Grain Industry Working Group on Genetically Modified Wheat

Conditions for the Introduction of Genetically Modified Wheat

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Executive Summary

In December 2001, a group of farmer, grain industry, technology developer, customer and government representatives joined together to form the Canadian Grain Industry Working Group on Genetically Modified (GM) Wheat. The Working Group's membership and mandate is in Appendix 1.

The primary task the group took on was to develop a comprehensive set of conditions that would be necessary to meet before a GM wheat variety could be released. The enclosed document is the result of the Working Group's discussions to date.

At the time of release of this document in draft form in December 2002, members stressed that there was a need to discuss these conditions thoroughly throughout the industry and that the document did not represent the final opinion of the Working Group members on this topic. It also did not necessarily represent the views of each Working Group member's organization. The document was circulated to others in the grain industry and further dialogue ensued. This version of the document incorporated changes that were suggested during that process.

This set of conditions is comprised of four broad areas: market acceptance, segregation systems, agronomic information and cost-benefit analysis.

To begin, the Working Group endeavored to develop a definition of market acceptance. Rather than define a list of countries or a certain percentage of wheat markets that must be willing to purchase GM or co-mingled GM and non-GM wheat, the condition developed by the Working Group is that there must be identified markets for the entire production of GM or co-mingled wheat for multiple years. In addition, anticipating that demand for non-GM wheat in many markets will continue for the foreseeable future, there must be the ability to meet requirements in non-GM wheat markets, including the establishment of achievable tolerance levels for GM wheat in non-GM wheat shipments.

Consideration was given to a situation where it may not be possible to maintain all current non-GM markets. This would happen, for example, in markets where there are no established tolerance levels for GM wheat (i.e. zero tolerance). It is possible that in some cases the loss of some markets is more than compensated for by potential benefits, agronomic or otherwise. Because the loss of markets could be irreversible, this would have to be carefully evaluated by conducting a comprehensive cost-benefit analysis, outlined below.

In order to maintain access to non-GM wheat markets, it is imperative that an effective segregation system be developed. It was envisioned that if GM wheat was introduced, part of the solution would be to introduce it through a closed-loop segregation system that attempts to ensure the entire production goes to identified GM wheat markets. This is only part of the solution, however, and the greater challenge would be segregating and monitoring conventional or non-GM wheat shipments from farmer to customer.

Central to such a monitoring system is accurate, inexpensive and quick technology capable of detecting the presence of GM wheat at the primary elevator and beyond. It was envisioned that quantitative and qualitative technology would be required at different points in the wheat value chain.

The development of the condition for segregation systems raised some very difficult issues requiring further discussion, such as the establishment of clear lines of accountability and liability through the appropriate mechanism. The conditions document also identifies that costs must be identified and shared appropriately among industry participants. However, rather than define who pays and through what mechanism, options for further

consideration are outlined. It was pointed out that regardless of who pays at first, ultimately farmers pay all these costs. The question is then to which farmers the costs should be directed, those who adopt the technology or those who do not.

On the subject of agronomics, the Working Group developed a set of questions that must be answered prior to the introduction of GM wheat. These include the impact GM wheat introduction could have on management practices and profitability with respect to each type of farming operation (e.g., conventional tillage, conservation tillage, organic, pesticide-free, etc.) across a multi-year rotation. As well, the Working Group believes that research is required to assess the larger agronomic risks such as contamination and spread, the development of resistance and the cost and management of volunteers.

Although each condition must be met on its own accord, the interaction of these different attributes must also be measured in a comprehensive cost-benefit analysis. This allows a balancing of the risks and costs in some areas with benefits in others. The cost-benefit analysis must incorporate possible market benefits and costs, including segregation costs, as well as agronomic benefits and costs. The approach outlined also incorporates the use of option value, which suggests that when there is some uncertainty as to future benefits and costs associated with an irreversible decision, that there is always some benefit to waiting.

Finally, the Working Group suggests that a consultation process is necessary to solicit agreement by farmers, grain companies, customers, technology developers and marketers that all elements are in place, that costs are appropriately shared, that liability is clearly outlined and acceptable to all parties, and that the benefits of the commercial production of GM wheat outweigh the risks and costs.

Outline

A. Introduction

The following outline is a broad set of conditions that must be in place before a genetically modified (GM) variety is released in Canada. Each of the conditions must be met individually and then evaluated collectively in the overall cost-benefit analysis.

Throughout this paper the terms “genetically modified” and “GM” are used. They are intended to refer to products of modern biotechnology in the narrow definition of that term. In the Cartagena Protocol on Biosafety text modern biotechnology is defined as “the application of: (a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) fusion of cells beyond the taxonomic family that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.”

