How to Track New and Updated Regulations

September2018

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engage your senses

Discussion Points

1. Flat World

2. Cost of Regulations

3. Global Regulations

4. Data Hide and Seek

5. Size Matters

6. Crystal Ball

Thomas L. Friedman wrote "The World is Flat" (2005)

Convergence of technology and events that:

- Allowed India and China and others countries to become part of the global supply chain for services and manufacturing

- Flattening of the globe requires us to run faster to stay in place

- Has the world become too small and too fast for humans to keep up?

Our jobs require us to:

- Understand current and emerging regulations (and how they interrelate)

- Sift through massive amounts of data understanding that quality and quantity are not the same thing

- Process information and data at light speed

- Be a generalist and a specialist when required
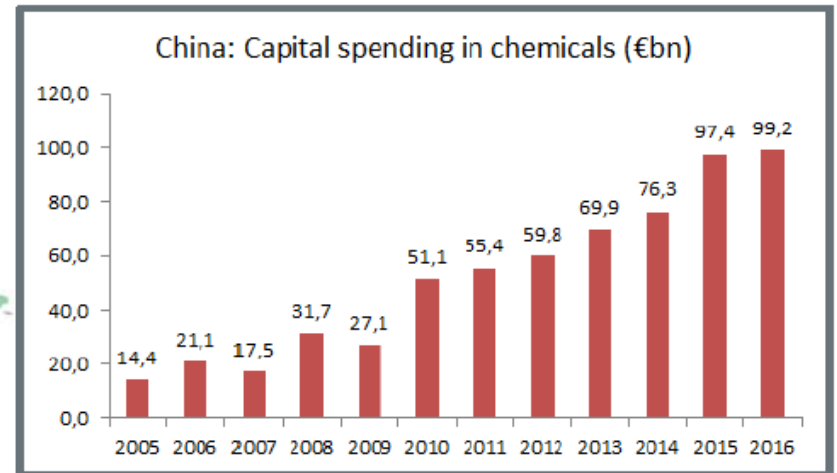
And don't forget Work/Life Balance!!!!!!

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Global Changes and Risks -
When the butterfly flaps its wings...

European Union
Low inflation and increasing incomes
New goverment in Italy
Strong Euro
Brexit-related uncertainty

Russia
Stabilization of oil price
Continuation of old and
newly imposed sanctions

USA
Political uncertainty
Protectionism
Tax reform
Increasing inflation and interest rates
Increasing public debt

China
Consolidation course of central government
Stronger regulation of financial sector
Less growth stimuli from the government
High debt of corporates
Real estate price bubble
Trade conflict with US

Middle East
Escalation of Syria conflict
Snapback of Iran sanctions

South America
Stable/increasing commodity prices
Dependency on China
Decreasing inflation
Elections in Brazil

Source: Cefic EOTF Meeting, (Milano, June 2018)

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China dominates world chemicals investment

Capital spending by region

- Rest of Europe*: 4.3 / 5.9
- EU: 18.6 / 21.7
- China: 21.1 / 99.2
- NAFTA**: 11.6 / 25.9
- Latin America: 2.7 / 5.3
- India: 2.0 / 5.0
- Japan: 6.4 / 6.6
- South Korea: 3.6 / 6.7
- Rest of Asia***: 11.9 / 34.4
- Rest of the world: 1.6 / 2.2

2006 chemicals capital spending (€ billion)
2016 chemicals capital spending (€ billion)

China: Capital spending in chemicals (€bn)

Year	Spending
2005	14,4
2006	21,1
2007	17,5
2008	31,7
2009	27,1
2010	51,1
2011	55,4
2012	59,8
2013	69,9
2014	76,3
2015	97,4
2016	99,2

