31 May 2018
 - Phase-in substances > = 1 t/y



EU REACH (cont'd)



- **Substances of Very High Concern (SVHCs)**
 - Authorization required for substances of very high concern (SVHC) (i.e., CMRs, PBTs, vPvBs) included in Annex XIV (Authorization List)
 - SVHCs identified in Candidate List – 53 SVHCs as of June 2011
 - Currently, 6 substances in Annex XIV
- **REACH notification obligation for manufacturers and importers of articles**
 - M/I must notify ECHA if any SVHC included in the Candidate List is present above 0.1% w/w and if over 1 ton per producer/importer per year
 - Deadline for notification June 1, 2011 (six-month deadline from Dec. 1, 2010 after substance identified as SVHC) if 1 ton reached
 - 76 page guidance on requirements for substances in articles

REACH-like regulations in Asia Pacific

- **Japan CSCL**

- Japan Chemical Substance Control Law (CSCL) – ‘Kashin-ho’ , effective April 1, 2011
 - Establishes mandatory reporting of all chemicals manufactured/imported over 1 ton in the previous year
 - Priority Assessment Chemical Substances (PACS) – currently 88 – specific notification requirements
 - Evaluation, Authorization/Restriction

- **Korea AREC Draft**

- Korea Act on Registration and Evaluation of Chemicals – ‘K-REACH’, Feb 2011 Draft
 - TCCL – handles already tested, proven hazardous chemicals
 - AREC – handles semi-tested, suspected hazardous chemicals
 - New chemicals notification under TCCL will be repealed and integrated into AREC
 - Establishes mandatory reporting on all chemicals manufactured/imported
 - No tonnage or other exemptions specified
 - Priority Evaluation Chemicals (PEC) – list of chemicals posing risk to human life and the environment – pre-registration period proposed

Global Harmonized System (GHS) on Classification and Labeling



GHS Regulation Passed

- **Asia Pacific**
 - New Zealand (2001)
 - Japan (2006)
 - Korea (2008)
 - Vietnam (2008)
 - China (2009)
 - Indonesia (2009)
- **Europe**
 - EU (2008)
 - Serbia (2009)
 - Russia (2009)
 - Switzerland (2009)
- **Americas**
 - Brazil (2009)
 - Uruguay (2009)
 - Mexico (2011)
- **Middle East/Africa**
 - South Africa (2008)
 - Abu Dhabi (2009)

GHS Draft Regulations

- **Asia Pacific**
 - Australia
 - Malaysia
 - Philippines
 - India
- **Americas**
 - US



GHS Preparation Activities

- **Americas**
 - Canada
 - Mercosur – Argentina, Paraguay
 - Andean Community – Bolivia, Columbia, Ecuador and Peru
- **Other**
 - Turkey
 - Thailand
 - UNITAR/ILO Global GHS Capacity Building Programme: Cambodia, Gambia, Laos, Nigeria, Senegal, Zambia

New and Emerging Regulations and Regulatory Trends

- Following Europe
 - REACH-like
 - RoHS/WEEE-like
 - Regulating nanomaterials
- More disclosure requirements on companies
- Green initiatives and eco-labeling programs
 - DfE
 - EU Ecolabel
- Taking non-governmental lists into consideration
 - EU SIN List



New and Emerging Regulations and Regulatory Trends

- Dodd-Frank Act – final rule was expected in April 2011
 - Section 1502 ‘Conflict Minerals Provision’
 - Applies to tungsten (wolframite), tantalum, tin (cassiterite), gold from the DRC and adjoining countries
 - Applies to products for which conflict minerals are necessary to their functionality or production
 - Establishes a new reporting requirement on publicly traded companies. A report to the SEC to include:
 - a description of the measures taken by the person to exercise due diligence on the source and chain of custody of such minerals, which measures shall include an independent private sector audit
 - a description of the products manufactured or contracted to be manufactured that are not DRC conflict free
- Impacted Industries
 - Electronics, Medical Devices, Aerospace, Automotive, Jewelry, Industrial Machinery

