Date: April 4, 2018

The Honourable Lawrence MacAulay, PC, MP Minister of Agriculture and Agri-Food House of Commons Ottawa, ON, Canada K1A 0A6

Subject: Driving Investment in Plant Breeding Innovation

Dear Minister MacAulay,

The seed and grain industries collectively contribute over \$50 billion annually to the Canadian economy in addition to improving the health and well-being of Canadian consumers and the environment. As the industry co-chairs of the Seed Sector Value Chain and Grains Roundtables, we work closely with industry and government leaders from across the crop sector on priority issues impacting Canadian competitiveness and profitability.

Agriculture is a highly competitive, innovative business, and Canadian producers operate in an increasingly integrated global marketplace. Against this already competitive backdrop, Canada has set the ambitious goal of growing our agri-food exports from \$55 to \$75 billion annually by 2025.

Innovation in seed and grain must be a driving force if Canada is to meet this target. Seed is the fundamental mechanism for delivering innovation to our farmers, and grain contributes more than any other sector to Canada's agri-food exports, with 90 percent of some of our commodities destined for international markets.

Given Canada's reputation for agricultural innovation and our history of success exporting products of biotechnology, we should be standing at the forefront, championing and encouraging the adoption of the newest tools that will drive innovation in seed and grain. Tools like gene editing systems can bring new varieties to the market faster and with lower costs than ever before. These varieties are higher yielding, healthier for consumers and the environment, and will improve food security while continuing to maintain Canada's high expectations for safety. Canadians should be poised to reap the economic and social benefits of plant breeding innovations.

Yet this is not the case. Our roundtable members are increasingly concerned with the state of Canada's readiness to adopt the newest cutting-edge innovations, and we see Canada at risk of losing our share of global investment in the newest technologies.

Budget 2018 recognizes that regulatory systems can act as innovation bottlenecks, preventing or delaying innovators from acting on new opportunities. Our seed and grain stakeholders have identified a pressing need to update the delivery of Canada's regulatory programs for plants with novel traits, novel

foods and novel feeds, to ensure we remain competitive with our trading partners. This view is uniformly reflected in recent industry policies including:

- The Seed Synergy Green Paper on the Next Generation Seed System
- The Canada Grains Council Policy Position on Plant Breeding Innovation
- CropLife Canada's Driving the Canadian Advantage

Canadian regulators are respected internationally for their science-based approach to regulating agricultural biotechnology. However, there are a number of challenges embedded in the delivery of our unique regulatory approach that will only be amplified by the coming global revolution in plant breeding R&D. These issues are already causing a drag on innovation and investment in Canada and discouraging the use of cutting-edge innovations among small and medium-sized companies and public researchers. Please consider:

- Twenty percent of the novel products approved in Canada were not subject to similar regulation elsewhere in the world. This means Canadian innovators faced lengthier times to bring these varieties to market and higher costs, in some cases reaching millions of dollars.
- Regulatory processes for agricultural biotechnology and plant breeding innovation in the US and Brazil are reportedly providing faster and clearer decision-pathways. Investment dollars are following.
- Recent research proposals for the development of gene-edited varieties in Canada have either been refused, delayed or modified due to regulatory concerns. We estimate that 20 to 30 percent of plant breeding research proposals are affected by these concerns every year.
- Researchers working in highly-valuable but small acreage crops have said that gene-editing
 techniques will not be pursued until there is a clear provision on how the resulting products will
 be regulated. Some have considered developing these varieties in the US or elsewhere, instead
 of in Canada.

There is much opportunity to provide greater predictability, transparency and efficiency within the existing scope and delivery of the CFIA's and Health Canada's programs for plants with novel traits, novel foods and feeds. We are asking for your commitment to undertake and support an AAFC-led exercise to update the delivery of these programs, to ensure that they are not inadvertently causing a drag on innovation and that Canada will not be left behind other OECD countries. Safety must always remain first and foremost, but beyond safety, the specific outcomes we would like to see from this exercise are detailed in the attached.

Thank you for your consideration.

Jeff Reid, Industry Co-Chair,

Seed Sector Value Chain Roundtable

Rick White, Industry Co-Chair,

Grains Roundtable

Encl.: Rethinking the Delivery of Regulatory Programs: Desired Outcomes

cc. Mr. Paul Glover, President, Canadian Food Inspection Agency
Mr. Chris Forbes, Deputy Minister, Agriculture and Agri-Food Canada
Honourable Navdeep Bains, PC, MP, Minister of Innovation, Science and Economic Development
Mr. John Knubley, Deputy Minister, Innovation, Science and Economic Development
Honourable Ginette Petitpas Taylor, PC, MP, Minister of Health
Mr. Simon Kennedy, Deputy Minister, Health Canada

Mr. Neil Bouwer, Assistant Secretary, Regulatory Reviews and Skills Review, Treasury Board Secretariat

Rethinking the Delivery of Regulatory Programs: Desired Outcomes

An exercise to update the Canadian Food Inspection Agency's and Health Canada's programs for premarket safety assessments of plants with novel traits, and novel foods and feeds must deliver on four outcomes:

- 1. Improved guidance and clarity for Canadian innovators on the interpretation of Canada's novelty-based regulatory trigger.
 - Measure of success: Innovators will be able to consult a single piece of
 government guidance to confidently determine if a product would trigger
 regulation in Canada. If the innovator seeks confirmation from federal regulators, a
 clear process will be available that provides an answer within a reasonable period
 of time.
- 2. The current case-by-base approach to safety assessment will be updated, based on scientific advances and Canada's vast regulatory experience. CFIA and Health Canada will codify the tiers that exist informally within the current system, and provide greater predictability and transparency of data requirements and product-review time-frames.
 - Measure of success: An innovator developing a lower-risk, lower-complexity or familiar product will have a service standard and transparent data requirements that are less than those for higher-risk, more complex or unfamiliar products.
- 3. Recognizing that global investment dollars flow to regions with the most efficient regulatory systems, Canadian regulators will examine their processes and remove any unnecessary complexities resulting from the existence of three separate offices which assess the food, feed and environmental safety of new products.
 - **Measure of success:** Assessments conducted by the three offices are streamlined to the full extent possible without compromising safety.
- 4. Recognizing that the global regulatory environment for biotechnology is complex, duplicative, cost-prohibitive for many innovators, and carries a risk of significant trade disruptions, Canadian officials will take steps to improve these conditions and reduce unintended barriers to market entry for plant breeding innovations.
 - Measure of success: Differences in the scope of Canadian and other countries'
 approaches to plant breeding innovation are minimized and the treatment of
 conventional breeding is aligned to the extent possible. Asynchronous approvals
 are avoided or managed. Trading partners are able to exchange sufficient
 information about products in the marketplace, their respective approaches to
 regulation and general product safety in order to facilitate two-way trade.