International Perspectives on Chemicals Policy Reform

Joel A. Tickner, ScD

Lowell Center for Sustainable Production
University of Massachusetts Lowell

www.chemicalspolicy.org

Joel_tickner@uml.edu

The International Drive to increase Industrial Chemical Hazard Data

- Long international history in chemicals policy debates
- Some older initiatives that are broad in nature
- Some newer ones focused on individual chemicals
- Examining new frameworks for global chemicals management
  - Chemical phase outs
  - Information Sharing and Harmonization
    - Toxicity data
    - Hazard Classification and Labeling

International Chemicals Policy Initiatives

- Global
  - Montreal Protocol
  - Rotterdam Convention on Prior Informed Consent
  - Basel Convention on Transboundary Movements in Hazardous Wastes
  - Stockholm Convention on Persistent Organic Pollutants
  - Strategic Approach to International Chemicals Management
  - Globally Harmonized System of Classification and Labeling
  - Intergovernmental Forum on Chemical Safety
- Regional
  - Great Lakes Water Quality Agreement
  - North Sea Convention
  - OSPAR Convention

IFCS Forum VI Recommendation on Substitution, Dakar September, 2008

- For governments to support international regulatory frameworks to promote the substitution of dangerous substances, with clear objectives and timelines, supported by national plans;
- For governments, international organizations, industry, and other stakeholders to promote global substitution of substances which have already been carried out in some parts of the world owing to their widely known and acknowledged harmful impacts on human health and the environment;
- For governments and international organizations to identify the substances and uses of highest priority concern (carcinogens, mutagens, endocrine disrupters, PBT, vPvB, sensitizers and neurotoxicants) through an international and publicly accessible database on hazardous properties of existing substances;
- For governments and international organizations to develop an international portal on substitution to raise awareness of a broad range of potential alternatives and to encourage adoption of tested, proven and documented alternatives. This portal should include tools and processes for alternatives assessment and an alternatives database that can be used across sectors and countries;

Strategic Approach to International Chemicals Management

OECD HPV Chemicals Program

- In 1988 the Organization for Cooperation and Development, (OECD) Chemicals Division launched its High Production Volume (HPV) Chemicals Program (revamped in 1998)
- The HPV program seeks Member Countries to adopt chemicals for assessment from a list of priority substances manufactured or imported into at least one Member Country in quantities of 1000 tons or more per year.
- The 2004 OECD HPV list includes 4,843 chemicals

OECD HPV Chemicals Assessments

- Each Member Country "sponsors" a chemical for assessment based (roughly) on the proportion of that chemical produced by its internal industries
- Currently there are 1000 chemicals in the Program with assessments completed or in process
- Progressing at 100 per year
- Program expanding to examine harmonization of testing and regulation of nanomaterials

OECD SIDS Template

- OECD developed the Screening Information Data Set (SIDS) as a cross country harmonized, minimum data base template
- Template includes:
  - General information
  - Physical/chemical information
  - Environmental fate and pathways
    - (photodegradation, water stability, distribution, biodegradation)
  - Ecotoxicity
    - (aquatic, terrestrial)
  - Toxicity
    - (acute, repeat dose, genetic, reproductive, developmental)
- E-Chem Portal – a one stop source for such data

Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

A single approach to classification and labeling that can be used world-wide:

- Standardizes:
  - the ways in which chemical hazards are categorized
  - the words and symbols used to communicate about those hazards on chemical product labels
  - guidance for the creation of MSDS
- Applies to chemicals and chemical products; not articles
- Covers both physical hazards and toxicity

European Actions

- RohS and WEEE
- REACH
- Older restrictions
- Member state actions

RoHS Regulations

RoHS: Restriction of Hazardous Substances

- On July 1, 2006 EU RoHS became effective.
- On March 1, 2007 China RoHS became effective.
- China RoHS modeled after EU RoHS, but has major differences
  - Mandatory certification in China and information disclosure

