The Future Is Now!

REACH & TSCA Reform: Influencing Risk Assessment

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Risk Assessment – REACH & TSCA Reform

1. Risk Assessment Regulations
2. EU Directive & REACH
3. TSCA & Safe Chemicals Act
4. Impacts on Risk Assessment
5. Benefits to Risk Assessment

Risk Assessment Perspectives-

Ready or not, risk assessment is about to take the leading role in all aspects of chemical product decision making.

Compelling Case - Improve Risk Assessment

- Overwhelming number of chemicals remain without adequate hazard and risk assessments
  - >100,000 produced at 10 Tons or more
  - Many have little hazard or risk characterization data
- REACH has now moved into the 2nd tier of registrations and submissions for those with the highest volumes produced
- US Environmental Protection Agency (EPA) issued a series of guiding principles for TSCA reform and modernization in the pending legislation – Safe Chemicals Act - to bring TSCA up to date.

Where Have We Been?
TSCA -- EU Directive – REACH – Safe Chemicals Act

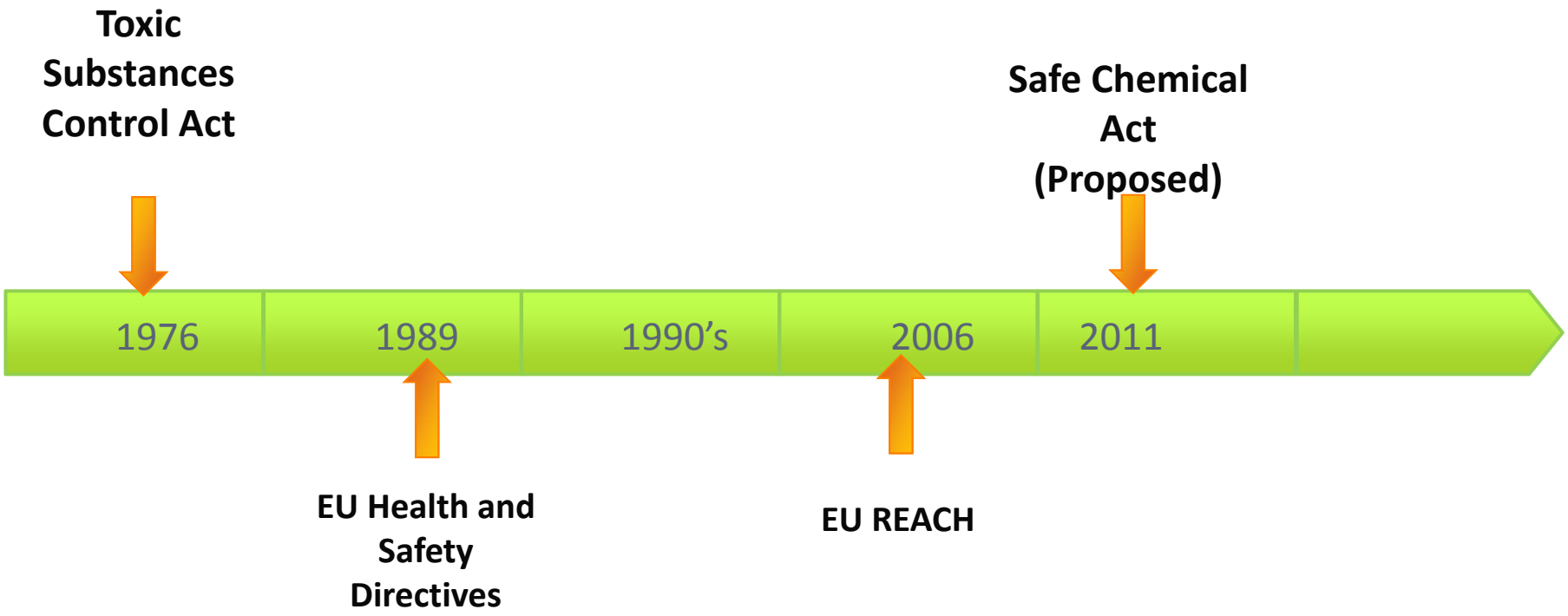
- Current practice in Europe and USA focuses many resources on searching for, or generating information about present hazards

