

National Forum on Seed Meeting Report - December 2006



Winnipeg December 1 2006

The sixth meeting of the National Forum on Seed (NFS) was held at the Radisson Downtown in Winnipeg December 1, 2006 with about 70 forum members and observers present. The Forum dedicated the morning to an information and discussion session on Genetic Use Restriction Technology (GURTs). During the afternoon, Forum members and observers discussed the status of the Adventitious Presence (AP) issue. This was followed by an update on Plants with Novel Traits (PNTs). Finally, Forum members prioritized agenda items for the balance of the fiscal year, and discussed some NFS Governance issues.

Genetic Use Restriction Technology

The GURT discussion stemmed from the July 2006 Forum meeting where NFS members agreed that a symposium should be held to raise awareness and understanding of GURTs and the regulatory environment surrounding them. Thus, the discourse was framed by three background presentations; and the emphasis of the discussion was on encouraging active participation and input not only from Forum members, but also from observers.

The first presentation by Dr. Murray Ballance, Head of the Department of Plant Science, University of Manitoba, was about the science behind GURTs. A GURT is essentially designed to restrict the use of the Intellectual Property (IP) or trait in the gene(s) contained in seed. Examples of traits might be disease, drought or herbicide tolerance. Dr. Ballance emphasized the distinction between V-GURTs, which control the ability of the plant to regenerate, and T-GURTs, which control the expression of traits. He explained a variety of scientific methods for restricting seed viability or the expression of traits.

Dr. Ballance outlined some of the benefits GURTs to seed companies, the environment, farmers and seed producers. He also referred to several potential concerns, including the challenge for seed producers of containment. Dr. Ballance's key message was that at this time, a GURT is a "hypothetical development" in the sense that it does not yet exist outside the research lab. In the absence of field testing, many

questions surrounding GURTs cannot be answered. He pointed out that GURTs would need to go through significant Health Canada and Canadian Food Inspection Agency (CFIA) risk assessment process before they could be approved.

The following captures the major areas of questioning to Dr. Ballance from NFS members and observers:

- increased concentration and restriction of germplasm as a result of consolidation of seed companies
- some concern about a GURT variety spreading to a non-GURT crop variety
- concern about types of chemicals which could be used for activators and repressors
- recognition that the technology is about more than genetic pollen control – that it can be applied to a wide range of areas; thus, an important consideration is the status of research into environmental and other triggers for switching a gene on or off, such as drought stress where the plant would be allowed to continue to grow under drought conditions
- the potential for a repressor gene to move around in subsequent generations and whether it can start turning on and off other trait genes where it was not intended to do so

The next presenter was Denise Dewar from CropLife Canada who discussed potential applications for GURTs; some of the safety, socio-economic and science concerns; and how those concerns could be addressed. Referring to the United Nations (UN) Ad Hoc Working group position on GURTs, she cautioned against viewing it as a ban on further research but rather as a precautionary approach to ensure the scientific data has been developed which can justify field trials before they occur. She stressed that a GURT would have to go through the same risk assessment regulatory approval process as do all novel trait plants. In closing, she set out CropLife Canada's recommendations on GURTs, namely that (1) CropLife supports the federal government's position on GURTs (2) GURT technology should be carefully assessed in an individual and scientifically based manner (3) an outright ban on GURT-related research activity does not serve society

Winnipeg December 1 2006

or the environment and (4) CropLife supports farmer and consumer choice in production systems and new technology. Discussion following Ms Dewar's presentation covered a range of issues:

- the view that not only scientific, but also socio-economic impacts of GURTs should be considered prior to field testing
- differing interpretations around the intention of the UN recommendation, with some noting it is a proposed moratorium driven mostly by concerns that the agriculture industries of developing countries, particularly in Africa, would be destroyed if seed was introduced which became sterile after the first generation
- whether Agriculture and Agri-Food Canada's (AAFC) Next Generation of Agriculture and Agri-food Policy could be one possible forum for considering socio-economic issues
- consumer acceptance: while farmers and science may determine that a GURT is safe, consumers may not be convinced. Ms Dewar replied that industry spends upwards of \$150-million to bring a new trait forward so industry takes seriously its role in assessing farmer and consumer acceptance of a particular trait.

