Briefing Paper on the Montebello Agreement under the Security & Prosperity Partnership of North America

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Introduction

On August 20-21, 2007, United States President George Bush, Canadian Prime Minister Stephen Harper and Mexican President Felipe Calderon met in Montebello, Quebec, to discuss the Security and Prosperity Partnership of North America. Upon conclusion of the meeting the U.S. Environmental Protection Agency (EPA) announced, as part of a trilateral agreement (the Montebello Agreement), a major shift in how chemicals will be addressed and managed in the U.S. The Montebello Agreement sets out a plan to coordinate risk assessment and risk management activities across North America, building on work done under the Canadian Chemicals Management Plan and the U.S. EPA High Production Volume (HPV) Chemical Challenge. The goal of the agreement is to enhance trade among the three countries, while ensuring protection of human health and the environment and retaining sovereignty.

Current and Future Chemicals Management in North America

Under the Canadian Environmental Protection Act (CEPA) of 1999, the Canadian Parliament required Environment Canada to work with Health Canada to conduct screening-level risk characterizations on all chemicals in the Canadian marketplace. As part of an already close working relationship, Canadian authorities met with their colleagues at the U.S. EPA to discuss tools and methods used in the U.S. to evaluate new chemical substances. The mandate of CEPA 1999 led Canadian regulatory authorities to devise novel and workable approaches to risk evaluation, leading to a truly tiered, targeted and risk-based approach to chemical risk assessment and risk management, which is called the Canadian Chemicals Management Plan. The initial tier makes use of conservative, predictive modeling and assimilates hazard data from chemicals with similar molecular structures—i.e., structure-activity relationship analysis, or SAR—to assist in the hazard characterization of the chemicals. Potential exposure to the substances, the other integral part of the risk equation, was characterized employing general use categories and production/import volumes. These methods allowed the Canadian authorities to evaluate 23,000 chemical substances quickly and focus scarce resources on those substances that require further study and possible risk management action.

In 1999 the U.S. EPA announced the HPV Challenge, a voluntary program in which chemical companies would sponsor toxicity and other testing on chemicals that were produced or imported at amounts greater than 1 million pounds per year in aggregate. Chemical companies responded and volunteered to provide information on over 2,100 HPV chemicals. The program has resulted in an unprecedented amount of hazard data being made available to the public. EPA has already posted initial hazard characterizations of approximately 100 HPV chemicals on the EPA Web site

(http://iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report) and will post 200 more by the year's end. The Agency says it will screen out the low toxicity chemicals first, and then use data from the 2006 Inventory Update Rule (IUR) reporting to characterize the risks of the remaining HPV chemicals that are categorized as moderately to highly toxic.

After conducting risk characterizations of the HPV chemicals, EPA says it will turn its attention to moderate production volume (MPV) chemicals, those produced or imported in amounts between 25,000 and 1,000,000 pounds annually. Like Environment Canada, EPA will use existing data, conservative modeling and structure-activity relationships to characterize the hazards of the MPVs where measured data do not exist. EPA will group MPVs in specific hazard categories, weeding out chemicals with low hazards first; then, similar to the Canadian Chemicals Management Plan, EPA will employ general use categories and production/import volumes to initially characterize the potential for exposure to the MPVs.

The hazard and risk characterizations for HPV and MPV chemicals will provide EPA with information necessary to conduct future risk assessment and risk management activities. EPA will be able to use the information to make its exposure and risk findings for potential Section 4 test rules that may require more definitive (and more expensive) testing. The Agency can also use this information as the basis for potential risk management actions. EPA announced last year that it will issue test rules each year to cover those HPV chemicals that have not been sponsored under the EPA HPV Challenge.

Potential Impact of the Montebello Agreement on International Chemicals Policy Debates

Chemicals management policy, including the legislation and regulations that result from such policy deliberations, is one of the few types of law that can directly affect a company's ability to sell chemicals into the marketplace. For the past five years, chemicals management policy has been vigorously debated throughout the industrialized world. One of the primary factors leading to these discussions is the new European Union REACH legislation, a dramatically different chemicals management policy.

The chemicals policy debates in the U.S. accelerated several years ago when environmental groups saw the European REACH system as a model to achieve their goal of banning toxic chemicals. 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. The Agreement provides regions that do not currently have chemicals management policies a rational and workable alternative to REACH. 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. Industry would also be well-served to advocate this type of chemicals management approach to international forums, such as the United Nations and Organization for Economic Cooperation and Development.