

Washington Watch

Chemical Management, North American Style

The Montebello Agreement

Lynn L. Bergeson

With so much attention focused on the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulations, domestic manufacturers may be less aware than they should be of regulatory efforts in North America.

In August 2007, the United States, Canada, and Mexico entered into a regional agreement for assessing and managing potential chemical risks. The new effort, which was announced in Montebello, Quebec, seeks to ensure the safe manufacture and use of industrial chemicals.

This "Washington Watch" column discusses the Montebello Agreement, noting its origin in the Security and Prosperity Partnership of North America and explaining its potential implications for the future. The discussion also provides context on other chemical management schemes -- particularly REACH.

Security and Prosperity Partnership of North America

The Montebello meeting -- a summit of North American leaders attended by United States President George Bush, Canadian Prime Minister Stephen Harper, and Mexican President Felipe Calderon -- grew out of the Security and Prosperity Partnership (SPP) of North America.

The SPP was launched in March 2005. The partnership is intended to:

- Establish a cooperative approach to advance the three countries' common interests in security and prosperity;
- Allow the development of a common security strategy for North America; and
- Promote economic growth, competitiveness, and quality of life.¹

Following the first meeting in 2005, each nation agreed to establish ministerial-level SPP "working groups" in targeted areas, including (among others) the environment.

SPP Regulatory Cooperation Framework

The three nations also created various "framework" documents, one of which is the Security and Prosperity Partnership of North America Regulatory Cooperation Framework. Under this document, the parties agreed to "improve trilateral regulatory cooperation among the governments of the United States, Canada and Mexico, with the principle aim of lowering costs for North American businesses, producers, governments and consumers; maximizing trade in

goods and services across North America's borders; and protecting health, safety, and the environment."²

The framework's three primary goals are to "strengthen regulatory cooperation; streamline regulations and regulatory processes; and encourage the compatibility of regulations, where appropriate and while maintaining high levels of health and safety and environmental protection."³

The Regulatory Cooperation Framework seeks to achieve these objectives in several ways, as outlined in the following sections.⁴

Strengthening Regulatory Cooperation

- Increase the transparency of the rulemaking process.
- Promote good governance by sharing best practices.
- Increase information sharing among regulators.

Streamlining Regulations and Regulatory Processes

- Increase joint analysis or evaluation of regulatory issues of mutual interest.
- Increase work sharing or information exchange on approaches to implementation.
- Leverage existing mechanisms (such as the SPP Prosperity Working Groups, North American Free Trade Agreement Working Groups, and bilateral or trilateral undertakings) to anticipate regulatory issues.

Encouraging Compatibility of Regulations

- Work towards more compatible and coordinated regulatory approaches.
- Promote the use or adoption of relevant international standards, as well as domestic voluntary consensus standards in regulations, consistent with the participant nations' World Trade Organization obligations.
- Work to eliminate redundant testing and certification requirements.

The Montebello Agreement

The Montebello Agreement was intended to further the goals of the SPP. Under the Agreement, the United States, Canada, and Mexico will coordinate their efforts to assess and manage chemicals.

As part of the Montebello Agreement, the United States has stated that, by 2012, it will “complete risk characterizations and take action, as needed, on more than 9,000 chemicals produced [in quantities] above 25,000 pounds per year.”⁵ In addition, the Agreement

provides for the sharing of scientific information and technical understanding, best practices and research on new approaches to chemical testing and assessment. The agreement establishes goals to be met by 2020, which includes creating and updating chemical inventories in all three countries, as well as coordinating the management of chemicals in North America as outlined in other international agreements.⁶

Chemical Management Initiatives: An International Perspective

To understand the implications of the Montebello Agreement, some international background on chemical testing and management programs is useful for context and perspective. The sections that follow describe the relevant programs in Canada, the United States, and the European Union.

Canadian Chemical Management Plan

In Canada, chemical testing is mandated by the Canadian Environmental Protection Act (CEPA). CEPA requires the relevant government agencies (Environment Canada and Health Canada) to “conduct screening-level risk characterizations on all chemicals in the Canadian marketplace.”⁷

CEPA’s mandate has resulted in the development of new risk assessment approaches that are reflected in the Canadian Chemical Management Plan (CCMP). To date, the Canadian government has evaluated 23,000 chemical substances under the CCMP. In order to “focus scarce resources on those substances that require further study and possible risk management action,” the program uses tools such as structure-activity relationship (SAR) analysis to group chemicals of similar molecular structure, and applies predictive modeling techniques.⁸

