## EXECUTIVE SUMMARY

From March 2–4, 2004, the Canadian Food Inspection Agency (CFIA) hosted a technical workshop on the segregation and handling of potential commercial plant molecular farming (PMF) products and by-products. Participants included representatives from the PMF industry, federal government bodies, agricultural and agribusiness associations, and experts in grain handling and identity preservation (IP). This workshop was a preliminary step in developing an appropriate regulatory framework for commercial PMF in Canada.

As many of the novel plants currently being developed for PMF are known food and feed crops, such as safflower and alfalfa, a first step in developing a regulatory framework was to take a closer look at whether PMF products and by-products can be adequately segregated from other commodities, more specifically, from commodities intended for the food and feed chains. Workshop outcomes are summarized below.

This report is meant to be an accurate reflection of the workshop proceedings. Please be aware that the views and personal opinions of participants expressed during the workshop have been included for accuracy but do not necessarily reflect the views of the CFIA. In addition, the objective of the plenary discussions was not to seek consensus among participants but rather to provide a forum for participants to share their expertise, views, comments and recommendations.

### Grain Handling and Transportation Systems

Participants generally agreed that the conventional bulk grain handling and transportation systems are not well equipped to safely handle most PMF crops, though they may be adequate for crops expressing low-risk novel products, such as food processing enzymes. Many participants also felt that categories of risk for PMF products should be established and that the stringency of regulation for each category be commensurate with the associated risk.

Participants believe that accidental commingling of PMF crops with other commodities may be reduced if the number of steps in commercial production systems is limited. In particular, many participants suggested that, when possible, harvested PMF products be transported directly from farm to processing facility. In addition, it is believed that commodities sold at a premium price will provide an added incentive to producers and suppliers to minimize product loss along the production chain. In this context, many participants feel that PMF crops expressing low-value novel products are those that will pose the greatest risks.

### IP Programs

Although existing IP programs are not designed to deal with potentially hazardous materials or their containment, workshop participants generally agree that IP programs are a good starting point for drafting appropriate closed-loop confinement systems for commercial PMF. Risks associated with novel PMF products will vary greatly, and their individual production systems (including audit requirements) should be designed to be commensurate with their risk.

Workshop participants also observed that the regulation of commercial PMF will not be solely the CFIA's responsibility. Where pharmaceutical production is concerned, Health Canada's regulatory oversight will come into play, and provincial and municipal regulations may also apply with respect to the disposal both of PMF by-products and of waste materials from processing.

**Detection Methods**

It is anticipated that, as a major requirement for approval of commercial PMF production systems, applicants will need to submit appropriate detection methods for novel products.

Challenges facing laboratories with regard to detection tests include the sample type collected (i.e. raw material versus processed food), the technical feasibility of implementing a testing method, the detection limit of available tests, and the absence of required information for developing and carrying out detection tests (i.e. lack of co-operation from developing companies in allowing access to confidential business information, such as company-developed detection tests, DNA sequence of novel gene of interest, etc.).

It was also emphasized that laboratories are only capable of certifying that the level of a particular novel product in a sample is undetectable, as a test will not certify the absolute absence of a novel product in a sample.

Workshop participants discussed, in plenary, the advantages and disadvantages of DNA-based, protein-based, biochemical, and phenotypic detection methods.

**Gaps in Knowledge and Science**

Workshop participants identified gaps in knowledge and science, which they felt should be addressed before a regulatory framework for commercial PMF is in place. These gaps include, but are not limited to, acceptable detection tests for novel products, presence and persistence of novel products in by-products/waste, pathways (other than unclean equipment) which contribute to the movement of seed outside of confined area(s), and methods by which to measure toxicity/allergenicity exposure of novel product to workers (through handling or accidental ingestion).

**Code of Best Agricultural Practices for PMF**

Participants also helped in the preliminary development of a table of contents for a code of best agricultural practices for PMF, by detailing information/requirements which they believe should be included in such a document. The CFIA hopes to resume its collaborative efforts with the United States Department of Agriculture (USDA) to include, in an appendix, a code of best agricultural practices for PMF in the Canada–U.S. bilateral agreement.

**Next Steps**

Next steps include expanding, in collaboration with colleagues from USDA's Animal and Plant Health Inspection Services (APHIS), the table of contents for a code of best agricultural practices for PMF and finalizing a Memorandum of Understanding (MOU) between the CFIA and Health Canada that will outline each organization's respective responsibilities in the assessment and authorization of plants with novel traits (PNTs) intended for PMF. As well, the CFIA will continue to work with Health Canada to develop an appropriate regulatory pathway, leading to the development of regulatory directives for commercial PMF in Canada.