



Stewardship and Compliance Services

Chemical Product Regulations for non-European Countries

CentroReach, December 15, 2011

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Introduction – Wim Jetten

Cardno ENTRIX Senior Advisor – EU

- Business development in Europe
- Cardno Legal entities in Brussels and London
- Leverage global resources

30 Years of Chemical Industry Experience

- Director EH&S Dow Europe, Middle East & Africa
- Issues strategy and management
- REACh Program Director



Overview:

- Cardno ENTRIX
- Product Safety and Compliance Practice
- Scope and Services

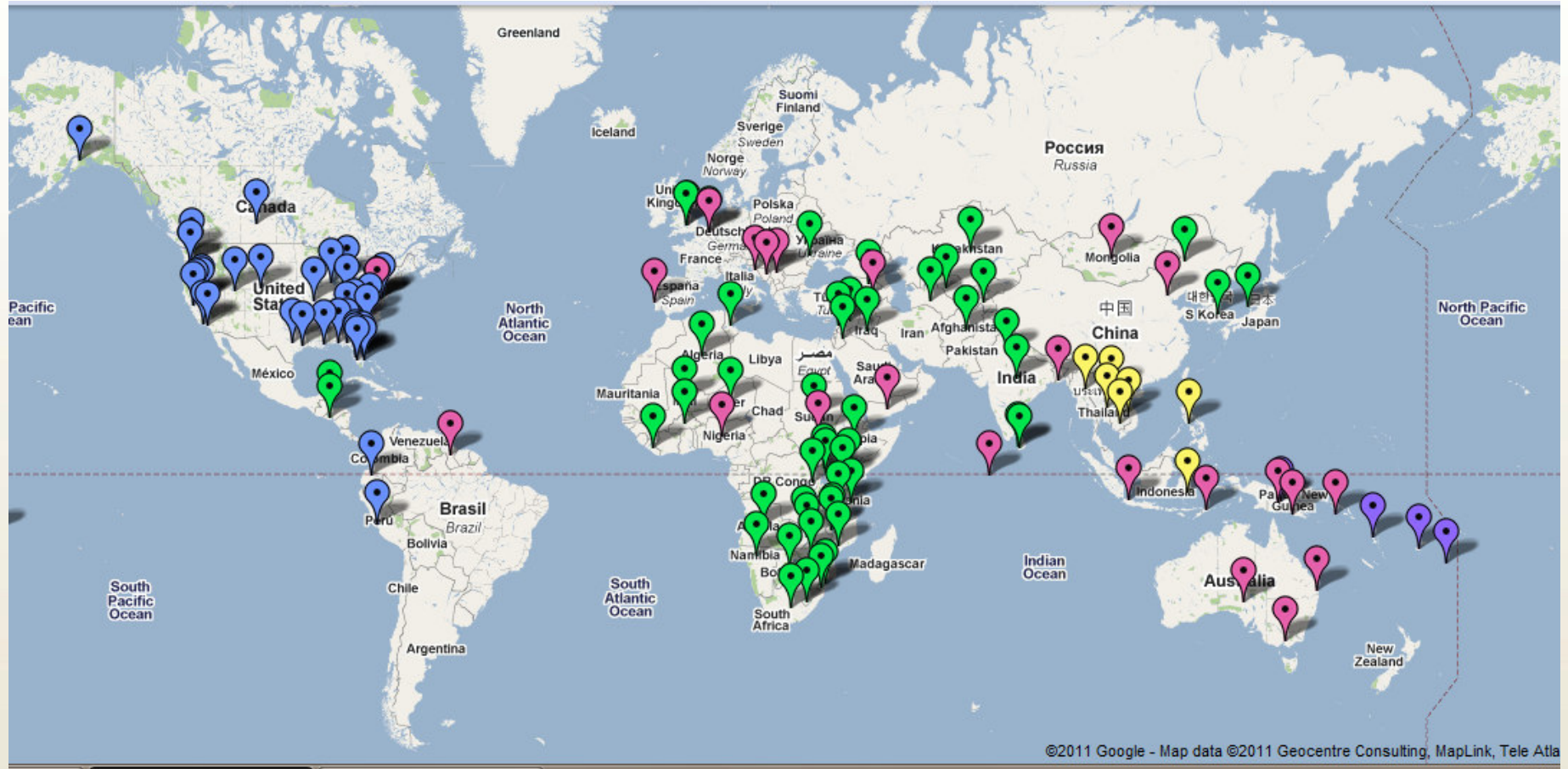


Cardno ENTRIX

- Globally Integrated Scientific Consulting Firm
- Focus on human health, environmental and regulatory compliance
- Cardno : ca. 4,000 employees, 125 offices, 70 countries
 - Cardno ENTRIX: ca. 400 employees