B. Market Acceptance

1. Defining Market Acceptance

Defining market acceptance for a particular product requires flexibility and must be done on a case by case basis. Generally, however, market acceptance does not mean that every wheat customer has to be willing to buy GM wheat. There do have to be, however, identified markets for the GM product, as well as the ability to meet the needs of key non-GM markets so that farmers are not negatively affected by lost market access. The following elements must be considered in defining market acceptance for each product. Whether or not a certain market should be considered key depends upon, among other things, the relative return and volume that market represents.

a) Regulatory Approval

- The most basic condition for market acceptance is that there must be regulatory food, feed, and environmental safety approval, whichever is applicable, in the country of destination. But this is not a sufficient condition and regulatory approval does not necessarily result in a customer's willingness to purchase.

- Where regulatory approval has not been received, an achievable tolerance level for unapproved events must exist in order to be able to market non-GM wheat into those markets given the potential for the adventitious presence of GM wheat in non-GM wheat shipments.

b) Identified Markets for GM Wheat

- Market acceptance means that markets for GM wheat have been identified. In the case of GM wheat for domestic human consumption and/or export, customers must have expressed to the CWB their willingness to purchase GM wheat or co-mingled GM and non-GM wheat at competitive prices.

  In the case of GM feed wheat destined for the domestic market alone, customers must be identified by the technology developer.

- Markets for off-grade GM or co-mingled or geographically isolated wheat must be identified.

- Markets must be assured for the entire quantity of GM wheat intended for production or co-mingled wheat expected for multiple years.

c) Ability to Meet Non-GM Market Requirements

- In those markets where acceptance of GM wheat is not forthcoming, a recognized non-GM certification system including achievable tolerance levels for the presence of GM material in non-GM shipments must be established.

- A certifying agency must be prepared to verify that the customer requirements can be met with available technology and systems (e.g., the Canadian Grain Commission is prepared to issue the Certificate Final).

- Tolerance levels must be physically possible and economically feasible to meet. (The International Grain Trade Coalition is proposing a tolerance level of five per cent.)

  Tolerance levels must be defined for each stage of the supply chain. For example, tolerances will be tighter at the seed level than for farmer deliveries than for cargoes.

2. Market Harm

Without adequate market acceptance, market harm can result. The extent of market harm must be estimated and evaluated against any possible market, agronomic or other benefit expected.

Market harm exists if all of the following conditions are present:

- Major customers have indicated that they will not purchase GM wheat and require certification that their shipments do not contain GM wheat. This may be because they require "GM-free" certification for their customers, or they must meet government import controls or labeling requirements, or they export products processed from the wheat into markets that have in place import controls or labeling requirements.

- Alternative suppliers are able to provide "non-GM" wheat to those markets.

- It is not possible to provide sufficient assurance that the shipment is "non-GM", i.e., the tolerance level is not achievable, or the cost of doing so is prohibitive and makes the product noncompetitive relative to non-GM wheat available from other exporters.

C. Segregation Systems

The necessary segregation system principles must be developed for each product based on the potential market benefits and risks. As one part of efforts to prevent co-mingling of GM and non-GM product streams, a closed loop system is outlined for the handling of GM wheat upon introduction. An equally important part of that quality control system is a monitoring program for the handling of conventional wheat, outlined in Section C.2.

1. Closed Loop System for GM Wheat Based on CFIA Contract Registration Guidelines[1]

It is not suggested that Contract Registration would by itself be an effective solution for GM wheat segregation issues, nor that GM wheat would necessarily even be registered under this category. However, the segregation model developed for Contract Registration could be used as a basis for the closed loop system for GM wheat, as long as the other conditions in this document are satisfied.

a) Quality Control System

- The applicant must submit a proposed Quality Control System (QCS) in the form of a quality manual to be used by the relevant parties for the handling of the variety. Components of the QCS include, but are not limited to the following.

b) Management Responsibility

- A written statement of potential adverse effects that could result if the variety were to enter the traditional commodity channels.
- Who is responsible for ensuring the quality policy is followed and the variety is handled appropriately.
- Commitment that the quality policy for the variety is understood, implemented and maintained at all levels of the organization.

[1] From on Canadian Food Inspection Agency. "Quality Control System Requirements for Varieties Subject to Contract Registration". http://www.inspection.gc.ca.

