

# Innovation Topics and Priorities in the Seed Sector

## Summary Report of Planning Workshop



Ottawa October 26-27, 2005



*This report is to serve as a record of discussion only. This record will be presented to the National Forum on Seed members at the December 07, 2005 meeting for the purpose of facilitating decisions on next steps and further work to be assumed by the Forum. Approval of any of the recommendations from this record will be determined by the Forum.*

This consultation and planning workshop, convened by the **National Forum on Seed**, brought together about 30 key stakeholders and resource persons for a focused discussion on innovation needs and issues facing the seed industry. The ideas raised during the October 26 brainstorming sessions were far-ranging and diverse, but several common themes emerged as the group shared their observations and perspectives on industry needs, barriers and opportunities, and specific issues related to Plants with Novel Traits (PNTs). They also reviewed current and anticipated events and initiatives which could impact innovation in the seed sector. (A summation of some of the key points from these discussions appears at the end of this report.)

A small group of workshop participants met on October 27 to review the outcomes of the previous day's in-depth discussions and to develop recommendations for further action by the Forum. In particular, the group sought to identify areas that could be addressed by, and benefit from, the unique national convening and consensus-building role of the Forum and its Working Group process. The results of the Planning Workshop will be presented to the National Forum on Seed when it meets in Winnipeg in early December, at which point the Forum will determine whether and how to act on these recommendations.

## CONCLUSIONS

Of the many factors which impact on innovation and commercialization in the seed sector, the following elements were seen as being the most critical for future success:

### 1. Environment for Investment

Fostering a positive investment climate for the development and adoption of plants with higher value traits requires clear, transparent and predictable

policies and regulations. Moreover, the regulatory system needs to be internationally credible and capable of responding in an appropriate and timely manner as scientific advances and shifts in market demand occur. In order to maintain and improve the current investment climate for plant breeding in Canada, participants cited the importance of strong Intellectual Property protection (IPP), identity preservation (IP), and clearer PNT guidelines that are more responsive on the basis of actual risk associated with the novel trait.

### 2. Profitability and Shared Benefits

Return on investment is clearly a driver in attracting investment into research in both the public and private sectors. But participants pointed out that innovation challenges in the seed sector also include the extent to which risks and benefits can be equitably distributed. Crop and livestock producers cannot capture the value of better crops nor afford to purchase the products of innovation unless agriculture production has a sound profit base. Continuous innovation requires the entire chain, from plant breeder through end user, to be able to extract value in a fair and reasonable way, reflecting both the investment they have made and the risks they have taken.

### 3. Infrastructure

Adequate human resources and physical infrastructure are crucial inputs to successful innovation. Canada is better off than many others in this regard, but does have weak spots, including declining public sector investment in research, aging facilities and equipment and waning expertise/capacity in traditional crop breeding and seed physiology.

### 4. Public Attitudes and Education

General attitudes and public support for entrepreneurship have a bearing on innovation and commercialization in all sectors, including seed. Additionally, user perceptions about the merit or potential drawbacks of new processes and products strongly influence market acceptability. Health and environmental concerns—both real and perceived—will continue to play a significant role in shaping the Canadian regulatory framework for plant breeding and

the commercialization of plants with novel traits. Informed discussion and debate are needed if that framework is to fulfill its dual purposes of fostering innovation and protecting consumers and the environment. Therefore, more effort is required to educate and inform both the general public and those within the seed sector and its value chain about the risks and benefits involved in developing and adopting higher value plant traits. This should include expanding knowledge and understanding of the current regulatory system and future options, including ways to better identify and quantify potential harm and to vary regulatory requirements based on these different levels of risk.

### 5. Research Strategy

Coordination among key industry players, government and universities is seen as crucial to continued success in the research and development side of Canada's seed sector. Several workshop participants cited the need for an overall national strategy to set goals both private and public sectors could work towards and develop priorities that everyone could work within.