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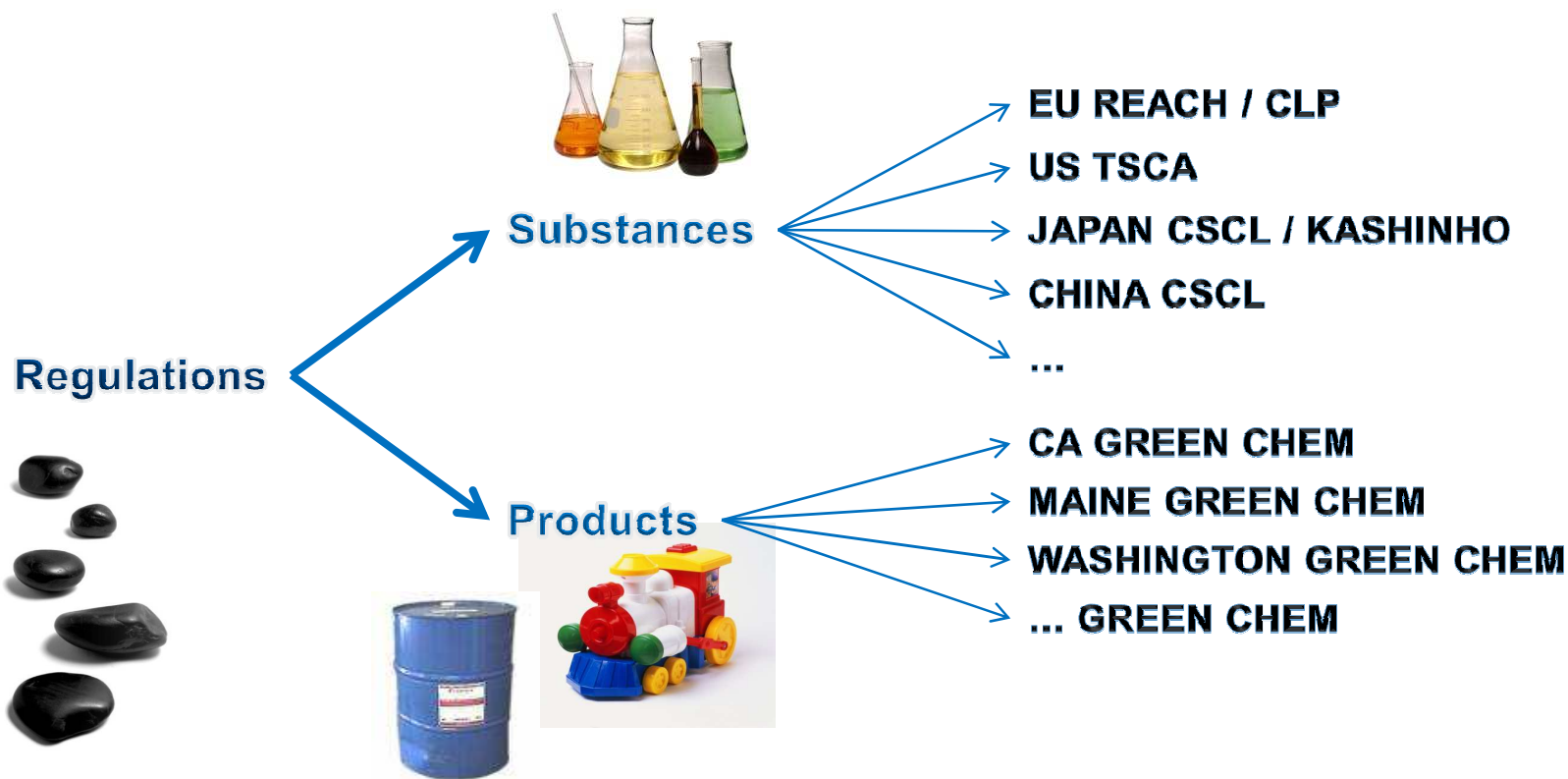
**Business Response to
Expanding Regulatory
Challenges**