- Submit procedures, internal quality audits, and their documentation.

c) Training of Personnel and Communication

- Submit and maintain documented procedures for training needs.
- Provide appropriate training of all personnel involved in the QCS.
- Indicate the level of availability of QCS. procedures documents to personnel.
- Indicate how the results of audits and quality management systems will be communicated to personnel having responsibility in the area audited.

d) Contract Review

- Each contract should be reviewed by the management representative.
- Records of such contract reviews should be maintained.

e) Product Identification and Traceability

- Documented procedures and records for identifying the variety during all stages of seed and crop production, handling, processing, storage, delivery and use.
- This will include procedures for monitoring of growers' fields, identifying harvested product, processed product, etc. to ensure that the quality policy has been addressed by contract adherence.
- Where isolation distances are required, documentation of actual isolation distances used must be maintained. Any non-conforming procedures or product must be identified, including deficiencies in documentation.

f) Inspection and Testing

- Inspection and testing to ensure the specific product quality requirements are met including the testing of harvested products.

g) Control of Non-Conforming Product or Process

- Any seed or harvested product that does not conform to the specified standards is prevented from entering traditional commodity markets or being used as seed for further planting.
- Where isolation distances are required from surrounding traditional commodity crops, and where these distances were not maintained, details must be provided on the disposal of seed or grain produced within the required isolation zone.

h) Corrective and Preventive Action

- Investigating causes of non-conformities,
- Immediately notifying those individuals/growers/organizations concerned,
- Developing and implementing a corrective action plan to prevent recurrence,
- Analyzing all processes, work operations, quality records and service reports to detect,
- Identify and eliminate potential causes of non-conforming product
- Initiating preventive actions to address potential non-compliance;

i) Control of Records

- Records shall be maintained by all parties involved to demonstrate achievement of the required quality policy.
- Product identification and traceability
- Monitoring, audit, inspection and testing results
- Records of nonconformance
- Disposal/action records
- Reviews of QCS.
- Training of personnel on the QCS.
- Contract reviews
- Record retention times.
- Records must be clear, legible, readily retrievable and accessible.

j) Other Elements Not Included in Contract Registration Guidelines But Requiring Attention

(1) Customer(s) identified for entire production of GM wheat for multiple years, plus an alternative plan if customer does not follow through.

(2) Identification of the appropriate authority and third party auditing conducted prior to the implementation and during the first year, to be potentially scaled back based on performance, including identification of compliance requirements.

(3) The availability of a driveway test (see C.2 and C.3 for further discussion).

2. Monitoring Program for Conventional Wheat

There must be in place a legal definition of what varieties are eligible to be delivered as conventional wheat. This would be in the form of class eligibility lists and varietal declarations. In addition to that, a sampling and testing program must be in place to ensure that GM wheat is not misrepresented upon delivery to the elevator or movement to terminal. System to include, but is not limited to, the following elements (further detail to be developed based on the Canadian Grain Commission's proposed Variety Eligibility Declaration system).

a) Quality control procedures, documentation and training in place

b) Detection technology

c) Testing through a pilot project and other means

d) Dispute settlement mechanism established

e) Monitoring program in place

f) Clear lines of accountability and liability that are related to the causes of the problem are established through the most effective mechanism, including legislation

g) Costs must be identified and appropriately shared among industry participants according to level of responsibility.

3. Detection Technology Requirements

a) Ensure that required technology is in place throughout the system and that users (i.e., elevator managers, testing labs) are trained to use it

b) The technology must be in place for one full year prior to introduction of the GM variety

c) An assessment of elevator manager's capability to use the technology conducted through random sample testing

d) Technology also required to test for all foreign GM wheat varieties

e) The same detection technology is required for farmer deliveries, rail car unloads, etc.

f) For all types of tests, a sensitivity level must be identified, related to acceptable tolerance levels.

g) Appeal mechanism in place if a farmer's delivery or grain company shipment is rejected based on the test results, strip or lab.

h) Technology required

- Qualitative tests, which yield a yes/no result, are generally less expensive than quantitative tests, which yield the percentage of GM material in a sample. Qualitative tests will be used in most cases along the supply chain. Quantitative tests would be used to back up qualitative tests and on the final cargo shipments to customers. The following outlines how the two tests would be used at different points of transfer.

- Qualitative strip – deliveries to country elevator. Initial check for GM wheat at the primary elevator with a strip test. This will be a rapid (at least less than 10 minutes and for practical operational reasons less than three minutes is preferable), inexpensive ($10 or less), qualitative (yes/no), protein-based test that will determine the presence of GM wheat at a desired level of sensitivity (as low as possible, but definitely less than 1%).

- Quantitative PCR – deliveries testing positive. Deliveries testing positive for GM wheat will be segregated and samples will be tested using quantitative PCR. This is a lab-based detection, slower and more expensive.