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How Quickly Are Chemical Regulations Growing?
And what does it mean for companies
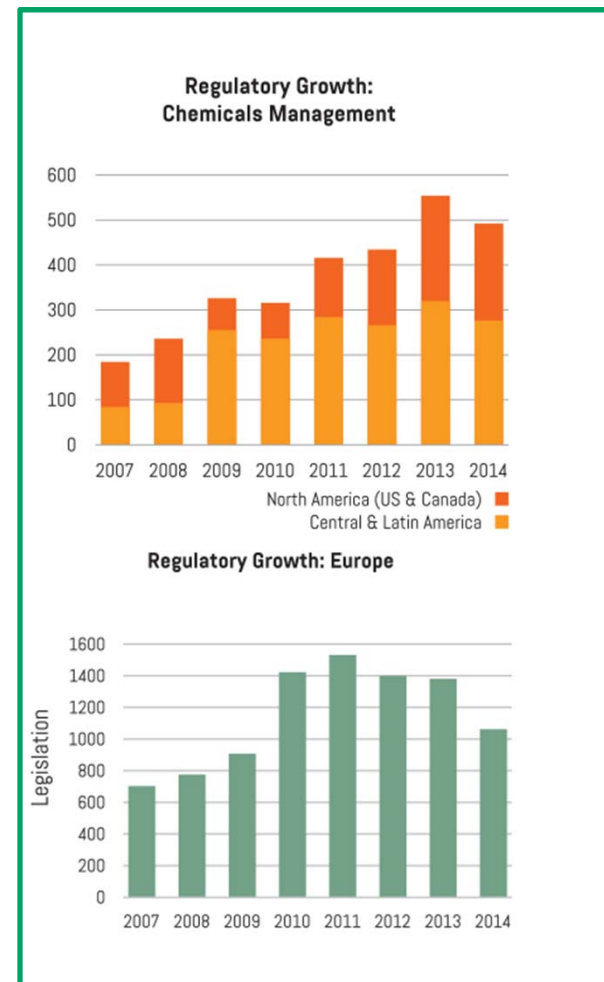

Impact of regulatory cost* on the chemicals sector
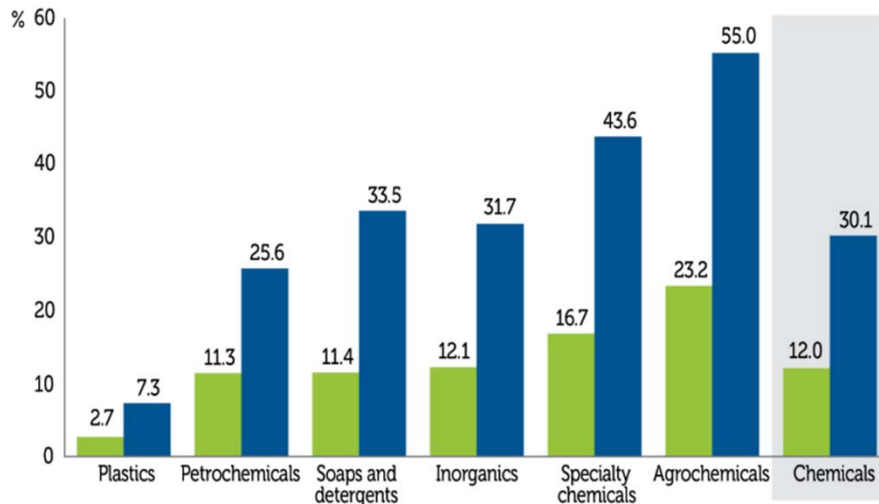
Regulation cost (% of Added Value)
Regulation cost (% of Gross Operating Surplus)

Source: EU Commission Report, "Cumulative Cost Assessment, (CCA) for the EU Chemical Industry" (11 July 2016)
* Average cost per year (2004-2014)

Unless specified, chemical industry excludes pharmaceuticals
Unless specified, EU refers to EU 28

Courtesy of CEFIC EU28 report

Regulatory Growth: Chemicals Management

North America (US & Canada)
Central & Latin America

Regulatory Growth: Europe

Courtesy ENHESA'S 2015 GLOBAL EHS REGULATORY FORECAST

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Global Regulations -
Environmental Regulations

- Clean Air and Water

- Release of Hazardous Chemicals to the environment

- Hazardous Waste

- Community Right to Know

- Chemical Toxic Substance inventories (e.g., TSCA - TSCA Reform)

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Global Regulations

Food & Cosmetics

- Food contact direct addition/indirect contact (e.g., FDA)

- Cosmetic (FD&CA)

- European Food Safety (EFSA)

International Trade Restrictions

- Drug precursors, Chemical Weapon Control (CWC) and Narcotics – National Country Regulations

- Denied Persons List

- Embargoes

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Global Regulations -
Worker / Consumer Safety

- **Consumer Product Regulations**
  - Consumer Product Safety Act and CPSC
  - Canada Consumer Product Safety Act (S.C. 2010, c. 21)
  - General Product Safety Directive (GPSD) 2001/95/EC

- **Biocide Regulations**
  - EU Biocidal Products Regulation (528/2012) (EU BPR)
  - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - EPA State Regulations

- **RTK**
  - State legislations ((e.g., NJ, NY, MA, PA,)
  - PROP 65

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Global Regulations -
Worker / Consumer Safety

- **California Senate Bill 258**
  - Cleaning Products Right to Know Act of 2017 (disclosure required Jan 1, 2020)

- **REACh** (Registration, Evaluation, Authorisation and Restriction of Chemicals)

- **Hazard communication regulations**

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Where Does the Data Come From?