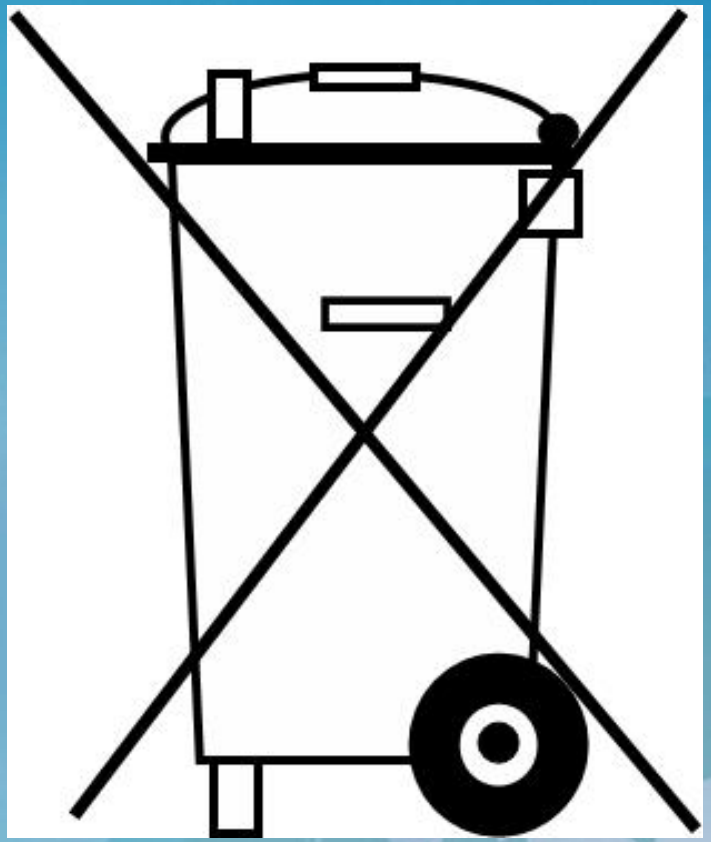
What Does RoHS Restrict?

- Heavy Metals
  - Lead (Pb)
  - Mercury (Hg)
  - Hexavalent Chromium (Cr+6)
  - Cadmium (Cd)
- Flame Retardants:
  - Polybrominated biphenyls (PBBs)
  - Polybrominated diphenyl ethers (PBDEs)

WEEE Directive

Objective:

Divert WEEE (waste electrical and electronic equipment) from landfills and incinerators to environmentally sound re-use and recycling



Relationship Between WEEE and RoHS

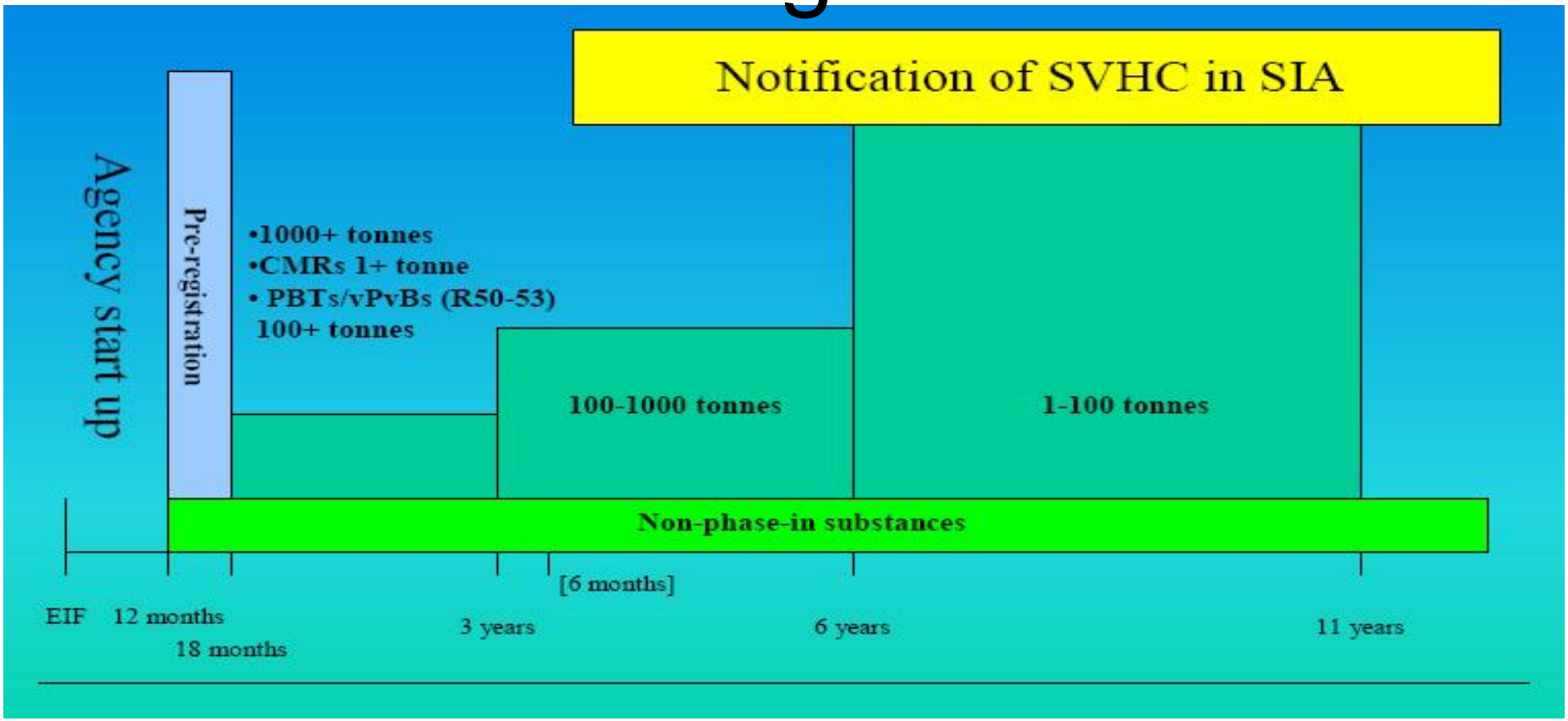
- WEEE encourages the design of electronic products with environmentally-safe recycling and recovery in mind.
- RoHS dovetails with WEEE by reducing the amount of hazardous chemicals used in electronic manufacturing, thereby reducing the hazards associated with recycling and recovering WEEE.