- Quantitative PCR – train sample. When trains are loaded and in transit to port (or domestic or US customer), quantitative detection on the loading sample (either each car or a train composite) will be required, with results available before car unload.

- Quantitative PCR – vessel sample. At the terminal, load out samples will be tested for a quantitative verification prior to vessel departure.

4. Potential Costs and Options for Cost Sharing

A condition for the introduction of GM wheat is that costs must be identified and appropriately shared based on responsibility. The following outlines some options for how costs would be shared. Further discussion is required to determine the best alternative.

Regardless of who pays at first, ultimately farmers pay all these costs. The question is then to which farmers the costs should be directed, those who adopt the technology or those who do not. Any potential for a market premium for either the GM or non-GM product must be considered when determining the appropriate cost-sharing mechanism. However, based on examples from other commodities, there is unlikely to be a market premium in most cases.

The costs listed below are those that can be expected even with a functioning segregation system. The ultimate cost, however, would be system failure resulting in lost markets and contract penalties.

a) On-farm segregation

Option 1 Both GM and non-GM farmers cover own on farm segregation costs.

Option 2 Levy on GM wheat seed sales to cover monitoring and segregation costs of non-GM wheat. This could be point of sale (i.e., based on seed purchased) or end-point (i.e., based on tonnage produced or sold). The administrator of the fund and rules around dispersing the fund would have to be determined. Levy fund would cover non-GM farmers' on farm segregation costs.

Option 3 Federal government assists GM and non-GM farmers to pay for the implementation of certification programs.

b) Post farm segregation and monitoring costs (e.g., sampling and testing of non-GM and GM wheat deliveries and shipments, special handling requirements and fees)

Option 1 Technology developer pays all post farm segregation and monitoring costs directly.

Option 2 CWB pool covers monitoring and segregation costs (i.e., costs are shared among all producers equally, with the exception of farmers selling into the domestic feed market).

Option 3 Levy fund covers segregation and monitoring costs for non-GM wheat shipments.

c) Contamination costs (e.g., contract penalties, demurrage and unforeseen costs)

Option 1 Technology developer pays the costs of contamination directly.

Option 2 CWB pool covers costs (i.e., costs are shared among all producers equally, with the exception of farmers selling into the domestic feed market).

Option 3 Levy fund serves as insurance fund to cover costs of contamination.

D. Agronomics and Stewardship

1. A clear understanding of the impact commercial release would have on the management practices and profitability with respect to each type of farming operation (e.g., conventional tillage, conservation tillage, organic, pesticide-free, etc.) across a multi-year rotation.

2. Sufficient research completed to assess agronomic risks, including, but not limited to:

   - Contamination and spread through mechanisms such as pollen flow and physical handling, including research on selection pressure.

   - Development of weed, insect or disease resistance (depending on the agronomic trait).

   - Cost and management of volunteers.

3. Agronomic factors reviewed by a panel of agronomists. Their analysis would be reviewed during consultation process outlined below.

E. Positive Cost-Benefit For Farmers

An analysis of the market and agronomic benefits and the market and agronomic risks and costs, for all production and marketing systems, and for technology adopters and non-adopters. The required elements of the cost-benefit analysis are as follows: [2]

1. Agronomic Impacts

a) Yield impact

   - A comparison of the yield of the GM wheat versus conventional and existing wheat varieties.

   - This is dependant on the type of agronomic benefit the new variety may possess, the current prevailing conditions and any benefit the new variety confers. For example, for a herbicide-tolerant crop, this is dependant on the level of weed infestation and subsequent control provided by the herbicide used by the producer, plus any impact of crop injury compared to the conventional wheat herbicides.

b) Cost of production

   - A comparison of the cost of producing the GM wheat versus conventional and other GM wheat varieties in commercial production. Includes the following elements if applicable:
     - Seed cost
     - Herbicide cost
     - Insecticide cost
     - Other form of value-sharing between the farmer and the developer

[2] Based on: Holzman, J.J., W.H. Furtan and R.S. Gray. "The Optimal Time To Register Genetically Modified Wheat in Canada". University of Saskatchewan. January 2002.

c) The interaction between GM wheat and other crops in the farmer's rotation.

Possible sources of impact include:

- Volunteer GM wheat in other crops in the rotation that may result from harvest losses and the cost to control those volunteers. This is of particular importance if the GM wheat is herbicide-resistant and if there are other crops resistant to the same or other herbicides in the crop rotation.

- Rotational concerns if the GM wheat is herbicide-resistant and that herbicide is used for chemical-fallow, as a spring burn-off chemical, and as a pre-harvest desiccant. If tillage is required the following years on a minimum-till operation, consideration must be given for the additional fuel and labour costs for the producer.