Frank Kochendoerfer, Ph.D.
Director Industry Business
Unit Chemicals SAP

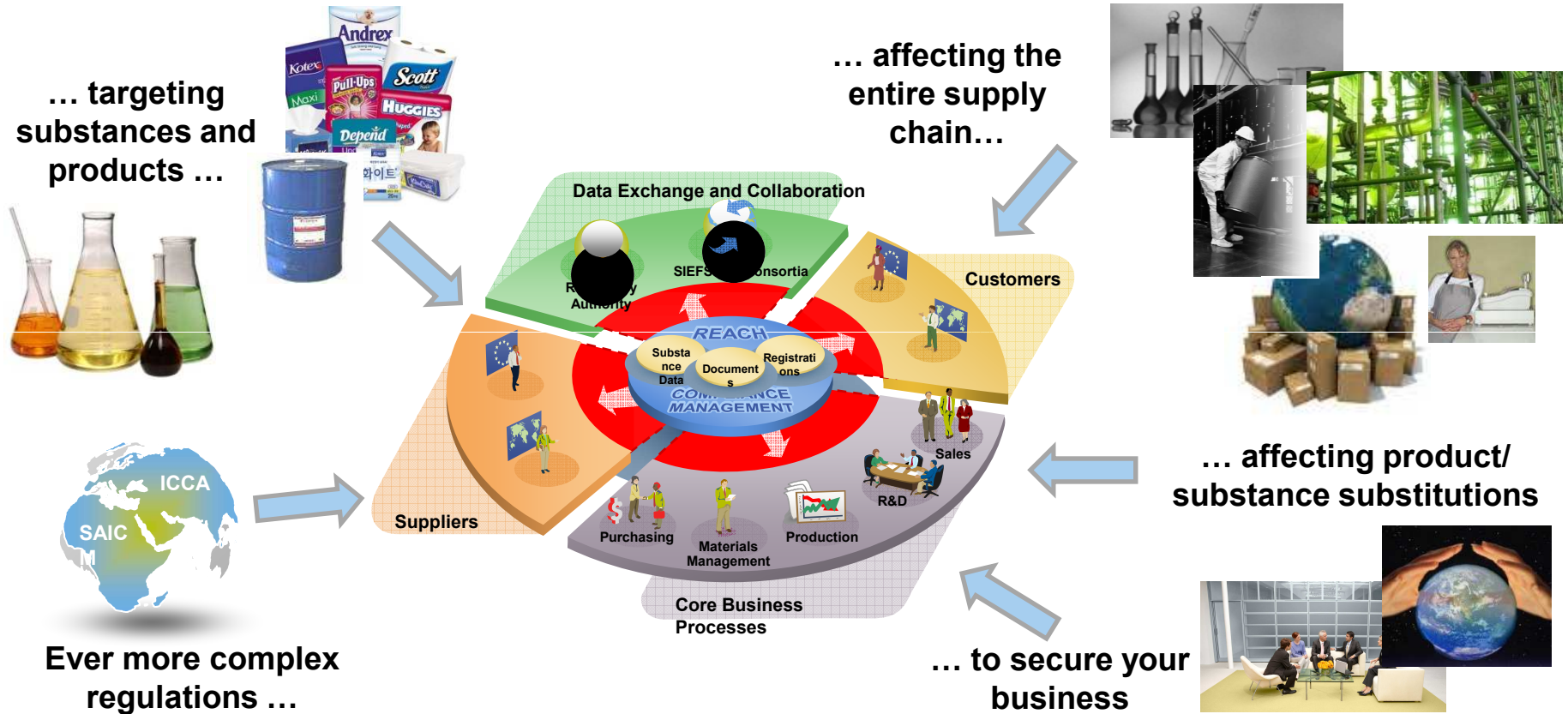
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New and Upcoming Regulations



Regulations will affect Businesses Everywhere



Commonality of Requirements – an Business Process Perspective

Past:

- **Provision of product and substance data**
- **Monitoring of compliance status – ‘need for action’?**

New:

- **Registration or notification based on risk assessment**
- **Uses and exposures have to be described and assessed**
- **Determination and tracking of substance volumes**
- **Upstream and downstream communication**
- **Monitoring of compliance status – ‘need for action’?**

Embedded Product Compliance

Legal Product Compliance Requirements



How do you **manage** relevant product compliance related **regulations** (Definition, Monitoring, Extraction of requirements, inclusion into product development, etc.) ?