REACH –in force 1 June 2007

- **Single coherent system for new (non phase-in) and existing (phase–in) chemicals**
- **Elements:**
  - **Registration of substances ≥ 1 tonne/yr (staggered deadlines)**
  - **More information and better communication through the supply chain**
  - **Evaluation of some substances by European Chemicals Agency (MS support for substance evaluation)**
  - **Authorisation only for 'Substances of Very High Concern' (SVHC)**
  - **Restrictions - the safety net**
  - **Agency to manage system**
- **Focus on priorities:**
  - **high volumes (early deadline)**
  - **greatest concern (CMRs and high volume R50/53 early)**
  - **Establishes new European Chemicals Agency (ECHA)**

A Tiered Approach

REACH – (Pre) Registration Timeline



"Registration" of *substances, substances in preparations, substances in articles.*
"Registration" on basis of "tonnages", "SVHC or not", "phase-in or not".
"Registration" after 3 1/2 year (> 1000 t/j) , 6 year (100-1000 t/j), 11 year (1-100 t/j).
"Notification" of Substances of Very High Concern (SVCH) in articles.

REACH: Registration Information

- Technical Dossier
  - Substance identity
  - Chemical-physical characterization
  - Existing human and ecological toxicology data
  - Information on potential uses
  - New Chemical "Safety Data Sheets"
    - based on 16 elements of the Globally Harmonized System of Labeling and Classification of Hazards
  - "Chemical Safety Report"
- Additional testing over 10 tons per year to be shared among manufacturers and importers
- Data public through through REACH IT system and confidential information sharing agreements

REACH: Registration Chemical Safety Report

- Manufacturers or importers of substances with quantities on 10 tons or more per year must prepare a Chemical Safety report which includes a Chemical Safety Assessment
- Chemical Safety Assessments must include:
  - human health hazard assessments
  - environmental hazard assessments
  - PBT and vPvB assessments
  - and , if the substance is high hazard, then
    - exposure assessment
    - risk characterization

Substances in Articles

- Substances intended to be released from articles, and present above 1 tonne per M/I per year, are subject to the same registration requirements and deadlines as for substances on their own or in preparations
- Importers need provide a notification only to the ECHA if the article contains a substance of very high concern (SVHC) and it is not intended to be released.
- The ECHA may request the registration of a notified substance in an article if it poses a risk to human health or the environment.