## PRIORITIES AND RECOMMENDATIONS

Based on the foregoing conclusions, the core group is bringing forward the following priorities and recommendations:

### 1. National Research Strategy

There was broad consensus that the seed sector and its value chain would benefit from a more focused and inclusive approach to innovation. Responsibility for moving in this direction is widely dispersed, but the National Forum on Seed could stimulate and encourage government leadership in this area. Therefore, it is recommended that:

**the National Forum on Seed convey to the federal government its support for the development of a national strategy on research and development for the seed sector and, in the interim, provide input regarding seed industry needs**

**and priority issues to appropriate planning venues and initiatives such as Agriculture and Agri-Food Canada's Agriculture Science and Innovation Consultations.**

### 2. Profitability and Shared Benefits

There was a very strong sentiment among workshop participants that innovation cannot be sustained in the seed sector without benefits accruing throughout the value chain, reflecting the investment and risk that each component takes on. Of particular concern at the present time is the issue of adequate returns in the primary agriculture production sector. However, this issue is broader than the scope of the Forum and there was no consensus on what a Working Group could accomplish at this time. It is recommended that:

**the National Forum on Seed recognize the critical importance of ongoing profitability throughout the crop production chain and endorse the desirability of sound government policies and regulations which ensure that the benefits of innovation in the seed sector can be captured and shared by the entire value chain from crop breeders to seed growers, crop and livestock producers, processors and end users.**

### 3. Plants with Novel Traits (PNTs)

There was consensus that the regulations governing PNTs should be reviewed, clarified and possibly revised to ensure that they do not constitute an unnecessary barrier to innovation and commercialization, particularly related to new traits resulting from conventional plant breeding techniques. There was support for increased clarity with regard to the case-by-case regulatory assessment of PNTs as it relates to lower risk plants. There was also interest in the idea of a single administrative window for PNT applicants so they would not have to run separate gauntlets for food, feed and environmental assessments. It is recommended that:

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**the National Forum on Seed establish a Working Group to explore ways of making the current regulatory system for PNTs work better for everyone.**

#### 4. Adventitious Presence

There was consensus that health and environmental concerns warrant strict controls on genetically modified plants that have not been approved for production in Canada. However, when such plants have been approved for growing in Canada or other countries, it was acknowledged that it may be difficult, and in some instances practically impossible, to prevent a low level of adventitious presence. Workshop participants cited a need for the Canadian regulatory system to recognize this reality and expressed a willingness to work with the appropriate departments and agencies to assess the risks associated with unavoidable, low levels of commingling and to develop ways to handle this within the regulatory and crop breeding, production and management systems. Therefore, it is recommended that:

**the National Forum on Seed establish a Working Group to explore regulatory policies which recognize that the level of risk associated with genetically modified plants varies and that some acceptance of a very low level of adventitious presence may be required within the Canadian regulatory and management systems.”**

#### **WORKSHOP DISCUSSION BACKGROUND**

The following summarizes some of the key points raised by individual participants during the October 26 workshop sessions:

##### 1. Industry Needs

- Money—a mix of public and private investment—is key. There is particular need for more \$ for early stage development and proof of concept work.

- An overall climate that encourages innovation is vital. It needs to be present in business, government, education system, and broad public culture.
- The importance of equitable distribution of added value benefits across the entire development and production chain cannot be overstated. Profit for all components is necessary in order to sustain risk taking and innovation.
- Need continued and improved ability to differentiate and segregate value in the marketplace and transportation system. Coexistence of grain with totally different characteristics to serve different markets requires cooperation and a strong will to make our system work. Ability to guarantee quality of exports remains crucial. But transportation system also needs to support domestic marketing, so changes are desirable; for instance, could we load and seal containers for specialty crops?
- Not enough resources to do everything, so Canada needs a national R&D strategy on biological processes and products that would set goals and recognize and address barriers. Such a strategy must involve governments, universities and private industry.
- Intellectual Property protection tools are essential, including a policy on patenting life forms.
- Plant breeders and those investing in crop innovation need a timely, predictable regulatory environment that is internationally credible/compatible.
- Need to have commodity groups, processors, and seed sector working with government so regulation and certification systems reflect consensus on what specifications and guarantees can/should be offered; we should speak with one voice when it comes to health claims and other endorsements.

- Regulatory processes affecting innovation, as well as oversight of post-innovation production and use, need to be based on potential harm; we don't need burdensome regulations where there is no significant potential for harm.
- Regulatory system needs to be adaptable to change (niche crops, emerging markets).
- Besides \$, you need people, facilities, equipment and international access to plant material. Some erosion has been observed in public sector investment in research infrastructure and getting new concepts to the commercialization stage.
- Industry needs to capitalize on crop leftovers and by-products and plan on basis of whole plant; extracting value from straw, hulls, etc. could add needed profit throughout value chain.
- Canada needs to stay competitive in existing markets at same time as pursuing higher value traits for new markets. Innovation efforts must renew our base (i.e. improve input traits and add value to old crops) as well as developing new products and processes.
- Enhanced producer education on markets is required so there's fuller understanding of the consequences of unintended leakage of new products into the general commodity stream.

