Materials Management through the Product Value Chain
Evaluation, Compliance and Innovation

Environment, Energy and Sustainability Symposium and Exhibition (E2S2)
May 12, 2011

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SciVera, Inc.
1. SciVera Background
2. Chemical (and Material) Safety Assessment
3. Drivers in Companies and Supply Chain
4. Automated Chemical Safety Assessment
5. Q&A
Deep and Broad Industry Experience

- Developing chemical strategy
- Addressing product chemicals challenges
- Solving supply-chain information challenges
- Understanding organizational needs
## SciVera Leadership Team

### Joseph P. Rinkevich [Co-Founder & CEO]
15+ years management consulting in product development, supply chain improvement and environmental strategy.
- Project Teams include Raytheon, Wal-Mart, Nike, BASF, DuPont, General Motors, Dell, eBay, FAO Schwarz, PepsiCo
- Vice President, CommonWealth Biofuels LLC; Vice President, MBDC LLC
- Master Urban & Environmental Planning, University of Virginia; BSc. Business Administration, UNC Chapel Hill

### Thomas G. Osimitz, Ph.D., DABT [Co-Founder and Chief Scientific Officer]
25+ years in industry and consulting in a range of management and research functions.
- President, Science Strategies, LLC; VP Global Safety Assessment & Regulatory Affairs, SC Johnson & Son;
- Ph.D. Toxicology, University of Michigan; BS Biology, University of Minnesota; Board-certified Toxicologist

### Patricia J. Beattie, Ph.D., DABT [Vice President]
25+ years in industry and consulting in a range of management and research functions.
- Director, Chemical Risk Management and Environmental Services, General Motors
- Ph.D. Toxicology, University of Michigan; BS Chemistry, University of Arizona; Board-certified Toxicologist

### Wiebke Droege, Ph.D., [Director of Research]
15+ years of experience in applied toxicology, data analysis and chemical assessment
- Ph.D. Pharmacology, University of Tübingen, Germany BS Pharmacy, University of Münster, Germany
“Current Situation”

- Aerospace and defense (like most industries) typically rely on Restricted Substance Lists (RSLs) for chemical management guidance in materials.

- New requirements in regulations and the marketplace are rapidly changing the way companies will do this work.

- Aerospace and defense are particularly affected by these changes given the decades-long service of its products and the need to predict regulatory trends over that period.
“The purpose of the Chemical Safety Assessment (CSA) is to assess risks arising from the manufacture and/or use of a substance and to ensure that they are adequately controlled.

A CSA has to be performed by registrants for substances manufactured and imported in quantities starting at 10 tonnes per year and by downstream users if their uses are not addressed by their supplier.”

---European Chemicals Agency “REACH & CLP Guidance”
Drivers

NEED

Regulations
RoHS/WEEE/CEPA/REACH/ TSCA/States (CA)

Competition
Stewardship, efficiency, innovation, “green” products

Customers/Investors
Concerns about chemicals in products

Globalization
Distributed supplier networks
Complex ingredient info

Public/NGOs
Advocacy groups, community groups, Good Guide, etc.

Demand

• Regulatory pressures toward chemical hazard and risk assessment as part of product development

• Competitive response requires a unified framework for efficiency and clarity

• Customer demand for clearer hazard/risk information is driving product liability concerns

• Urgent need for robust chemical tracking while protecting suppliers’ proprietary information

• Advocates are driving public concern over chemicals in products

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Chemical Safety Assessment Best Practices

Chemical decisions during product development require information not normally available to manufacturers of complex products.

1. Identify
   - What chemicals?
     - BOM/BOS data
     - Supplier engagement
     - Where-used data

2. Characterize
   - What hazards?
     - Authoritative Lists
     - Research
     - Modeling
     - Expert Judgment

3. Assess
   - What “score”?
     - Restricted (RSLs, etc.)
     - GHS Categorization
     - Aggregate to material and product level

4. Manage
   - What action?
     - Establish priorities for action
     - Substitute
     - Eliminate
     - No action
Chemical Safety Assessment Need

The aerospace and defense industries have a growing need to make proactive decisions based on the chemical hazard and risk attributes of the chemicals and materials in products.

