

TOWARDS A MORE EFFICIENT AND PREDICTABLE REGULATORY SYSTEM FOR PLANT BIOTECHNOLOGY IN CANADA

2015 Pre-Budget Consultation Submission to House of Commons Standing Committee on Finance

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WHO WE ARE

CropLife Canada is the trade association representing the manufacturers, developers and distributors of plant science innovations, including pest control products and plant biotechnology, for use in agriculture, urban and public health settings. We are committed to protecting human health and the environment and we believe in driving innovation through continuous research.

CropLife Canada is a member of CropLife International, a global federation representing the plant science industry and a network of regional and national associations in 91 countries.

Our mission is to enable the plant science industry to bring the benefits of its technologies to farmers and the public. Those benefits manifest themselves in many different forms, including driving agricultural exports, job creation, strengthening the rural economy and increased tax revenue for governments.

Increased production due to crop protection products and plant biotechnology generates \$7.9 billion worth of additional economic activity annually for farmers of field, vegetable and fruit crops. About 65 per cent of Canada's \$10 billion food surplus can be directly attributed to increased yields as a result of modern farm practices, the use of crop protection products and biotechnology. Canada's canola industry, for instance, saw a 20 per cent increase in yields between 2000 and 2009, attributed largely to improved genetics.

The pace of innovation in the industry is increasing. For example, between April 2010 and March 2011, 177 new varieties of seeds were registered by the Canadian Food Inspection Agency. Seventy-nine per cent or 139 of those varieties were registered by private sector seed companies. Biotechnology was a strong driver of this growth. Globally, companies invest about 11 per cent of their profit directly back into research and development, about the same percentage as seen in the pharmaceutical sector.



EXECUTIVE SUMMARY

Canada's plant science industry has a proud history of encouraging and facilitating innovation that has been immensely beneficial to farmers, consumers and the environment. Canada's climate of innovation at present is a good one relative to many other nations. Our science based regulatory system is sound and durable, not only serving Canadians well but acting as a strong model for nations around the world.

There is, however, a risk that Canada may be left behind as biotechnology booms around the globe. In order to keep pace with what will certainly be sharply increasing number of novel traits seeking approval, there is an urgent need for the Canadian Food Inspection Agency (CFIA) and Health Canada to undertake regulatory review, eliminating duplication and providing increased speed and predictability for innovators. This is in keeping with the spirit and recommendations of the Red Tape Reduction Action Plan.

We understand and support the need for regulations that safeguard the public and give them confidence in the safety of Canada's food supply. At the same time, it is vital for governments to understand the role of regulatory reform in building a climate for innovation and investment. We need the leadership of CFIA and Health Canada to acknowledge this imperative, and to commit to working with industry towards a mutually agreed plan on streamlining and harmonization. This initiative does not require legislative or regulatory change. What it does require is an understanding of the challenges that increased innovation will pose, and a determination to keep Canada's regulatory system modern and flexible.

Our industry's ability to act as an engine for innovation and growth is dependent entirely on the foundation of a predictable, efficient science-based regulatory system. In the area of plant biotechnology, that system now requires changes to improve efficiency. In order to help drive jobs and investment, we would ask the Government of Canada to help us meet this goal.



ISSUES SURROUNDING REGULATORY REFORM

The members of CropLife Canada have long-term frustrations with Canada's regulatory system for plant biotechnology. In short, it increasingly lacks timeliness, transparency and predictability.

This has created unnecessary impediments to plan and launch our innovations both domestically and globally. While our regulatory managers attempt to deal with submissions on a case-by-case basis, frustrations have mounted and hindered the kind of confidence that is necessary for a well-functioning system.

We believe that there is the possibility to directly address our concerns in a manner that will increase speed, improve predictability and reduce the use of scarce government resources, while maintaining Canada's regulatory technical rigour.

We have made a detailed submission to both Health Canada and CFIA, outlining the regulatory changes that we believe would improve efficiency. Again, these recommendations do not involve legislative or regulatory change, but simply the elimination of duplication and changes in practices at the agency level.

We believe that our recommendations would ensure that Canada continues to support very substantial innovations at home that result in significant economic benefits, national job creation and global leadership.

There has now been two decades of experience with plant biotechnology regulation. During this time, companies have acquired top notch capacity to develop safe products and understand the implications for prudent utilization. This is reflected in the improved yields and farm gate receipts for farmers who have benefited from these agricultural innovations.

In this same period, the regulatory agencies have developed the human resource capabilities to assess the implications of potential new products entering the market. Therefore, this is no longer an unknown science, but one that is fully understood, with ongoing safeguards to ensure the public's confidence.

Our report to CFIA and Health Canada contains recommendations that align with the short and long-term needs of government, as well as meet the concerns of the industry in a manner that will:

- Free up scarce government resources;
- Support the modernization and transformation agenda;
- Be the catalysts for the kind of culture shift that regulators are promoting;
- Create the conditions for Canada to be the 'best in class' regulator of innovative and safe products;
- Build a regulatory environment that supports entrepreneurship, investment and innovation; while ensuring
- A regulatory system that is anchored in evolving science.



There are important benefits that we also wish to secure for our industry. It is critical that we improve the current system so that we can:

- Assure competitive benefits to Canadian growers;
- Facilitate timely launches of products in Canada;
- Deliver substantial economic benefits and job creation; and
- Enable Canadian corporate operations to lead their companies' global launches.

The CropLife member companies are recommending that the government of Canada commence streamlining and improving processes, and adopt new approaches within the current system.

In addition, we believe it is both timely and imperative that Canada establishes a modern system of regulatory service standards, while charging requisite user fees.

We ask the government to agree to work with our industry in order to achieve an average elapsed duration for submission reviews of one year, and accomplish this within the next 24 months. Furthermore, we believe that the government can set a target of a net reduction in government resource utilization within an improved system.

Again, it is important to underscore that we are not seeking changes in legislation, nor alterations in regulations. We do not challenge the regulatory mandates given to the Minister of Agriculture and Agri-Food Canada and the Minister of Health. We do however believe that the Canadian Food Inspection Agency (CFIA) and Health Canada can jointly agree to streamline and improve certain processes and thereby achieve significant gains for all parties.

Canada's plant biotechnology sector stands at an important crossroads. While we are immensely proud of the contributions we have made to Canada's thriving agriculture and agri-food sectors, we know that there is so much more that can be done. The pace of innovation in biotechnology will be increasing significantly over the next decade, and we believe that Canada can, and should, capture benefits from this growth and be amongst the world leaders in this sector. This can only happen, however, if the will exists to modernize the regulatory framework governing biotechnology.

Thank you for giving us the opportunity to express the views of our members. We would welcome the opportunity to explore these issues further with the Committee as you continue your Pre-Budget deliberations.