## 2. Barriers and Opportunities

- Reward system for plant breeding not optimal; publishing papers tends to be more valued than patents in public and academic sectors; different reward systems for breeders at different universities, AAFC, private companies.
- Current regulatory system seen as both a barrier and an opportunity. Deficiencies cited included lack of harmonization (domestic and international), uncertainty (e.g. definition of

PNTs, regulations for production of pharmaceuticals in containment), lack of communication with regulators, and uneven enforcement. On the other hand, a strong science-based regulatory system around new plant traits was seen as a marketing asset. Canada's IP system was seen as generally effective in protecting and extracting value, though some outstanding issues were mentioned related to recourse, liability and corrective action.

- Opinions varied on how Canada's regulatory system should be positioned internationally. By and large, confidence in the current regulatory systems was seen as an advantage to be exploited in international markets. Some expressed the view that we are focusing too much on having a unique Canadian system to police health claims and should just work to the U.S. system. Others saw emphasis on harmonizing regulations with the U.S. as a barrier to branding Canada in other markets. Some felt the regulatory system was biased towards exports which may be impeding innovations that would allow producers to capitalize on domestic market opportunities (e.g. baking industry).
- There is opportunity to compete on quality rather than quantity.
- Joint ventures with other countries (e.g. China) are worth considering.
- Invasive species legislation may be a barrier to importation of needed plant breeding inputs.
- There is some perception that Health Canada legislation/regulations do not adequately support development of functional foods, nutraceuticals and biopharmaceuticals.
- Public ignorance and lack of acceptance of biotechnology is a barrier that needs to be addressed through public education.
- Seed certification system may be a barrier or

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opportunity depending how well the system is working and adapting to changing needs. Current system is field inspection based and the need for change to better address end user requirements should be assessed.

### 3. Plants with Novel Traits

- PNT definition needs to be clearer.
- PNT regulations are an irritant, but not a barrier, for large companies; smaller breeding programs are potentially more obstructed by novelty triggers requiring them to submit test results and other information.
- Novelty is currently triggered relative to “in Canada”, but since Canadian plant breeding frequently uses germplasm sourced outside Canada, this is perceived by some to be problematic. A suggestion was made to change the regulation to refer to “accepted range for the species” rather than “species in Canada”.
- Variety Recommending Committees may have expertise that could help determine when something is a novel trait; perhaps they could play an advisory role in PNT triggers/regulation.
- We should make a distinction between Genetically Modified Organisms (GMOs) and PNTs created by other means, and consider handling outputs of traditional development differently (i.e. they should be subject to different regulatory triggers) than those which have been genetically engineered.
- There are advantages of case-by-case flexibility of current regulations, but also many misperceptions and unknowns. If the regulatory net is cast too widely relative to low risk innovations, data requirements will discourage innovation. Separate assessments for feed and food safety and for potential environmental harm add to administrative burden and complexity.

- Opinions varied on whether Canadian PNT regulations should be stand-alone or whether they should be harmonized or synchronized internationally.
- Safety is, and should be, key driver in regulations for PNTs. Consumer knowledge and protection is also important (buyers getting what they are paying for). So we need full breeder/grower/producer awareness and cooperation and strong regulatory enforcement for any leakage resulting from “unapproved events”. At the same time, zero incidence of adventitious presence is a practical impossibility which regulatory system must somehow take into account with respect to “approved events”.

### 4. Upcoming Events, Activities and Policy/Regulatory Initiatives

The following are current or forthcoming events and initiatives that may impact innovation in the seed sector:

- Agriculture and Agri-Food Canada Science and Innovation Consultations (current)
- Coexistence Conference, Montpellier, France, November 2005
- CWB Coexistence Conference, November 2006
- WTO negotiations, Hong Kong Ministerial, December 2005
- Canadian Biotech Strategy Renewal
- Canadian Food Inspection Agency Variety Registration Proposal, March 2006
- PRRCG Reorganization, February 2006
- Industry Canada National Conference on Bio-Products & Bio-Based Economy, 2006
- Review of Canada Grain Act
- Bio-Safety Protocol Meeting, Brazil, 2006
- Canadian Grain Commission Review (soon)