- Significantly fewer resources spent searching for and generating information related to safer alternatives
  - input substitution
  - final product reformulation
  - and/or process changes

Key Points of Most Chemical Management Regulations:

- **Public and confidential sections**
- **Basic requirements –Hazard communication information 'PLUS '**
- **Chemicals already in commerce no longer assumed to be safe**
- **Substances, not mixtures, must be on inventories or exempt referenced to CAS #s**
- Manufacturer = Importer
- Must have a legal entity in country of import/use/registration
- Law/Directives, Regulations, Guidance
- Data and Fees required
- "Approval" or acknowledgement (registration number) needed
- TIME needed to get "approval"
- Country specific inventories

Risk Assessment Regulatory Drivers



Additional Risk Assessment Drivers and Tools

Hazard Banding
Globally Harmonized Systems

Control Banding
OSHA's proposed I2P2

TSCA - 1976

- 'Grandfathered' ~62,000 chemicals already in commerce in the USA
- New chemicals or new uses for chemicals provides a Risk Assessment requirement
- New findings on 'grandfathered' chemicals health effects may trigger risk assessments

1989-EU Health & Safety Directive

- Requires prevention and risk assessments for **ALL** hazards

BUT

- Employers could not or did not do the required risk assessments

2006 – EU REACH Directive

- Shifted the burden of Risk Assessment to the manufacturer or distributor for their products
- Driven by the failure of employers to perform adequate RA's
- Registration and Authorization is for ALL chemicals – no 'grandfathered' substances

2006 – EU REACH Directive

- Prescriptive process for Hazard and Risk Assessment process, using 'exposure scenarios' to be Authorized
- Communication of RA is standardized
- Employers accountable to use the prescribed controls in the Risk Assessment (eSDS)

Risk Assessment Improvements via REACH

- Chemical Safety Reports (CSRs)
  - Need requisite data set for human & environmental health
- Chemical Exposure Scenarios (Risk Assessments)
  - Required and done by the manufacturer for each use scenario
- "Safer Alternatives" must be identified in a "Substitution Plan" when the Risks cannot be mitigated

REACH Risk Assessments - USA

- TSCA
  - New Chemical Reviews will be initiated based on REACH findings/disclosures
  - Section 8(e) "substantial risk" notifications once aware of newly identified risks
    - New information
    - Re-assessment of existing information

REACH Risk Assessments - USA

- Product Disclosures in the USA will initiate substance reviews for:
  - Federal Insecticide, Fungicide and Rodenticide Act
  - Federal Food, Drug and Cosmetics Act
  - Federal Hazardous Substance Act
  - Consumer Product Safety Act
- Securities Disclosures
- State Laws
  - *e.g.*, Proposition 65

Risk Assessment Improvements via REACH

- Company-driven risk decisions are required
  - Additional traditional animal toxicity testing
  - Biomonitoring
  - Exposure Assessments
  - Nanomaterials and Emerging Sciences (Genomics & Low Dose)

What are the Tools of TSCA?

- • §4 – Test Rules
- • §5 – Premanufacture notification (PMN) – new chemicals
- • §5 – Significant New Use Rules (SNURs) & consent orders – new uses of existing chemicals
- • §6 – Unreasonable Risk
- • §8 – Recordkeeping/Reporting

STATE OF TSCA REFORM

- Toxic Substance control act of 1976 is the US law that governs most chemicals
- Reform Legislation –Safe Chemicals Act & Toxic Chemicals Safety Act
- Drivers of Reform is improved need for Risk Assessment
- 62,000 chemicals grandfathered in when TSCA formed in 1976
- Required testing on <300 substances in 34 years
- 5 chemicals regulated in limited ways
- Major reform of other global chemical policies like REACh goes beyond TSCA
- The 2010 elections increased the proportion of republicans who prefer to reduce regulations so unlikely TSCA will be revised in 2011, unless, the US Chemical industry pushes for it.

USA Position on Proposed TSCA Reform (Safe Chemicals Act)

- USA Industry generally welcomes the proposed set of principles primarily because
  - they are a risk-based
  - science-based
  - Parallel to the original underlying principles of TSCA 1976
- The underlying risk-based concept is in contrast to the REACH program's algorithm-based precautionary principle, much opposed by US chemicals producers.
- The unknowns for the TSCA reform include the potential to introduce REACH-like elements, such as incorporating the concept of "inherently safe technologies" (IST), which would essentially ban some products from use or sale and drive a transformed risk assessment strategy in the USA.