- If the GM wheat seeds spread into neighbouring fields it would also force neighbouring producers to change their weed management practices and increase the costs for non-adopters.

- Rotational considerations and refuge areas must be considered for insect-resistant varieties.

2. Market Impacts

a) Market benefit

- The particular market benefits, i.e., premiums, incremental sales and increased market share into premium markets, and value-added benefits, that the GM variety may provide.

b) Lost market revenue

- Markets into which Canada would no longer be able to sell wheat because it could not provide the necessary "GM-free" guarantee (see definition of Market Acceptance above), the tonnage and relative return to pool in each market.

- The potential impact of contamination in non-GM shipments, including breach of contract.

- The extent of trade diversion and the impact of increased tonnage going into markets that are indifferent to the product.

- The impact of logistical constraints caused by introducing another stream of products in the supply chain (e.g., reduced flexibility to blend and apply grain from different shipments in the event of supply problems).

- The impact of carry over stocks and the potential cost of storage and lack of cash flow for farmers.

- Lost reputation and damaged customer relations.

c) Segregation costs

- The total cost of implementing a segregation system is dependent on a number of factors including specific agronomic traits of the crop (i.e. the potential for variety out-crossing), testing costs and procedures, and the requested tolerance levels for GM contamination.

3. Real Option Value

- The use of option value is based on the concept that there is a value to postponing an irreversible investment. If the value of the investment opportunity increases, the decision maker has the ability to exercise the option to invest. If the value of the investment opportunity declines, the decision maker can leave the option unexercised. The loss of this option value should be factored in as an opportunity cost when determining the total cost of an investment opportunity.

4. Expected Net Return

- The expected net returns from introducing GM wheat are the direct production benefits associated with the new technology. The expected returns are calculated by taking the difference in net returns for both GM and non-GM producers before and after the introduction of GM wheat.

- The impact of introducing GM wheat must be evaluated for all groups potentially affected.

5. Irreversible Market Cost

- The market impacts from introducing GM wheat are treated as an irreversible cost. After the new technology is introduced into the environment it may be impossible to reclaim all of the genes. Therefore, it would be difficult to revert to a non-GM production system, making the market costs associated with the technology irreversible.

- The irreversible market cost is determined by estimating the expected reduction in the price of Canadian wheat exports due to the introduction of GM wheat. Assuming no segregation of GM and conventional wheat, the price discount will affect all wheat produced in Canada.

- Irreversible market cost includes the reallocation of trade and loss of premium markets.

6. Irreversible Environmental Costs

- The persistence of volunteer GM wheat will affect the profitability of other crops in the farmer's rotation, particularly the cost of controlling volunteer GM wheat in future crops for both adopters and non-adopters of the new technology.

- The cost of controlling volunteer GM wheat depends on the type of crops and tillage system used by the producer (e.g., the variety is herbicide resistant that there is already another crop resistant to that herbicide in the rotation, the farmer employs a zero-tillage system that rely on the specific herbicide for weed control in the spring.

- The total environmental cost associated with GM wheat is the sum costs of controlling volunteer GM wheat for both adopters and non-adopters.

F. Consultation

1. Consultation process to solicit agreement by farmers, grain companies, customers, technology developers and marketers that all elements are in place, that costs are appropriately shared, that liability is clearly outlined and acceptable to all parties, and that the benefits outweigh the risks and costs.

Appendix 1:
Canadian Grain Industry Working Group on Genetically Modified Wheat

Mandate

The Canadian Grain Industry Working Group on Genetically Modified (GM) Wheat will:

- Provide a forum for the exchange of information among industry participants on the issue of the potential introduction of GM wheat.
- Assemble existing information and identify additional information required to conduct a full assessment of potential benefits, costs and risks associated with the potential introduction of specific GM wheat varieties. Topic areas will include potential impact on markets, agronomic practices and the grain handling system.
- Define a set of conditions under which GM wheat could be introduced in a manner that would satisfy the concerns of customers, farmers, and other industry stakeholders.
- Define steps to be taken to satisfy these conditions, including recommendations for an effective segregation system for GM wheat, quality certification and monitoring, accountability and liability.

The Working Group will concentrate mainly on the immediate issue of assessing the possible introduction of Roundup Ready™ wheat, but will necessarily consider the impact of potential future GM wheat and barley varieties and other crops where relevant.

The Working Group does not intend to make a firm recommendation on whether Roundup Ready™ wheat should be introduced. It also does not intend to deliberate on the adequacy of the current food and environmental safety assessment process for Plants with Novel Traits.