Information / Data



How to **collect** data related to your **supply chain**?



How do deal with **missing data**

Product Development

Information / Data



How do you **integrate** product compliance aspects into the **business processes** (marketing, controlling, procurement, sales, logistic)?

Supplier

Controlling

Customer

Procurement

Manufacturing

Sales



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Challenges & Best Practices -
Supply Chain Collaboration &
Data Exchange

Tamie Webber

Director, Product Management
3E Company

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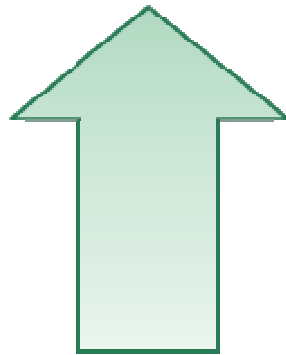
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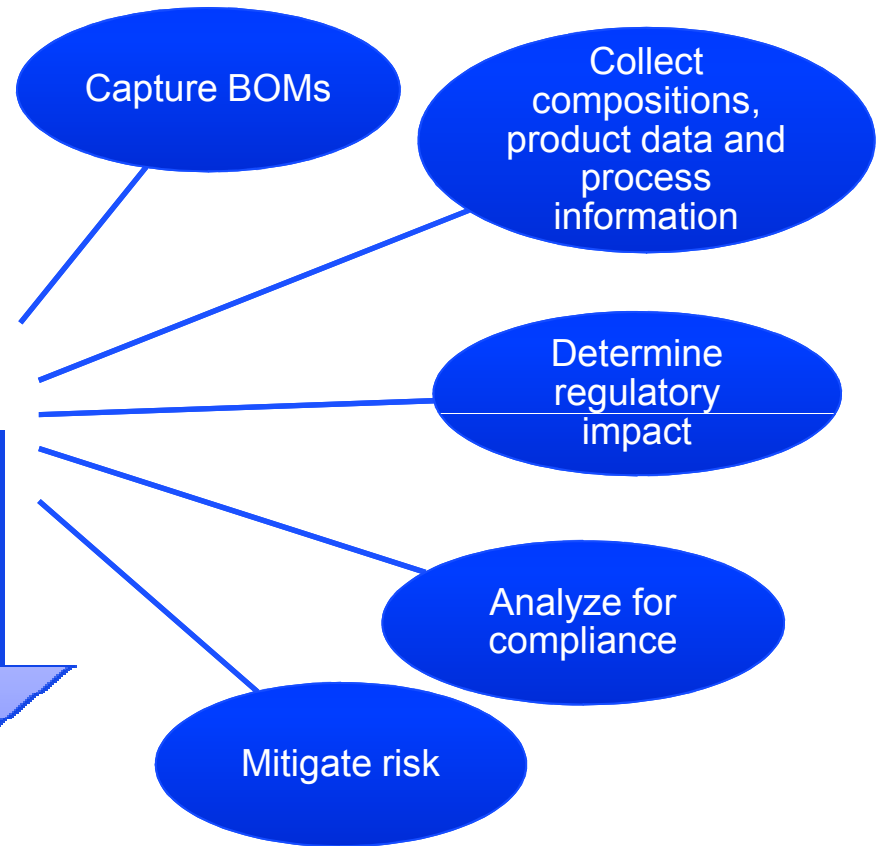
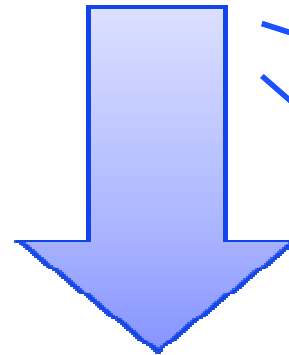