United States: HPV Challenge Program

In the United States, the most notable chemical testing initiative is the High Production Volume (HPV) Challenge Program. The initiative originated in 1998, when the U.S. Environmental Protection Agency (EPA), Environmental Defense, and organizations representing the chemical and petroleum industries set a shared goal of collecting and communicating data on large-volume chemicals.⁹

The information collected under the HPV Program includes a Screening Information Data Set (SIDS) dossier. This is a basic collection of health and environmental data required for making initial hazard assessments of HPV chemicals. SIDS data are used to screen chemicals and set priorities for further testing, risk assessment, and risk management activities.¹⁰

Under the HPV Challenge Program, chemical companies have provided information on over 2,200 chemicals.¹¹ EPA has evaluated approximately 100 HPV chemicals and posted initial hazard assessments for them on its website. The Agency hopes to post another 200 chemical assessments soon.¹²

EU's REACH

In the European Union (EU), REACH has dominated and revolutionized chemical management policy. This scheme, which became effective on June 1, 2007, is the EU's complex new chemical management regulation.¹³ REACH encompasses over 140 different articles, 17 distinct annexes, almost 300 pages of text, and hundreds of pages of guidance -- with the latter figure expected to grow considerably as more guidance is issued.

- ***Registration Requirements***

The core of REACH is its registration requirement, which mandates that all chemicals manufactured or imported into the EU in quantities of one metric ton or more per year be registered with the newly created European Chemicals Agency (ECHA). The registration obligation applies to legal entities that are established within the EU and that meet the quantity threshold. Covered entities include parties who manufacture or import "substances," either on their own or in "preparations" (i.e., mixtures). Also included are producers and importers of "articles" that meet certain specified criteria.

Registration will entail the generation of substance-specific health and safety data and preparation of a technical dossier. For those substances manufactured or imported in quantities of 10 metric tons or more per year, it will also involve assessment of the risks posed by the substance (including relevant exposure scenarios), as well as development and communication of appropriate risk management measures.

- ***Registration Process***

For existing chemicals (referred to in the regulations as "phase-in substances"), the REACH registration process will proceed in stages. Depending on the annual volume and hazard level of the substance involved, extended registration deadlines (of 3¹/₂, 6, and 11 years from June 1, 2007) may be available.

To obtain the benefit of these extended deadlines, manufacturers, producers, and importers must pre-register their substances or articles between June 1 and December 1, 2008. Pre-registration will enable the company to continue manufacturing or importing the substance until the extended registration deadline is reached.

Pre-registration will entail electronic submission to ECHA of certain basic information about both the chemical and the entity that is pre-registering it. By January 1, 2009, ECHA intends to publish on its website a list of pre-registered substances. The list will not identify the entities that have pre-registered, but this information will be available to all companies that have pre-registered the same substance.

Same-substance pre-registrants will then be required to participate in Substance Information Exchange Forums (SIEFs) for their relevant chemicals. SIEFs are intended to facilitate data-sharing on existing chemicals, collective identification of data gaps, and cost-sharing with respect to the generation of any new data.

- ***Substances of Very High Concern***

In late 2008, ECHA is expected to publish a candidate list of chemicals of “very high concern.” It is anticipated that approximately 1,500 substances of very high concern (SVHCs) will eventually be selected from the candidate list and placed on REACH Annex XIV, the list of substances that will be subject to the REACH authorization provisions.

Once included on Annex XIV, a substance will not be allowed to be marketed or used in the EU in any quantity unless authorization to do so is received from the European Commission. An application for authorization must include analysis of alternative substances and a plan for substituting other chemicals (if a suitable alternative exists).

The REACH authorization system is designed to assure that SVHCs are replaced over time by alternative substances or technologies in cases where it is economically and technically viable to do so. It is widely anticipated that some (perhaps many) manufacturers of SVHCs will cease producing them.

This will force downstream users of SVHCs to either reformulate their products or cease manufacturing them if substitute substances are not available. Some uses of chemicals, moreover, may be restricted under the REACH restriction provisions, and authorization for these uses may not be granted.

Montebello, REACH, and the Future of Chemical Management

Responses to the Montebello Agreement

Many in the U.S. chemical community and within EPA are excited about the Montebello Agreement. They see it as a significant opportunity for efficient and expeditious development of chemical hazard information, prepared along the lines of the HPV Challenge Program. In their view, the goals of the Regulatory Cooperation Framework are well suited to promoting assessment of large numbers of industrial chemicals, utilizing the respective strengths and leveraging the pooled resources of the three nations involved in SPP.

