April 26, 2017

REGULATORY COOPERATION: EXAMPLES

Alexa Burr
American Chemistry Council
What is Regulatory Cooperation?

- Promoting common elements in national regulatory systems - approaches based on sound science and risk
- Reducing regulatory divergences
- Regulator to Regulator dialogue; industry coordination
Regulatory Cooperation

• Opportunity for regulators to share scarce resources, increase transparency, and facilitate engagement with counterparts in key trading partner countries.

• Create efficiencies while respecting national sovereignty and statutory/regulatory requirements in any jurisdiction.

• Most efficient approach for chemicals management - combination of transparent, risk-based regulations and voluntary industry initiatives.
Canada-Australia Mutual Acceptance Scheme

- Efficiency of new industrial chemical notifications and assessment by providing greater transparency in assessments, reduction in animal testing, reduction of resources needed for new industrial chemicals
- Under Canada CMP & NICNAS - recognize each other’s assessments for new chemicals
- Regulators worked together to develop necessary forms and info requirements
U.S. - Canada Regulatory Cooperation Council (RCC)

“...facilitate closer operation between our two countries and develop smarter and more effective approaches to regulation to make the United States and Canadian economies stronger and more competitive, while meeting the fundamental responsibilities to protect safety and welfare of our citizens.”

• Initially launched in 2011

• 29 initiatives covering a variety of areas from transportation to agriculture, to emerging areas (e.g. nanotechnology)

• Cooperative activities managed between agencies at all levels, including:
  • High-level governance
  • Opportunities for stakeholder input/engagements
  • Annual review of Work Plans
U.S. - Canada Regulatory Cooperation Council (RCC)

GHS Implementation

• Reduce and prevent variances between U.S. and Canada on GHS implementing regulations (OSHA HCS 2012 and WHMIS respectively)

• Will be some differences in SDS requirements, but major differences are avoided

• Originally had a working group of regulators and industry to examine existing variances and collect feedback from stakeholders

• Ongoing working group to discuss and reduce variances, coordinate on matters at UNSCEGHS
U.S. - Canada RCC

Risk Assessment

• Align chemical regulatory processes and risk assessment approaches for greater efficiencies and effectiveness

• Technical Working Group made up of industry, regulators, and NGO’s

• Comparing and contrasting the information requirements and assessment approaches used by each country to identify priorities, analyze how those priorities were selected, and the conclusions of each country
  • 5 specific chemical case studies

• Goal: case studies inform a possible joint risk assessment process in the future. Based on the findings of the case studies, the TWG will develop a framework of collaboration
U.S. - Canada RCC

Nanotechnology

• Developing joint initiatives and regulatory approaches

• Common criteria for determining characteristics of concern/no concern, information sharing, and approaches to risk management

SNAc/SNURs

• HC, EC, and EPA working to identify and develop common approaches for regulatory reporting requirements for new uses of chemicals

• SNAc = Significant New Use Activity in Canada; SNUR = Significant New Use Rule in US
TTIP Example

EU-US Trans-Atlantic Trade & Investment Partnership

- Comprehensive free trade negotiations with regulatory cooperation as a top priority for both sides
  - Horizontal issues (Technical Barriers to Trade)
  - Sectoral discussions (including chemicals)

- Objective is to promote streamlined, more efficient regulatory systems by developing more consistent requirements for regulators and companies to meet high standards of health and environmental safety, while also ensuring timely access to market.
TTIP Objectives for Regulatory Cooperation

- Starting point: the U.S. and EU regulate chemicals differently - we did not propose any changes in existing regulatory frameworks under TTIP

- TTIP provided an opportunity to help the different regulatory approaches in the U.S. and EU work more effectively together

- Enhanced regulatory cooperation can result in cost savings for governments and industry alike, while maintaining high levels of protection for human health and the environment
TTIP Example: Pilot Projects

- **Prioritization**
  - Collaboration towards a common approach of prioritization for chemicals assessment and management.
  - Prioritize chemicals of highest concern with a focus on chemicals in commerce with highest potential for exposure.

- **Classification & Labelling**
  - Reduce divergences in GHS regulations
  - Label reciprocity
  - Reduce/eliminate need for dual classifications
ASEAN Regulatory Cooperation Project

• Began with ASEAN industry meeting in January 2016
  ➢ Purpose was to equip local trade association representatives with the knowledge to advocate to their own governments for risk-based approaches to chemicals management and regulatory cooperation principles.

• Included ASEAN industry and government representatives

• Agenda Topics:
  ➢ ASEAN Economic Community
  ➢ Chemical Industry’s contribution to SDG’s
  ➢ Regulatory Cooperation
  ➢ Industry-Government Coordination
  ➢ Risk-based approaches to chemicals management
  ➢ Hazard vs. Risk-Based Approaches
ASEAN Regulatory Cooperation Project

• Industry & government representatives agreed to work on 2 regulatory cooperation initiatives:
  • GHS Alignment (starting with building blocks)
  • ASEAN Chemical Inventory
Other examples

• APEC CD Virtual Working Group on GHS - working to reduce divergences in GHS implementation in APEC region

• Trans-Pacific Partnership (TPP)

• Canada, US, and Brazil

• Inventories

The list goes on...