Supply Chain Collaboration & Data Exchange

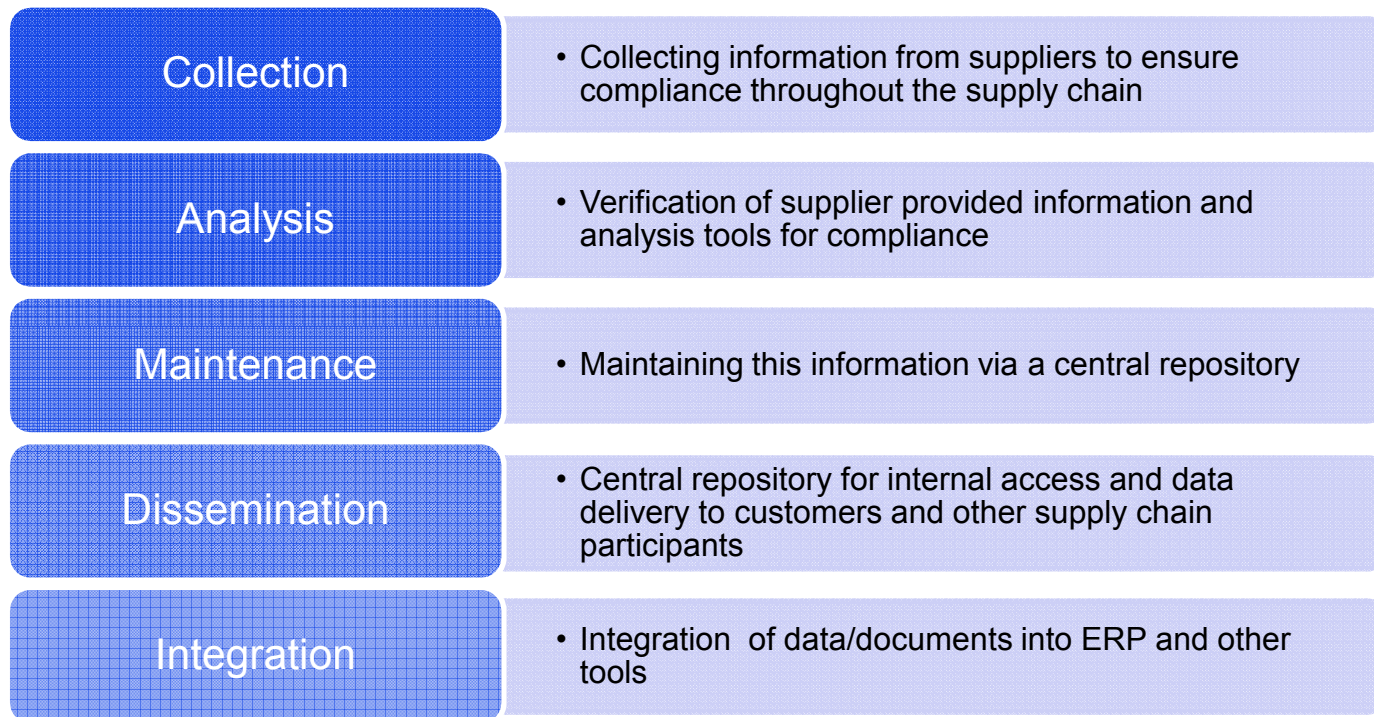
- Securing Raw Material Information
 - Content
 - Source