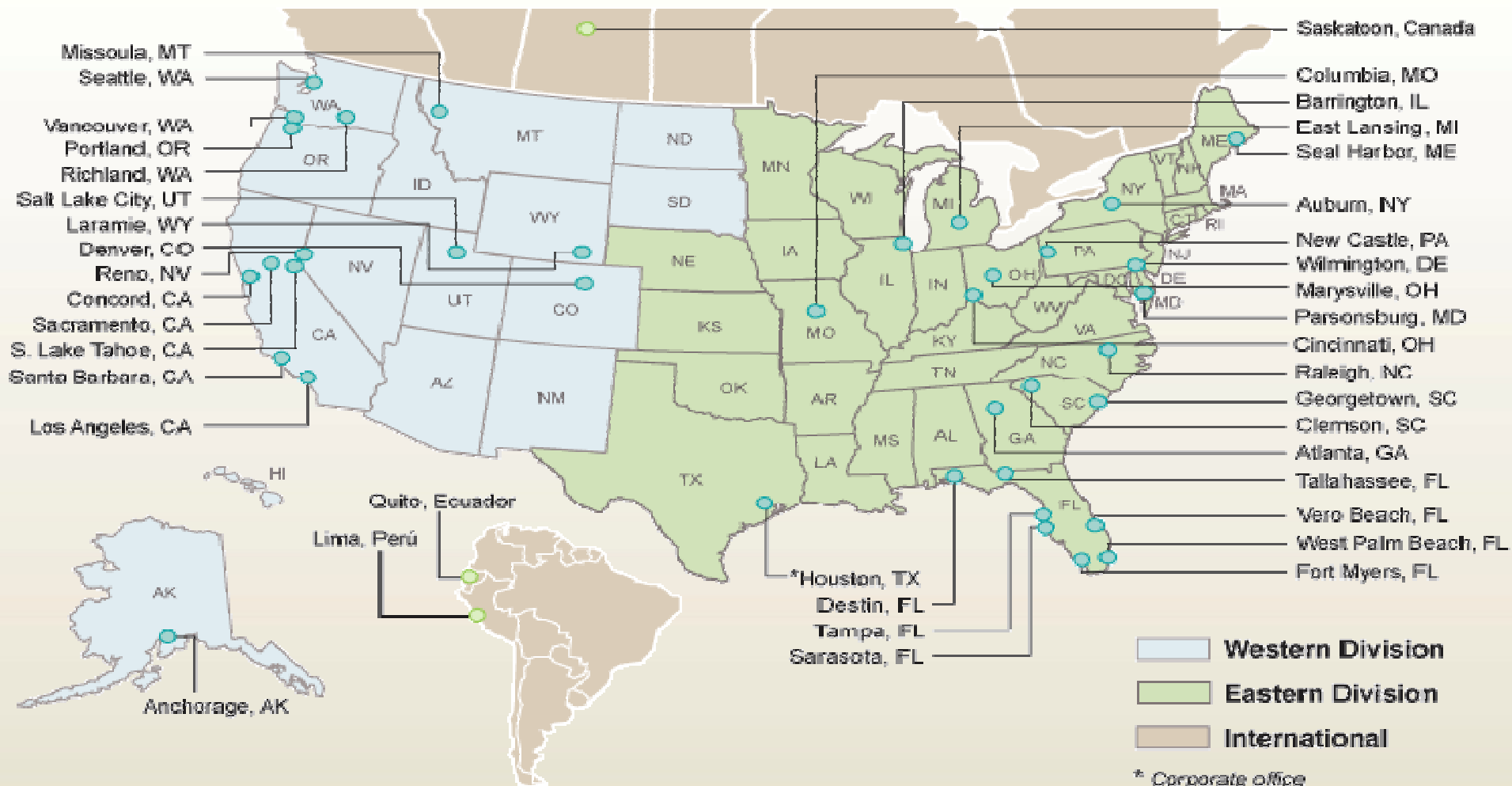


Cardno Global Locations





Cardno ENTRIX North & South American Locations





Cardno ENTRIX Product Safety & Compliance Services

- Product Stewardship
 - Toxicology and Risk Assessments
 - Occupational Health Program Management
 - Regulatory Support
 - Global Chemical Registrations & Inventories
 - TSCA
 - REACH
 - Globally Harmonized System
 - Green Chemistry Initiatives
 - Endocrine Disruptors
- North America
 - European Union
 - Rest of Europe
 - Latin America
 - Asia-Pacific
 - Middle East/Africa



How do we provide services?