- Vendors (Safety Data Sheets)/questionnaires

- Industry associations (e.g., International Organisation of the Flavour Industry (IOFI), American Petroleum Institute (API), Synthetic Organic Chemical Manufacturers Association (SOCMA))

- Subscription data (e.g., LOLI (List of Lists), ARIEL (3E), SERC (SAP))

- Product test data - in vivo, in vitro

- LISTSERV alert services (Federal Register, EPA, FDA, Individual States)

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Databases

National databases

- European Chemical Agency (ECHA) (https://echa.europa.eu/information-on-chemicals/cl-inventory-database)

- PubChem (https://pubchem.ncbi.nlm.nih.gov)

- OECD e-Chem Portal (https://www.echemportal.org/echemportal/index.action)

- NIH TOXNET (https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm)

Additional Resources

- TOXNOT (tox, Declare Labels) (https://toxnot.com/Home)

- Healthy Building Network (www.pharosnetwork.net)

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Complexity of data and regulations

Regulations can be specific to:
- Substances
- Materials
- Consumer Products or Formulated Products

Test data can be relevant to:
- Pure Substance
- Raw material
- Finished product

Data to be managed increases exponentially you apply:
- Increasing number of regulations
- Multiple level of material data
- Multiple countries and languages

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How Much Data is TOO Much?

Global companies doing business in multiple countries can manage over:

- 6000 pure substances

- 30,000 raw materials

- 600,000 finished goods

Approximately 7 terabytes of data

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SDS Sheet Authoring
How to manage data and create compliant SDS sheets?

One size does not "fit all"!

- Manual input, evaluation and SDS generation

- Outsourced "pay to play" service

- Automated Enterprise Resource Planning (ERP) System

- When choosing a solution consider:
  - The number of products/raw materials/substances in the company portfolio
  - Geographic reach of the company
  - Available budget
  - Available resources to implement and maintain your chosen system

simple and inexpensive

expensive and
very resource intensive

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Small to Medium Enterprises

- Excel spreadsheets – not a viable option

- EHS Enterprise Software Solutions
  - WERCS (https://www.ulghs.com/)
  - 3E (https://www.verisk3e.com/products-services/sds-authoring-distribution/sds-authoring-software)
  - IMAGEWAVE (https://www.imagewave.com/sds-authoring-software)
  - GSM Global Safety Management (https://www.gsmsds.com/)
  - HAZOX (http://www.hazoxinc.com)

- What to look for:
  - Multiple country GHS
  - Multiple languages
  - Ability to link to your manufacturing software
  - Offer data download from data content provider
  - Change management - traceability

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Medium to Large Enterprises

Enterprise resource planning (ERP)

- Business process management software

- Allows an organization to:
  - Use a system of integrated applications
  - Manage the business
  - Automate functions related to technology, services and human resources

- Based on chemical industry best practices

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Buy an ERP
(… and the computer will do everything… NOT)

- Expensive, but worth the effort

- Resource intensive
  - Your business and IT experts will need to work closely with their IT experts – it is a marriage
  - They know their software and industry best practices
  - Your product safety, EHS and regulatory experts know your current data structure

- You will get out what you put into it

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Benefits of an ERP

- There is a rule for everything

- Data is black and white

- Exceptions (manual overrides) are annotated and identified by user

- Traceability of changes

- Versioning of SDS maintains history

- SDS variants can be based on specific country legislation

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Challenges Implementing an ERP

Land mines to avoid

- Under-resourcing the project
  - Recruit best and brightest not who they can do without
  - Consultants are expensive

- Thinking your business is UNIQUE (usually it is not)

- Customization is to be avoided whenever possible

- Project team must be dedicated (for a certain period) to the project during implementation and testing phases

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Hazardous Communication Updates and Changes

- Vendor SDS review – automate as much as possible

- Define Significant vs insignificant change

- Impact analysis

- Determine method and frequency to communicate changes

- Regulatory requirement:
  - 1st shipment
  - SDS change
  - One year after 1st shipment

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What Does the Future Look Like?

- Regulations and Enforcement will continue to increase

- Compliance - cost center or profit center?

- Do more with less people -Self Service Portals

- Emerging countries developing their own rules to protect people and the environment

- Customers:
  - Expect regulatory documents to meet individual national regulations
  - Demand SDS's to be delivered via electronic means and **ONLY** when required by legislation

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Thank you

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