

CSTA Response to the Issue of Mechanisms to Address Market Access/International Regulatory Approval of GM Crops

February 25, 2003

Section A: Background Statements

The issue of market access is frequently raised during discussion of the Variety Registration review. The CSTA position paper, *Variety Registration in Canada*, December 3, 1998 includes the following comment.

The CSTA position would require that procedures be science based and predictable. International market approvals of seed and/or "products of" would not be acceptable to include in registration criteria. Many potential markets are not predictable and could radically change within months due to weather disasters or market forces like exchange rates. If a new market develops, would varieties currently in production need to be withdrawn? How enforceable is such a requirement? While markets and customer acceptance are essential, the approval procedures for international shipments will probably be determined by other international agreements such as the Biosafety Protocol.

The CSTA response to the FAAR questionnaire as part of the Variety Registration Review was:

**Written comments submitted by CSTA January 31, 1999 to:
The FAAR Biotechnology Group Inc.**

6. Should social, political or trade factors also be considered within the context of merit in variety registration? Please explain why:

"DO NOT AGREE"

All the above factors are subject to change from one year to another and subject to vagaries of many external and uncontrollable factors ranging from weather disasters to exchange rates. How can a Variety Registration Committee anticipate such factors and will the Registration Committee and Variety Registration Office be held liable for approving varieties which subsequently cause a loss of market due to a change in social, political or trade factors?

As additional background information, the issue was discussed during the *Advisory Committee on Variety Registration Meeting (October 11 & 12, 2001)* and the following is recorded in the minutes:

Mechanisms to Address Market Acceptance/International Regulatory Approval of GM Crops

G. Watson provided the background for discussion. He indicated that the product rather than the process of genetic modification is regulated. Once the health and safety requirements are met, the VRO cannot refuse to register a variety if it meets all of the merit requirements. There has been some pressure to consider market acceptance (socio-economic factors) when making registration decisions. However, it is important to remain science-based so that all plants with novel traits (PNT's) are looked at objectively. If socio-economic factors were to be evaluated as part of the variety registration process, then it would have to apply to all varieties, not just PNTs.

Confined research trial guidelines allow for a maximum of five trials, each no more than 1 hectare/province. This will be extended in 2002 to include trials of unapproved PNTs to generate data for registration.

Discussion:

Market acceptance and foreign regulatory approval are two separate issues. It is recognized that the variety registration system may not be the best mechanism to handle either. However, there is concern that there does not seem to be another regulatory body to deal with this issue at this time.

Some breeders have invested considerable amounts of time and money into the development of a PNT before they find it cannot be commercialized because regulatory approvals are not in place in key markets and the market is not yet ready to accept it.

Some short and longer term solutions were suggested. In the short term, marketing organizations could set up industry committees to deal with the market acceptance/international regulatory approval of

new traits. In the longer term, new legislation may need to be developed to control the marketing of agricultural, horticultural and ornamental GM crops.

The Canadian Wheat Board (CWB) and other members of the Canadian Grain Industry Working Group on Genetically Modified Wheat have developed a draft discussion document entitled '*Conditions for the Introduction of Genetically Modified Wheat*' containing conditions for the introduction of genetically modified wheat in Canada. A copy of the document can be obtained from the CWB website, "Hot Topics", Biotechnology.

The CWB position on this issue is the following:

Under the current registration process, a new variety will be registered for commercial production if it meets science-based criteria for end-use quality, agronomic quality and disease resistance. There is currently no process in place to prevent the introduction of a new variety even if it is clear that the new variety will have a negative market impact and will result in lower farmer returns. The CWB is seeking to have the federal government include market impact as an additional criteria for the introduction of a new variety.

The Agriculture Policy Framework (APF) pillar for *Science and Innovation* speaks of the need for the "right environment to foster innovation".

The Government of Canada and provincial and territorial governments working with industry are considering a range of options on how best to meet these goals. One option is to build and strengthen communication links throughout the value chain. Another is for Canada to promote the establishment of science-based domestic and international standards. This would help capture new and premium markets around the world and maintain existing ones. Yet another option is to develop a national strategic approach to attract foreign investment in Canada's agricultural life sciences.

Section B: Analysis

Previous CSTA statements remain valid and CSTA is supportive of CFIA current position that market access not be included in the mandate of Variety Registration. Members of variety registration committees are appointed to consider science-based criteria such as agronomics, pathology or quality. The ability to forecast future markets often eludes the best efforts of professional marketing groups and there is no reason to believe that the Variety Registration Committee or CFIA have the expertise to accept that responsibility. As an example, in 1995 when the first PNT canola was approved, was China even on the "radar screen" as a potential new market?

If Variety Registration is not appropriate, is there a need for some other regulatory body to address this?

Some points to consider are:

- Variety Registration applies to very few crop species and the issue of market access may soon apply to other species with PNT's including horticulture and ornamentals.
- Market access, or the lack of, is largely driven by political and socio-economic issues and rarely science-based. Markets can change within a very short period due to many factors such as weather related catastrophes, an embargo due to war or foreign policy, tariffs, subsidies or trade agreements.
- Market development activities and the marketing agencies vary greatly within Canada and it is unlikely a single authority will be appropriate for all crop kinds. Some crops like western wheat and barley are exclusively managed by the CWB while markets for other species, particularly Identity Preserved crops, are developed by a strategic alliance of stakeholders including the foreign buyer or consumer.
- Market access may be a problem because the regulatory procedure either does not exist in some countries or it is still evolving. In Canada, we are working towards further changes to the regulatory procedures to allow for trace level approval. Regulations are drafted and approvals granted based on the best available information at the time. How does one decide to approve a trait

- because the benefits to one sector outweigh the loss of market in a country that chooses not to implement an approval procedure?
- The solution to some market access problems may depend on an effective segregation system with reasonable tolerance levels.
 - If regulatory authority is put in place to oversee market impact, what will be the liability implications if market conditions change for reasons that are unforeseen or beyond the regulatory authority's ability to control?
 - The APF wants to encourage the "right environment to foster innovation". A regulatory requirement dealing with the uncertainties of market access would have a negative impact on investment and fostering innovation.

Section C: CSTA Statement

The issue of market access is complex without a simple solution. Consultation among stakeholders is essential. CSTA supports the Agriculture Policy Framework (APF) *"to build and strengthen communication links throughout the value chain"* and *"for Canada to promote the establishment of science-based domestic and international standards. This would help capture new and premium markets around the world and maintain existing ones."* As new traits are proposed for introduction, CSTA would support crop-by-crop industry committee meetings to study the complexity and possible consequences of introducing a Plant with a Novel Trait (PNT) to the species.