COMMENTS ON THE EUROPEAN REGULATION CONCERNING THE REGISTRATION, EVALUATION AND AUTHORIZATION OF CHEMICAL (REACH) BY THE GOVERNMENT OF CANADA

The Government of Canada welcomes the opportunity that the European Commission has provided to participate in the public Internet consultation process for the Registration, Evaluation, and Authorization of Chemicals (REACH) system. As we have expressed before, we share the goals of REACH to protect human health and the environment, and to promote innovation and competition. We also share the challenges this presents and the belief that international collaboration is an essential element in addressing them. Finally, we see this consultation as a signal of the Commission's willingness to benefit from the experience of other jurisdictions like Canada to advance the proposed regulations and their implementation.

In our response that follows, we are presenting a number of comments and suggestions relating to specific aspects of REACH, considerations relating to competitiveness, market access, international trade obligations, coordination, and finally, the benefits of strengthened international cooperation and regulatory alignment. At the same time, we identify areas where we and others would benefit from clarification about certain aspects of the regulatory proposal so that our understanding is current and our concerns can be put in better context.

It is the understanding of the Government of Canada that the Internet public consultation process is considered an early notice as stipulated under Article 2.9.1 of the WTO *Technical Barriers to Trade Agreement*. In this regard, Canada will also avail itself of further opportunities to comment on this proposal once the European Communities (EC) formally notifies the WTO as required under Article 2.9.2 of the WTO *Technical Barriers to Trade Agreement*.

Canada as a Source of Experience and Knowledge

As the Government of Canada noted in its previous comments, dated April 2002, it is of the view that REACH could have sweeping impacts on virtually all domestic industries including those outside European jurisdiction. Therefore, the Government of Canada would like to emphasize that the proposed regulation should give greater consideration to the potential for regulatory cooperation with other jurisdictions outside the EC.

As you are aware, Canada recently renewed the *Canadian Environmental Protection Act*, 1999 (CEPA 1999). Canada is at present the only other jurisdiction undertaking comprehensive prioritization and review of the risks of existing chemicals to human health or the environment. Based on experience acquired to date in this area, it is unlikely that any one jurisdiction will be able to meet this challenge from within its own resources. Canada believes that all OECD and possibly other nations should cooperate and share the burden of dealing with this legacy from the past. Innovative methods and techniques developed for the prioritization of existing chemicals for testing and assessment under Canadian legislation also offer opportunity to minimize animal testing, while still protecting health and the environment. Moreover, there is bound to be considerable overlap in the chemicals and polymers that have to be prioritized and assessed. Canada is willing to share its experience relevant to priority setting, scheduling and impact on resources, and to collaborate with the EC in meeting this challenge.

Based on our experience in OECD relating to new chemicals and to pesticides, we would like to encourage you to fully consider incorporating a provision in REACH similar to section 316 of the CEPA 1999 that would permit sharing of assessment and other information with other governments under specified conditions and restrictions including protection of confidential or proprietary data.

Canada has recently undertaken a review of its new chemicals regulatory process, resulting in recommendations to simplify and streamline the notification process, to reduce the number of schedules and eliminate unnecessary testing. One of the outcomes of the two years of consultation with industry was consensus about a broadly applicable suite of tests, the results of which support sound and effective decision-making. Other tests that are at times critical to the risk assessment and the circumstances where the regulator is most likely to request them will also be described in guidelines accompanying the regulation.

Although the REACH testing requirements are more extensive than our own for new chemicals and polymers, we are pleased with the extent to which the proposed requirements are consistent with planned changes based on the consultation recommendations. Where there are substantive differences in testing requirements, they often appear to reflect different policy preoccupations (e.g. occupational safety.)

Canada suggests that it would be mutually beneficial for Canada-EC to try to achieve greater consistency in base data required for new chemicals, in the use of exclusions and exemptions, and to promote a greater degree of flexibility in the use of waivers. Canada, for example, is currently considering reduced regulatory requirements for low concern polymers and would like to continue collaboration with others on substances of low regulatory concern. Canada has learned a lot from its relationship with Australia and would like to pass along the enormous future value of incorporating provisions in REACH for recognizing foreign notification schemes and the information that may be available from them that would directly support decision-making in Europe.

Canada and the EC have much to gain from bilateral cooperation, including cost-savings, less duplication, reduced burdens on industry and elimination of barriers to trade. The Government of Canada believes that it would be most beneficial for both sides to explore opportunities for: (1) sharing data and findings; (2) accepting or using common assessment methodologies; (3) standardizing approval packages; (4) work sharing and (5) recognizing each other's efforts in support of regulatory decision-making. Given the high cost associated with toxicological research, both financial and animal impacts, it would be beneficial for jurisdictions within the EC as well as the EC's trading partners, such as Canada, to make every effort to harmonize their requirements. The Government of Canada encourages the continuing dialogue between Canada and the European Commission on chemical risk assessment and risk management, including the development of a possible bilateral cooperation arrangement.