REACH: Evaluation

- Evaluations are conducted by the Member States
- Based on a “rolling plan” informed by substances of concern with a quota of 5% of Registrations per year
- There are 2 types of Evaluation
  - Dossier Evaluation
    - a compliance check on the data
    - a review of testing protocols
  - Substance Evaluation
    - a check on validity of findings
    - a request for additional information or testing

Authorization

- Substances of very high concern – CMRs, vPvBs, PBTs, and others of equivalent concern
- Manufacturers/importers must apply for authorization to continue use for each general use.
- Authorization can be given – time limited – if adequate control can be demonstrated
- If 'adequate control' cannot be demonstrated, or the 'adequate control' route is not available then a decision on authorising a use will take account of the risks posed by the substance, socio-economic impacts of authorising or not the use, possible alternatives and substitutes (substances and processes)
- Fed into system on a case by case basis as resources allow.

How REACH addresses limitations in Chemicals Management

- *Lack of data* – Registration, Chemical Safety Reports
- *Unequal treatment new vs. existing* - Applies to both new and existing substances (no more grandfathering)
- *Slow, Burdensome Chemical-by-Chemical Risk Assessment/Management Processes* – Chemical Safety Reports, Authorization for Substances of Very High Concern, Evaluation Process, Restrictions.
- *Lack of stimuli for innovation* – Authorization, Lower requirements for new chemicals. But little attention to R&D and technological support for industry

Cultural Change of REACH

- No data = No market
- Responsibility on companies to develop safety data, define safe uses of chemicals, and communicate with supply chain
- Responsibility on manufacturers/importers to ask for permission (authorization) to use chemicals of very high concern
- Greater sharing of information on substances in products (preparations and articles). Greater supply chain dialogue
- Forced cooperation on testing

The impacts of REACH in the US

- REACH will impact chemical use and supply in the EU and beyond. US Co's will have to comply. Impacts at state level?
- Withdrawal of substances from the market is inevitable; how will this affect supply chains?
- Greater information generated by REACH may affect liability
- Impacts on imports into the EU; importers and customers will require help (scientific, technical etc)
- Size and scope means REACH will provide opportunities as well as threats.
- Opportunities: information, public confidence, safer products/reduced liability
- Highlights diminishing US leadership in environmental policy innovation

Canadian DSL Chemicals Screening

- Domestic Substances List (DSL) of existing chemicals published in 1994
- Contains 23,000 substances
- Enactment of the Canadian Environmental Protection Act (CEPA) in 1999 required that all DSL chemicals be screened and categorized
- The screening was jointly conducted by Health Canada and Environment Canada
- The screening and categorization project was completed in September, 2006
- Now: U.S. commitment to complete assessments and take action as needed, on more than 9,000 chemicals produced above 25,000 pounds per year by 2012.

Criteria for DSL Categorization

- **Environment**
  - **Persistent**
  - **Bioaccumulative**
  - **Inherently Toxic to the Environment**
- **Human Health**
  - **Greatest Potential for Exposure**
  - **Inherently Toxic to Humans**
    (cancer, birth defects, damage to genetic material, etc.)

DSL Categorization

- The screening relied primarily on existing data with QSARs and “read across” used for data gaps
- Final report lists some 4,000 substances categorized into high hazard tier
- These high hazard substances will be assessed for risk in future actions

AP
SL Program
Categorization
Screening Assessment
Pilot Project
DSL Notices
Related Activities
Substance Search
DSL Comments
ection 75
THE CHEMICAL SUBSTANCES PORTAL
nicalsubstances.gc.ca

Domestic Substances List
Categorization and Screening Program

One of the initiatives in the *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires the Minister of the Environment and the Minister of Health to "categorize" (Section 73, CEPA 1999) and then if necessary, conduct screening assessments (Section 74, CEPA 1999) of substances listed on the Domestic Substances List (DSL) to determine whether they are "toxic" or capable of becoming "toxic" as defined in the Act. Under the Act, a substance is "toxic" if it is entering or may enter the environment in a quantity or concentration or under conditions that;

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
(b) constitute or may constitute a danger to the environment on which life depends; or
(c) constitute or may constitute a danger in Canada to human life or health.

The DSL includes substances that were, between January 1, 1984, and December 31, 1986, in Canadian commerce, used for manufacturing purposes, or manufactured in or imported into Canada in a quantity of 100 kg or more in any calendar year. The purpose of the List was to define what was 'New to Canada' and it has been amended from time to time following assessment under the New

Conclusions

- Increasing number of international chemicals initiatives which will have impacts in the US
- These initiatives highlight the lack of US federal leadership
- They are likely to provide new sources of information for actions at the local level
- They provide opportunities for global collaborations to advance safer chemicals and products
- Local/State governments have an important role to play in these initiatives – providing pragmatic and visionary input