



January 20, 2009

Trade Negotiations Consultations (European Union)  
Foreign Affairs and International Trade Canada  
Regional Trade Policy Division (TBB)  
Lester B. Pearson Building  
125 Sussex Drive,  
Ottawa, Ontario  
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**RE: DEPARTMENT OF FOREIGN AFFAIRS AND INTERNATIONAL TRADE  
CONSULTATIONS ON POSSIBLE COMPREHENSIVE ECONOMIC AGREEMENT  
NEGOTIATIONS WITH THE EUROPEAN UNION**

BIOTECanada appreciates the opportunity to provide comments on the *Consultations on Possible Comprehensive Economic Agreement Negotiations with the European Union* published in the Canada Gazette on December 20<sup>th</sup>, 2008. BIOTECanada is the national trade association representing nearly 200 companies across the entire spectrum of agriculture, health and industrial biotechnology sectors. Our mission is the sustainable commercial development of biotechnology in Canada. In behalf of BIOTECanada, I would like to provide the following recommendations with regards to measures affecting exports destined for the EU including regulations and standards applied to agricultural biotechnology products such as food labeling and traceability, policy regarding animal cloning, approvals of agricultural biotechnology products, data exclusivity period for high-technology medicinal products and a regulatory framework for subsequent-entry biologics.

**BIOTECanada's advice, views and experience regarding measures affecting exports destined for the EU:**

**Technical Barriers to Trade – including technical regulations, standards and/or conformity assessment procedures, and sanitary and phytosanitary procedures:**

- **Labeling and Traceability:** Mandatory labeling should only be required in the EU where there are known allergenicity, toxicity and nutritional issues associated with the product. If the food is compositionally equivalent to other varieties, labeling and traceability should not be required. Canada's Food and Drug Regulations require mandatory labeling only if there is a health or safety concern, from allergens or a

significant nutrient or compositional change. The regulations permit voluntary positive labeling on the condition that the claim is not misleading or deceptive and the claim itself is factual. Voluntary negative labeling is permitted on the condition that the claim is not misleading or deceptive and the claim itself is factual. Mandatory labeling is only required when genetically engineered products have a significant health, safety or compositional change. There are no traceability requirements for the commercialization of agricultural biotechnology products in Canada. Traceability and labeling are not scientifically defensible and could force manufacturers to avoid biotechnology products. This could pose a significant technical barrier to trade. The EU must align with Canadian policies regarding labeling and traceability to eliminate the potential trade barrier posed by such policies.

- **Cloning:** Regulations and policies regarding cloning must be based on credible peer-reviewed science. Clones must not be considered genetically modified or novel. Canadian and EU policies regarding the trade of cloned animals must recognize that the progeny of clones are physiologically indistinguishable from conventionally bred animals and that they are safe for human consumption, as indicated in the European Food Safety Authority (EFSA) Scientific Opinion on Animal Cloning, published in 2007. Ethical and Animal welfare issues related to cloning should not inform policy decisions on cloning as they should be based on science and food and environmental safety.
- **Approvals of Biotechnology Crops:**

Over 50 agricultural biotechnology products are awaiting approval in the EU incompatibly with the timelines foreseen in the EU legislation for product approvals. Science-based, timely decisions must be made in compliance with the WTO report where in, under Annex C91 (a) of the Agreement on the Application of Sanitary and Phytosanitary Measures, it was indicated that European communities must undertake biotech approvals without undue delay.

In order to facilitate more timely approvals, the evaluation of submissions should take precedence over other scientific matters related to agricultural biotech dealt with by EFSA. Thereafter, the Commission should propose draft approval proposals to Member States respecting the legally binding timeframe. Member States should show confidence in EFSA's scientific opinions in their decision making by approving products that have been assessed as safe. Moreover, individual Member States should not restrict farmer access to approved products through arbitrary and illegal localized bans and coexistence rules. Any review of risk assessment and guidelines for GM food and feed or of environmental risk assessment guidelines must also include a mechanism to ensure that new guidelines are not applicable to products that are already in the approval process and allow adequate transition time for companies to adapt their testing methodologies and practices. In addition, companies that based their dossiers on negative segregants as

comparators prior to the EFSA GMO panel decision that a negative segregant is not sufficient as the only comparator, should not be forced to start over.

Canada has a robust agricultural biotechnology industry and a well established science-based regulatory process that has completed over 80 biotechnology crop approvals. A strong economic partnership between Canada and the EU will be successful in agriculture when there is compliance with WTO obligations and there is alignment of policy and regulation of the products

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- **Support CODEX:** EU and Canada must support the CODEX work on the low level presence (LLP) of biotechnology grains in traded commodities. In the interim, the European Union must develop a pragmatic approach to the management of low level presence of products that have been recognized as safe based on internationally recognized criteria.
- **Raise Public Awareness:** Canada and EU Member States must increase their contribution to the education of citizens about the benefits of agricultural biotechnology, the safety of the products and the strength of the regulatory frameworks in place. Approaches to sustainable agriculture development must be science-based a non-discriminatory towards agricultural biotechnology that has been proven to be safe.

### Protection of Intellectual Property Rights

- **Data Exclusivity Period for High-technology Medicinal Products:** The European Union has established a period of ten-years of data exclusivity for high technology medicinal products including biotechnology products. This period of exclusivity as described in the Directive 2001/83/EC Section 10 provides an intellectual property incentive for the development of novel biotech therapies and vaccines that is superior to that which Canada recently implemented through amendments to the Food and Drug Regulations. BIOTECanada believes that a successful economic agreement between the Canada and the European Union would require Canada to adopt this longer period of data exclusivity in order to ensure equivalent incentives for the development of innovative biotechnology products in Canada.
- **Regulatory Framework for Subsequent-Entry Biologics:** The European Union through the European Medicines Evaluation Agency (EMA) has established a regulatory review system for Subsequent-Entry Biologics (biosimilars). This regulation is defined in Article 10(4) of Directive 2001/83/EC and Section 4 Part II, Annex I of this Directive as well as in Guidelines of the Committee for Medicinal Products for human Use (CHMP) Directives CHMP/437/04 and CHMP/BWP/49348/2005 and CHMP/BMWP/42832/2005. These directives and guidelines provide a clear regulatory framework for the approval of SEBs in the European Union. They require reference products to be approved in the European Union and they clearly establish the terms of data exclusivity for innovator

products within the system as well as the clinical trials required for approval of a SEBs. Within the framework of economic discussions we believe that Canada should adopt a similar rigorous, transparent and innovation promoting regulatory system for SEBs.

BIOTECanada believes that there are significant benefits to be gained from the establishment of closer economic relations with the European Union. The purpose of these negotiations should be to enhance commerce and investment in both economies. We strongly recommend that the Government of Canada adopt positions that result in policies and agreements that stimulate investment in biotechnology across industry sectors through greater market access for Canadian products, for clear and transparent regulatory systems and through world-leading intellectual property protection incentives for innovative companies.

We appreciate the opportunity to provide these comments and look forward to participation in future discussions on this important initiative.

Sincerely,

(signed)

Philip Schwab  
Vice President, Industry Affairs  
BIOTECanada