<u>REACH</u>

Faster, more efficient, predictable decisions would appear to be an important goal of the REACH system. The detail provided in the proposal about the responsibilities of industry, registration, testing, and evaluation is significant and impressive. However, based on our own experience where there is only one level of government involved in activities analogous to REACH, the

Government of Canada recommends simplification of the oversight that will be exercised in Europe by regulators which looks to be the Commission and Member States. We would recommend that detailed guidance be developed for regulators to ensure or enhance consistency and comparability of decisions among Member States and the European Commission. Guidance of this nature is being developed for the requirement under CEPA 1999 to systematically prioritize and assess Existing Substances, and we are very interested in sharing this as it emerges for our mutual benefit.

The Government of Canada suggests that the Commission may want to give further consideration to the use of scientifically justified surrogate data, and robustly validated Structure Activity Relationships (SARs) as a means of diminishing the amount of animal testing required, and if necessary, to extend the deadlines for registration and authorization to reduce the burden on regulated industry. We are exploring this ourselves and have a modest degree of expertise to share.

Registration

To facilitate the sharing of data, it has been suggested that industry pre-register substances. The Government of Canada strongly supports the pre-registration of substances by means of a simple postcard system. It will help identify substances in commerce, the companies involved, and the scope of the available information and testing needs.

It is not clear whether there are circumstances where the Commission will accept foreign test data or available information about existing substances that may not precisely conform to Good Laboratory Practice. Based on our experience, company labs are producing high quality data on the physical/chemical aspects of their substances yet they may not be in conformity with the GLP requirements. In this case, we are considering flexibility while at the same being rigid where it concerns toxicological testing. If the Commission considered a similar approach, there would be reduced testing burden on industry and it could help the EC meet its international trade obligations. The Government of Canada would welcome additional clarification of the resource implications of the proposed system, which appear to be considerable. Additional consideration of the implications of the duty to register significant new uses for downstream users, which are often small and medium-sized enterprises (SMEs), is also advised.

Evaluation and Data sharing

The Government of Canada shares the EC's concern about the lack of information on existing substances. Canada believes that OECD countries and industries that have benefited from these substances being on the market have a responsibility to make this information public. Canada believes that the EC's narrow focus on "free riders" may set back the achievement of an open global inventory of suitably assessed substances. The Government of Canada encourages the European Commission to set up information exchange procedures with its major trading partners.

The Government of Canada would also like to underline the importance it attaches to a predictable and reliable process for the assessment of chemical substances. Clarification of the process for setting priorities and assigning responsibility and recognition of the need for guidance for consistent interpretation of what is required under the proposed REACH system is advised.

Authorization

The Government of Canada is of the impression that authorizations can only be granted to individual applicants. We would welcome dialogue on whether alternative or compatible options may also be available including more general-purpose authorizations. Such thinking might alleviate administrative burdens that might be disproportionate for organizations such as SMEs. Given its experience under CEPA 1999, Canada is also of the opinion that it may be useful to consider providing the authority to extend sunset dates for the authorization of certain substances of concern. While decisions based on risk assessment and socio-economic impact study would be analogous to Canada's regulatory process, it is important to define "unacceptable risk" to eliminate confusion and possible unintended barriers to trade. The Government of Canada would like to know if the decision to designate a substance as dangerous will be made on the basis of a risk assessment.

Consortia

The efforts of the European Commission to encourage industry to form testing consortia to share the costs of developing assessment data are laudable. Precise rules governing cost sharing, dispute arbitration, and market access are needed. Canada believes that some uncertainties remain with consortia.

Canada operates an open chemical inventory – once chemicals are added anyone can manufacture and import them. REACH appears to limit the use of chemicals to members of testing consortia. New entrants to the market would have to buy-in to the consortia and may find equivalent testing they have conducted will not be recognized. It is important to ensure that consortia facilitate market access and do not result in anti-competitive behavior.

Canada would like further clarification on the following questions. How to recognize existing data where provided by a non-member of a consortium? How to resolve differences in test results when submitted by different suppliers? How to establish priority with regard to submission of animal test data when two submitters provide data, the second submitter carried out the tests earlier in time than the first submitter did? What is the basis for refusing to accept animal test data from other than the first submitter, where the testing was conducted prior to the passage of REACH? How will questionable animal studies be dealt with when subsequent studies are not being accepted?

The Government of Canada would find it useful in obtaining further clarification on the roles and responsibilities of various parties over the lifecycle of the chemical are unclear. The Government of Canada would like the European Commission to provide clearer guidance and criteria that establish when and to what extent the participants have a duty to transmit additional information through the supply chain.

REACH may have a serious financial impact on Canadian industry exporting chemical substances to the European Union (EU) marketplace. While Canadian industry may choose to become partners in various EU testing consortia sharing the costs and preparation of submissions, the Government of Canada would appreciate clarification of the implications for Canadian exporters who are not members of a consortium and who may want to export substances to the EU market.

