

October 12, 2011

Dr. Susan Preston,
Environment Canada
Ecosystems and Biodiversity Priorities
18th Floor,
351 St Joseph Blvd
Gatineau, Quebec, K1A 0H3
Canada

Re: Canada's potential signature of the Nagoya Protocol on Access to Genetic Resources

Dear Dr. Preston,

On behalf of BIOTECCanada's members, we would like to provide our perspective on Canada's potential signature of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. BIOTECCanada is the national trade association representing over 230 companies across the entire spectrum of agriculture, health, and environmental and industrial biotechnology sectors. BIOTECCanada would like to thank the Canadian government for the opportunity to contribute to this dialogue and for the efforts of the Canadian government that has put in the negotiation and conclusion of the Nagoya Protocol.

Our comments and perspectives on ABS are guided by the principle that robust and predictable intellectual property (IP) protection regimes are absolutely critical to the development of innovative industries in Canada. As Canada strives to position itself in an increasingly competitive global economy, innovation has become critical to Canada's continued success. As participants in a knowledge-based economy, Canadians have a vested interest in their Government striving for a best-in-class IP protection regime domestically, and that we vigorously promote and defend IP rights internationally. Care must be taken in both areas to ensure that the policies that are developed enable the ability of research-based companies to invest in the research, development and commercial application of new agricultural and industrial biotechnology and biopharmaceutical innovations.

We understand that there are several critical issues yet to be resolved on the international protocol and we would like to provide you with the perspective of our members, who are assessing the Protocol but do not yet have a firm view as to whether the Canadian government should or should not sign the Protocol. Nonetheless, we have identified several issues of concern, if the Protocol were to be implemented:

- It must be implemented in a manner that sets out clear and transparent rules that provide legal certainty and, more generally, contribute to an enabling environment for innovation.
- As noted in the discussion document, for example, the Nagoya Protocol does not contain any provisions concerning changes or introduction of new requirements into intellectual property laws. It is essential that any implementation adhere to this model.

- We are aware of proposals of several CBD Parties to introduce new requirements, e.g., requirements for disclosure of origin or source of genetic materials (or for evidence of prior informed consent and benefit-sharing) in the patent system. Such proposals were made in the negotiations leading up to the conclusion of the Protocol and are being made currently at the WIPO. We remain steadfastly opposed to any such proposals. For reasons explained in great detail in prior industry comments, such proposals would inhibit innovation in the biotechnology sector by creating a minefield of legal uncertainty and potential liability that would undermine valuable intellectual property. As a result, innovation and incentives to invest in biotech would be eliminated, even where there was no bad faith or illicit activity by a company or researcher. Without an ability to attract investment, Canada's biotech industry and related jobs would disappear.
- We also understand that other CBD Parties are advocating that the "compliance" measures in "user" jurisdictions should include use of intellectual property or other regulatory offices as "checkpoints" for ABS. Similarly, we steadfastly oppose such attempts to integrate the ABS rules into other regulatory areas, e.g., concerning intellectual property or marketing approval regimes for pharmaceutical or agricultural chemical products. The implementation of the Protocol should avoid such an approach in favor of a single "checkpoint" that would be the National Focal Point or competent authority, e.g., the agency that would have authority over the ABS laws.
- In addition, we note that the discussion paper states that the Nagoya Protocol applies solely to those genetic resources acquired after the entry into force of the Protocol in any particular country. It is important that any implementation adhere to this principle of prospectivity. To do otherwise could subject companies to liability through ABS laws for alleged "misappropriation" that may have taken place decades before – even when there is no evidence of bad faith or illicit activity.

BIOTECanada greatly appreciates the position that the Government of Canada has taken to date in these international negotiations in opposition to the inclusion of new disclosure requirements within the patent system specifically and on the issues of retroactivity and scope. We ask that the Government of Canada maintain these reasonable and defensible positions in opposition to any proposals that would seek to undermine the current balance of rights and obligations that exist within the Trade-Related Aspects of IP Rights Agreement and related international agreements.

We appreciate the Government of Canada's continued collaboration and consultation with our respective industries on this important topic. We look forward to working with Environment Canada, the Department of Foreign Affairs and International Trade, Industry Canada and other federal departments, P/T governments, and other stakeholders to help provide practical solutions and an industry perspective on both international and domestic ABS related issues.

Sincerely,

Peter A. Brenders,
President & CEO