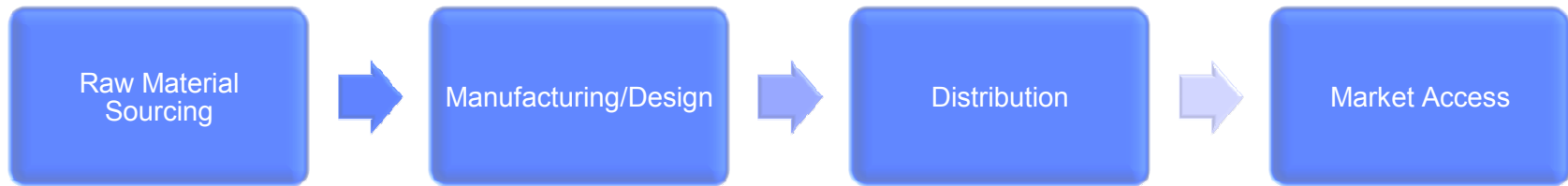
- Distributing Product Information
 - Distributors
 - Customers



Key Components to Supply Chain Data Flow



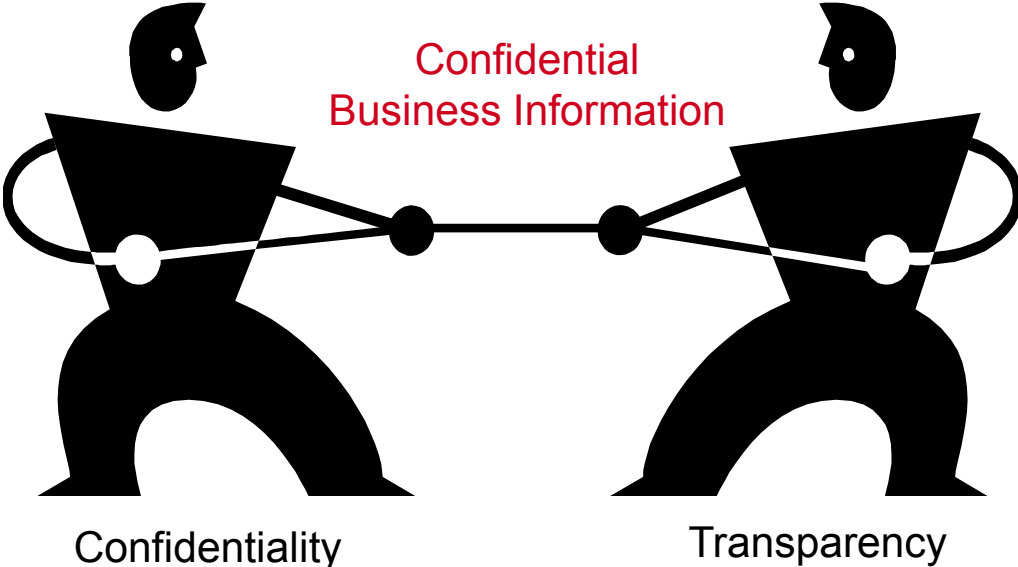
Supply Chain Collaboration



- Challenges

- Engaging all relevant supply chain participants is difficult
- Supplier participation key to fulfilling data requirements
- Critical data needed to satisfy all internal stakeholders must be validated
- Data maintenance is critical to support complex dynamic regulatory landscape
- Global regulatory knowledge
- Change Management : Ensuring suppliers are staying current with newly revised global regulations and proposed legislation

Supply Chain Collaboration



Emerging Trends

- Supply chain processes are adapting to new regulatory requirements
- New methods for protecting CBI - 3rd party validation
- In absence of standards (IPC, JIG, GADSL), industries looking for alternative methods for collecting data
- Required information beyond product and ingredients

Best Practices

- Work with all internal stakeholders to ensure streamlined approach
- Develop supply chain collaboration processes with participation goals in mind
- Data maintenance is critical to reducing supply chain risk



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Roundtable

- **Organized by topic area:**

- Julia Tsvetkova (discussion leader), Elliot Blatt (scribe)
- Frank Kochendoerfer (discussion leader), Scott Feldman (scribe)
- Tamie Webber (discussion leader), Jane Howell (scribe)

- **Instructions:**

- Join roundtable based on topics of interest associated with the panelist and generate ideas where industry collaboration would be beneficial (e.g., best practices, benchmarks, specific issues approach) and how (e.g., formal teams vs. peer to peer portal) for 30 minutes
- Each roundtable should select a spokesperson to speak about recommendations (10 minutes each)



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