Some aspects of the functioning of these voluntary consortia may lead to the creation of undue barriers to market entry and may need further considerations.

Canada would like further clarification about how issues of equivalency will be addressed under REACH. For example, Canada would like to know more about how substances from different sources and manufacturing processes that are deemed to be equivalent; mixtures and articles will be treated under REACH.

Further consideration regarding the handling of data considered to be confidential business information for substances where production processes are proprietary would be very helpful. REACH calls for the unprecedented disclosure of data about production, and planned use, product composition, and other potential commercial secrets. This is definitely the case for patented substances or processes. Industry may insist on protecting this data. This aspect of consortia formation also merits further exploration.

Competitiveness

Any regulatory proposal should be accompanied by a thorough analysis of its potential business impacts, and attempt to mitigate its impacts on regulated industries. Canada acknowledges the difficulty of quantifying the economic impacts of REACH. Costs associated with registration, testing and dossier creation could be considerable. Canada would also like to note that the impact would be most severely felt on SMEs and that the chemical specialties sector would have to carry a disproportionate share of the burden. Although the proposed regulation outlines cost-sharing mechanisms many substances may have to be withdrawn from the market as a result of the cost of compliance. Increased compliance costs could also result in significant shift in industrial investment, leading to a decline in research and innovation. SMEs depend heavily on innovation to remain competitive and stay successful, and the role of these enterprises in the economy is significant. Consequently, Canada is concerned that REACH may reduce chemical industry trade, inhibit innovation by SMEs, and limit the range of chemical products available to downstream users.

Classification and Labelling

The Government of Canada believes that REACH should be consistent with the Globally Harmonized System (GHS) for classification and labeling. It is Canada's understanding that implementation of the GHS will be included in Phase 2 of the proposed regulation. The timing of Phase 2 appears to be years away.

All EC Member States and the European Commission have agreed to the WSSD Plan to implement GHS by 2008. Canada would like to know if the EC expects to meet its commitment for implementation of GHS by 2008. The Government of Canada would like further clarification of the EC's intentions and whether it will be able to meet its WSSD commitments.

Scope

The Government of Canada believes in the importance of being consistent with other OECD members in their approach to classification, including exclusions and exemptions. For example, if

naturally occurring materials such as crude oil, natural gas and coal are excluded from the registration process, naturally occurring ores and concentrates should also be exempt from registration.

Recyclable materials are included within the management scope of the draft regulation. Given the significant review, attention, and regulatory management controls currently applied to these substances, Canada questions the benefit of including hazardous recyclable resources destined for recovery operations in the scope of the draft regulation. These materials are subject to strict international regulations within Europe, OECD and the United Nations.

The European treatment of polymers also differs considerably from that of its other trading partners. There appears to be the need to more clearly define how inorganic alloys and inorganic intermediates will be treated by the proposed regulation. The differential application of REACH to inorganic and organic raw materials may create unfair competitiveness issues in common applications where substances derived from both types of raw materials compete. Consideration could be afforded to the acceptance of an inclusive risk assessment for a family of alloys and intermediates of an individual elemental metal. Canada would appreciate receiving further clarification as to how the EC will address this issue.

The Government of Canada would also like to express its concerns as to how the proposed legislation may handle "articles". We believe it should be limited to those articles where a hazardous ingredient may be released under reasonably foreseeable conditions of use or abuse, including release on ultimate disposal of the product. If REACH includes all articles under its umbrella, it may become an expansion of the use of process and production methods (PPMs) in distinguishing products by looking at how they are made.

International Harmonization

The Government of Canada believes that differences between the European and American approaches to chemical management will become more apparent as dialogue on the REACH proposal continues and that this may represent an example where impacts on market access may result. This potential situation raises the important question of international cooperation in chemicals management. The Government of Canada would like to reiterate the importance and the need for international harmonization. Given the high costs of toxicological research, both financial and animal impacts, Canada believes that all jurisdictions should make every effort to harmonize their requirements. With respect to REACH, it can not be emphasize enough that further regulatory cooperation should be encouraged among the EU's major trading partners in a way that will continue to ensure the protection of health and environment while ensuring a fair market access to all.

While REACH requirements tend to indicate that industry will have to prove virtually all substances in use are safe, Canada has identified priority substances for testing. In this respect, Canadian industry is not left in as great uncertainty while still achieving similar end results. There also seems to be two separate mechanisms for authorization under REACH; one at the state level and one for the Community, which may ultimately come into conflict.

Canada would like to conclude by reiterating its belief that Canada, the European Union and other jurisdictions share in the challenge of protecting human health and the environment while enabling our citizens to experience the benefits of safe chemicals. The proposals put forward relating to REACH are important because they are demanding engagement of all stakeholders to achieve the objectives in an effective and sustainable way. This consultation and the dialogue that will continue will be important in shaping how chemicals will be managed in the future and how countries and companies can cooperate to achieve our objectives. We hope that the Commission will continue to view Canada as a venue where ideas can be tested, experience can be drawn and collaboration can emerge.