- Leverage technical experts
 - Right level for the job
 - Mix of senior PhD scientists and junior staff
 - Maximum cost effectiveness
 - Highest level of scientific integrity
- Leverage databases
 - Corporate Solutions from the RightAnswer
 - Ariel WebInsight
- Leverage global offices
 - 150 offices in 70 countries
- Leverage global partnerships
 - e.g. partnership with CentroREACH



Product Stewardship & Regulatory Compliance Programs

Global Program Design

- Evaluate existing program(s)
 - International Council of Chemical Associations PS Guideline
 - Business Risk Review Process
 - Geographic Requirements
- Identify opportunities for improvement



Product Stewardship & Regulatory Compliance Programs

Global Program Design

- Provide recommendations for program design
 - Product Risk Categorization (Low, Medium, High Risk)
 - Risk Management Requirements for Each Category
 - Organizational Design and Resource Allocation
- Program Implementation Support
 - Information Gathering
 - Product Evaluations
 - Global Chemical Inventory Evaluations
 - Hazard Communication (Globally Harmonized System)
 - Product Stewardship Summaries



US Regulatory Compliance Services

- Toxic Substances Control Act (TSCA)
 - Program Design and Implementation
 - Pre-manufacturing Notifications (PMNs)
- Product Registrations Under:
 - Food and Drug Administration (FDA)
 - Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
 - Pesticidal Claims and Registration
 - Antimicrobial Testing and Registration
- Consumer Product Safety Act
 - Consumer Product Label Regulation Implementation



US Regulatory Support

Toxic Substances Control Act (TSCA)

- Pre-Manufacture Notifications (PMNs)
- PMN Strategy Development
- Test Market & Low Volume Exemptions
- Chemical Data Reporting Rule Submittals
- Chemical testing planning, placement and oversight
- Review and interpretation of chemical testing results
- TSCA Requirements Training
- TSCA Program Audits



US Regulatory Support

Occupational Safety Health Administration (OSHA)

- Assistance in establishing a hazard communication program
- OSHA Compliant (M)SDS and label authoring
- Training staff
- Industrial Hygiene program development and monitoring



US Regulatory Support

US Endocrine Screening and Testing Program

- Analyze the impact and business implications of the endocrine program and requirements on a company's business
- Assist clients in collecting and interpreting existing data on chemicals that could help firms in identifying testing needs and obtaining test waivers for specific tests
- Oversee the laboratory testing required and interpret the data
 - Conduct the cell-based H295R Steroidogenesis Assay
- Help develop and manage consortia that will be developed to meet the testing requirements



US Regulatory Support

Federal Government Agency Advocacy

- Public Policy Advocacy
- Product Advocacy

California Green Chemistry Program

- Program design
- Alternatives Assessment



US Litigation Support

- Evaluation of underlying assumptions
- Technical and strategic assistance with discovery
- Evaluation of opposing experts' reports or testimony
- Technical and strategic assistance with negotiating/settlement
- Assistance with deposition/trial strategy
- Support for presentation of evidence
- Expert testimony in trial or deposition
- Provide affidavits



China

- Compliance and obtaining certifications
- Notifications (e.g., new chemical substances, polymers, cosmetics, etc.)
- Import and Export of Toxic Chemical Substances
- Dangerous Chemical Substances (DC 591)
- GHS classifications and labeling
- Up-to-Date with unpublished interpretations and precedents
- Local support to facilitate interactions with regulators



Japan

- Annual reporting on Priority and General Chemical Substances
 - \approx 20,600 General Chemical Substances plus 6,000 Registered Chemical Substances
 - 88 Priority Assessment Chemical Substances in 2011
 - >100 More Expected in 2012
 - Forms completed in Japanese
- Representation to Japanese Government:
 - Identify exemptions (e.g., consumer products sold to consumers)