TSCA vs. TSCA Reform – Overview

Current	Under Reform
Data - very limited test data required	A minimum data set on all new & existing chemicals
Burden of Proof - EPA	Industry
Safety Assessment - No Mandate	Full safety determination
Prioritization of high concern - no criteria; case-by-case judgment	Expedite action to reduce use & exposure of PBT's, ID hot spots of exposures
Information Access - Claim CBI with no justification; never expires	All CBI claims must be justified up front
Scope of assessment - none normally done & no requirement to assess exposure	Safety determination based on aggregate exposure to all uses/sources - full life cycle
Regulatory Action - not successful in past under "unreasonable risk" clause	Health based - can restrict, place conditions on use; high hazard/exposure prioritized

TSCA 1976 vs. Safe Chemicals Act of 2011

SAFETY DATA

CURRENTLY UNDER TSCA

- Few data call-ins are issued, even fewer chemicals are required to be tested and no minimum data set is required even for new chemicals.

UNDER THE SAFE CHEMICALS ACT OF 2011 (S. 847)

- Up-front data call-ins for **ALL** chemicals would be required.
- Minimum data sets (MDSs) on all new & existing chemicals sufficient to determine safety would be required to be developed & made public.

TSCA 1976 vs. Safe Chemicals Act of 2011 *(Continued)*

BURDEN OF PROOF

CURRENTLY UNDER TSCA

- EPA is required to prove harm before it can regulate a chemical.

UNDER THE SAFE CHEMICALS ACT OF 2011 (S. 847)

- Industry would bear the legal burden of proving their chemicals are safe.

TSCA 1976 vs. Safe Chemicals Act of 2011 *(Continued)*

ASSESSMENT OF SAFETY

CURRENTLY UNDER TSCA

- No mandate exists to assess the safety of existing chemicals.
- New chemicals undergo a severely time-limited and highly data-constrained review.

UNDER THE SAFE CHEMICALS ACT OF 2011 (S. 847)

- **Both new & existing chemicals** would generally be subject to safety determinations as a condition of entering or remaining on the market, using the best available science that relies on the advice of the National Academy of Sciences.

- Chemicals designated by EPA to be intrinsically safe would not require assessment or further action unless new information altered their designation.

TSCA 1976 vs. Safe Chemicals Act of 2011 *(Continued)*

SCOPE OF ASSESSMENT

CURRENTLY UNDER TSCA

- Where the rare chemical assessment is undertaken, there is no requirement to assess exposure to all sources of exposure to a chemical, or to assess risk to vulnerable populations.
- No guidance is provided on how to determine whether a chemical presents an "unreasonable risk."

UNDER THE SAFE CHEMICALS ACT OF 2011 (S. 847)

- Would require EPA to account for **aggregate exposures** to all uses and sources of a chemical
- Intends to ensure protection of vulnerable populations that may be especially susceptible to chemical effects . . . . .
  - e.g., children, the developing fetus
- .. .or subject to disproportionately high exposure
  - e.g., low-income communities living near contaminated sites or chemical production facilities

TSCA 1976 vs. Safe Chemicals Act of 2011 *(Continued)*

CHEMICALS AND EXPOSURES OF HIGH CONCERN

CURRENTLY UNDER TSCA

- No criteria are provided for EPA to use to identify & prioritize chemicals or exposures of greatest concern, leaving such decisions to case-by-case judgments.

UNDER THE SAFE CHEMICALS ACT OF 2011 (S. 847)

- EPA would be required to develop & apply criteria to identify toxic chemicals to which people are exposed that persist and build up in the environment and people (PBTs).
- "Hot spots" where people are subject to disproportionately high exposures would be specifically identified & addressed.

TSCA 1976 vs. Safe Chemicals Act of 2011 *(Continued)*

REGULATORY ACTION

CURRENTLY UNDER TSCA

- Chemicals of highest concern, such as asbestos, have not been able to be regulated under TSCA's "unreasonable risk" cost-benefit standard.
- Instead, assessments often drag on indefinitely without conclusion or decision.