Business Process Requirements

- Secure and scalable engagement of suppliers
- Cost-effective access to disperse chemical information
- Efficient and defensible analysis of complex products
- Transparent implementation of assessment framework
- Actionable output for experts and non-experts
- Proprietary business information protection
Importance of Cross-functional Solution

Manufacturers and their suppliers across a range of functions all need better product chemical human and environmental health information.

- Safety
- Compliance
- Product Development/R&D
- Materials Engineering
- Procurement
- Public Affairs/Gov’t Relations/Legal
- Marketing

This diverse set of users requires a pragmatic solution that is useful across a range of expertise.
Need for Scaled Solution

Access to better chemical information requires visibility into large and complex supplier networks---by all participants.
The typical supplier network consists of thousands of companies supplying to the final manufacturer or brand.
Functionality Requirements

 ✓ Collect supplier data at scale
 ✓ Review materials for potential Substances of Concern (SOCs)
 ✓ ID specific SOCs from BOM/BOS data
 ✓ ID potential preferred alternatives
 ✓ Engage in secure, efficient dialogue on materials and SOCs with suppliers
 ✓ Access via simple subscription model
Importance of Disruptive Innovation

Dramatically reduce the cost and enhance the reliability of assessing chemicals for human and environmental health in complex products and diverse supplier networks—or it will not happen.
Importance of Secure Connectivity

Customers should securely access all features of a solution via their Web browser with option for selective data sharing with customers and suppliers.

ABC INC.
SCIVERA LENS
USERS

ABC INC.
SCIVERA LENS
SECURE SERVER
(HOSTED)

SUPPLIERS
SCIVERA LENS SECURE SERVERS/USERS
(HOSTED)
Efficient Chemical Dossier Development

Access to research, toxicology and data professionals can bring together data and expertise to create comprehensive dossiers on chemicals for assessment.

Hazard Assessment Filter

Authoritative Bodies (ECHA, IARC, NTP, ACGIH, etc.)

Scientific Literature (HSDB, GESTIS, TOXNET, inChem, OECD, etc.)

Predictive Models (EPI Suite, Oncologic, TOPKAT, PBTPro, etc.)

+ Expert Judgment

= Chemical Dossier

22 Toxicological Endpoints
Exposure Assessment Overview

REACH and other drivers will require companies to incorporate exposure scenarios for exposure estimation.

**EXAMPLE ENVIRO FACTORS**
- Compartment volume
- Air changes/hour
- Duration of exposure
- Part surface area
- Substance surface concentration

**EXAMPLE HUMAN FACTORS**
- Body weight
- Inhalation rate
- Skin surface area
- Dermal contact rate
- Hand-to-mouth rate

**EXAMPLE SUBSTANCE FACTORS**
- Hazard attributes
- Vapor pressure
- Skin penetration
- Saliva solubility
Companies then use these exposure scenarios to generate screening level risk assessment results for chemicals and materials.

1. **Automated Exposure Scenarios** can estimate human single dose and lifetime average daily exposure for various routes:
   - Inhalation Exposure
   - Dermal Exposure
   - Incidental Oral Exposure

2. **Companies can compare** aggregated exposure estimations with authoritative or calculated limits for various endpoints.
Importance of an Automated Solution

- Efficient and secure collection of supplier data
- Cost-effective hazard, exposure and risk assessment of chemicals
- Accurate and understandable output of results
- Backed by experienced scientific team
- Facilitates compliance with REACH CSA requirements
Example SciVera Lens Customer “Snapshot”:

Number of products in subscriber’s system: 3450
Number of unique substances: 572
Number of assessments processed: >421,000
Number of products w/SOCs found: 2070
Percent of unknown substances: 17%
Number of products with unacceptable risk: 340
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Benefits of Proactive Safety Assessment

✓ Get in front of regulatory trends via basic safety assessment processes
✓ Reduce business risk with extended life products and systems
✓ Engage supplier network to reduce evaluation burden and costs and enhance innovation
✓ Protect supplier confidential information during process
Thank you

FOR MORE INFORMATION PLEASE CONTACT

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