Some see the Montebello Agreement as North America's response to REACH -- and embrace it as an alternative approach. In a briefing paper dated October 30, 2007, for example, the National Petrochemical and Refiners Association stated:

The Montebello Agreement provides a unique opportunity to affect the future of chemicals management policy both here and abroad. It is the only regional model that is truly tiered, targeted and risk-based It is in the best interest of U.S.

industry to support the Montebello Agreement and work with authorities in North America to ensure its success.¹⁴

Others, however -- including some public interest groups -- maintain that REACH is the better, more appropriate model on which to base United States domestic chemical management policies. They prefer it to voluntary efforts such as those contemplated under the Montebello Agreement, the HPV Challenge Program, or similar initiatives.

The Impact of REACH

As REACH is implemented, it is clear that the European regulatory scheme will place considerable pressure on domestic chemical producers and regulators alike to demonstrate that U.S. laws and regulatory programs are sufficiently robust to assure that chemicals used as intended do not pose risks to human health or the environment.

Detractors of domestic chemical management policies can be expected to point to REACH as the new standard for chemical management -- one on which U.S. chemical management law and policy should be patterned.

The North American Alternative -- Or Not

Whether the Montebello Agreement will generally be viewed as a suitable alternative to REACH remains unclear. Such an outcome seems unlikely, however. Montebello is not mandatory. Nor does it address some of the fundamental deficiencies that critics point to in the Toxic Substances Control Act (TSCA), which is the main federal statute in the United States that addresses chemical testing and management.

Prominent among these perceived deficiencies is the legal burden that TSCA places on government to prove that chemicals pose unreasonable risks -- a serious shortcoming in the view of those who argue that the burden should be on manufacturers to prove that chemicals are safe.

State and Local Interest in Chemical Management

It is unlikely that Congress will soon amend TSCA to rehabilitate these alleged deficiencies. At the state and local level, by contrast, there has been an appreciable increase in chemical management laws and related measures over the past several years. These efforts are expected to continue in the future.

Two key factors contribute to the growth in interest at the state and local level. First, there is increasing recognition that national regulatory programs may not be adequate to control environmental releases effectively, and that state and local laws are better able to address and reflect local priorities.

Second, some states that have adopted new chemical management provisions maintain that the federal government has not been as active in the environmental arena as, for example, the EU. These jurisdictions have simply decided to take matters into their own hands.

Concluding Thoughts

Chemical manufacturers and users are urged to be mindful of the Montebello Agreement and to support its goals. They would also be well advised to monitor chemical management polices in the U.S. as they evolve. This is particularly important now that elections are fast approaching in 2008.

It is unclear which chemical management model -- REACH, the Montebello Agreement, or some other approach -- ultimately will prevail as the paradigm of choice for those who make U.S. domestic chemical management policy decisions. One point is certain, however: Chemical management issues will be anything but dull over the next several years.

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Notes

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- ¹ The White House, Office of the Press Secretary (2005, March 23). Fact Sheet: Security and Prosperity Partnership of North America. Available online at <http://www.whitehouse.gov/news/releases/2005/03/20050323-4.html>
- ² Fact Sheet: Security and Prosperity Partnership of North America Regulatory Cooperation Framework. Available online at http://www.spp.gov/pdf/spp_reg_coop_fact_sheet.pdf.
- ³ *Ibid.*
- ⁴ *Ibid.*
- ⁵ U.S., Canada and Mexico Take Lead to Manage Industrial Chemicals (2007, August 21). EPA Press Release. Available online at <http://yosemite.epa.gov/opa/admpress.nsf/0cd7fdf95b701616852572a000658ef2/77660c0da9fe643e8525733e0065d48b!OpenDocument>
- ⁶ *Ibid.*
- ⁷ Cooper, J. (2007, October 30). Briefing Paper on the Montebello Agreement under the Security & Prosperity Partnership of North America. National Petrochemical and Refiners Association. Available online at <http://www.tcata.org/MontebelloAgreement103007.pdf>
- ⁸ *Ibid.*
- ⁹ High Production Volume (HPV) Challenge website. *See* <http://www.epa.gov/chemrtk/pubs/general/basicinfo.htm#overview>
- ¹⁰ *See* EPA Office of Pollution Prevention and Toxics (1998, November 3). Guidance for Meeting the SIDS Requirements (The SIDS Guide). Available online at <http://www.epa.gov/chemrtk/pubs/general/sidsappb.pdf>
- ¹¹ HPV Challenge website. *Op. cit.* at note 9.
- ¹² Cooper, *op. cit.* at note 7.
- ¹³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission

Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union L 396/1. Available online at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf.

REACH entered into force on June 1, 2007, although most of its key provisions will not apply until June 1, 2008. See REACH Article 141.

¹⁴ Cooper, *op. cit.* at note 7.