UNDER THE SAFE CHEMICALS ACT OF 2011 (S. 847)

- PBTs to which people are exposed = mandatory exposure reductions .
- The remaining chemicals would be prioritized for assessment against a health-based standard, & deadlines for decisions would be specified.
- EPA would have authority to restrict production & use or place conditions on any stage of the lifecycle of a chemical to ensure safety.

TSCA 1976 vs. Safe Chemicals Act of 2011 *(Continued)*

INFORMATION ACCESS

CURRENTLY UNDER TSCA

- Companies are free to claim most information they submit to EPA to be confidential business information (CBI), denying access to the public , or to state & local government.
- EPA is not required to review such claims, & the claims never expire.

UNDER THE SAFE CHEMICALS ACT OF 2011 (S. 847)

- All CBI claims would have to be justified up front.
- EPA would be required to review them, & only approved claims would stand.
- Approved claims would expire after no more than five years
  - Except where EPA determines the five-year term would not apply
- Other levels of government would have access to CBI.

TSCA 1976 vs. Safe Chemicals Act of 2011 *(Continued)*

RULEMAKING REQUIREMENTS

CURRENTLY UNDER TSCA

- To require testing or take other actions, EPA must promulgate regulations that take many years & resources to develop.
- EPA must show potential for a chemical to cause harm in order to require testing, a Catch-22.

UNDER THE SAFE CHEMICALS ACT OF 2011 (S. 847)

- In addition to the MDS requirement, EPA would have authority to issue an '**order**' rather than a regulation to require reporting of existing data or additional testing, & need not first show evidence of harm.

Benefits of REACH & TSCA on Risk Assessment:

- Uniform methods to derive hazards and exposure Risk Assessment decisions
- Documented Risk Assessments with accountability by manufacturers / distributors
- Common standard of care in the communication of hazards, exposure risks and management (ERAM) from cradle to cradle
- Data and risk assessments provided by the chemical industry and approved / authorized by EPA or ECHA
- ALL chemicals will be assessed for risk for all aspects of chemical handling – 'cradle to cradle' – aggregate exposures and mixtures through the life cycle
- Common methodology for risk assessments & data generated for SCA or REACH may be leveraged – global economy & consistent standard of care in global markets
- PBTs risk being 'banned' and "Safer Alternatives" must be identified in a "Substitution Plan" when the Risks cannot be mitigated in the EU or USA
- More levels of government can access the data and risk assessments by reducing CBI use with the 5-year review

Product Stewardship Improvements

- New Chemicals Review
- Risk Assessment
  - Changes in paradigms and approaches
  - Adjustment of health benchmarks by federal and state agencies
- Biomonitoring
- Corporate EHS Policies and Procedures
- Deselection and Manufacturing phase-outs
  - *e.g.*, Certain suppliers could discontinue or limit production due to REACH regulatory burdens/health and safety considerations.
  - *e.g.*, REACH Authorization required for SVHC to remain in EU commerce ultimately may lead not only to restrictions in the EU, but to deselection around the world as other countries -- and even some U.S. states (*e.g.*, California) -- look to REACH as a chemical regulatory model

One Last Comment on SCA:

- Inherently Safe Technology
  - Industry **DOES NOT** support having DHS or EPA dictate which plants should produce what products using which processes.
    - Argument: IST mandates would just shift risk around rather than really reduce it.
    - e.g., a DHS mandate for reduced inventories of a specific feedstock at a plant site would require the operator to have more frequent deliveries of the chemical, thus raising the risks of in-transit accidents, spills related to loading and discharging hazardous cargoes, etc.

In Summary . . . .

- The US Environmental Protection Agency (EPA) issued a series of guiding principles for TSCA reform and modernization in the pending legislation to bring TSCA up to date.
- Industry generally welcomed that set of principles primarily because they are a risk-based, science-based approach that has been the underlying basis for TSCA since its beginning in 1976.
- That underlying concept is in contrast to the REACH program's algorithm-based precautionary principle, much opposed by US chemicals producers.
- The unknowns for the TSCA reform include the potential to introduce REACH-like elements, such as incorporating the concept of "inherently safe technologies" (IST), which would essentially ban some products from use or sale and drive a transformed risk assessment strategy in the USA.


Mission Impossible: Improved & Standardized ERAM?
…….or just Mission Difficult?