The third presenter was Andrea Johnston of AAFC who described the regulatory and policy environment for GURTs. The department supports continued research and fact-based dialogue in order to develop a better understanding of the potential risks and benefits of GURTS. She said that Canada is increasingly challenged to compete on the global market. Innovation is the key to sustainability, and that biotechnology will continue to play a role. She underlined that products of innovation always will have to meet stringent scientific assessment of environmental, human and livestock health and safety. This is consistent with Canada's regulatory approach for all plants with novel traits and consistent with the outcome of CoP8. Canada has always supported a cautious, responsible approach to the regulation of GURTS based on a case by case evaluation of each new product. Ms. Johnston noted that producers in Canada should always

have the choice to select varieties which offer the highest returns and benefits whether by cutting edge technologies or more established traditional plant varieties. With regard to concerns about market industry concentration., Ms Johnston emphasized that mechanisms are in place, such as the Competition Bureau to deal with adverse effect resulting from increased market concentration.

Two major themes emerged from the GURT discussion which followed the three presentations: (1) socio-economic impacts and (2) the capacity of the regulatory system.

There was broad agreement about the need to ensure adequate capacity in the government mechanisms that deal with innovation technology such as GURTs in order to maintain industry, farmer, consumer and international confidence in Canada's regulatory system. The view was widely expressed by several NFS members and meeting observers that lack of capacity within Canada's regulatory system should not become a barrier to innovation and international competitiveness. As one NFS member put it "producers and citizens must have confidence that the regulatory system is not put in an inferior position to a major company." Another aspect of this discussion was that AAFC's Research Branch should be more involved in the long-term regulatory research that does not occur in the private sector.

On the matter of socio-economic impacts, some NFS members and several observers discussed how to calculate into the regulatory equation socio-economic impacts of GURTs and other innovation technology. It was observed that the regulatory system does not seem to have the capacity to address socio-economic impacts and that this is left for the marketplace and industry to determine once the products have been commercialized.

Mike Scheffel from CFIA explained the federal government takes socio-economic considerations into account when it is developing regulatory frameworks such as policies, directives, guidelines, consultation and incentives. But, he said, bureaucrats cannot do the same with each regulatory decision that is required within that regulatory framework.

During the discussion, some questioned who benefits from innovation and whether policies sufficiently support profitability to the farm gate.

National Forum on Seed Meeting Report - December 2006



Winnipeg December 1 2006

In terms of the NFS role on socio-economic impacts of GURTs, members observed that this very discussion has helped facilitate debate and access to information; however, it was generally agreed that issues around GURTs need to evolve outside the NFS at this point. While these issues must continue to be discussed, NFS members were generally of the view that this would be better expressed through mechanisms such as the AAFC Next Generation of Agriculture and Agri-food Policy.

Decision:

➔ ***The NFS wishes to broadly distribute this Meeting Report in order to communicate to AAFC and other interested parties the major themes that emerged from the GURT discussion.***

The NFS members noted that as the GURT debate plays out in a broader context, issues may be referred back to NFS in the future which are legitimately a part of its mandate. Forum members concluded that no action by the NFS is required at this time.

Adventitious Presence (AP)

At its July 2006 meeting, the NFS decided to maintain a 'watching brief' on the AP topic and to schedule updates at subsequent meetings in order to track international developments and the progress of AP work by the Canada Grains Council (CGC).

At this December meeting, the AP discussion was informed by three presentations, the first by Dennis Stephens of the CGC. He defined AP as "the low level presence of an rDNA trait in a grain shipment for food, feed or for processing that has been authorized in one or more countries but not in the country of import." The challenges to the grain trade, he said, are first, that once an rDNA is authorized by a country of export, it is only a matter of time before that rDNA may appear as AP in grain shipments; second, that authorization of an event may never happen in all countries at the same time; and third, that importing countries have zero tolerance of rDNA their own regulatory agencies have not authorized. Mr. Stephens explained the CGC two-track AP strategy - international and domestic consultations. To support the latter,

CGC has developed a project proposal called Creating an Environment for the Successful Commercialization of Canadian Crop Innovation, whose objectives are to identify operational barriers, develop operational principles and establish a process for identifying and overcoming existing and potential non-tariff trade barriers, specifically AP in Canadian grains. While CGC awaits a funding application decision for the project from ACAAF, Mr. Stephens sought the support of NFS for the project.

Krista Thomas from CFIA updated the NFS on domestic and international developments around AP. Domestically, Standard Operating Procedures (SOPs) are being developed. By the end of December 2006, CFIA will have published to its web site a set of questions and answers on the CFIA approach to AP. By March 31, 2007 it will have published to its web site SOPs on health and safety related to AP, with SOPs on risk management to follow.

Internationally, CFIA continues to be involved in various international fora, including the Food and Agricultural Organization's (FAO) Codex Alimentarius Intergovernmental Task Force on Food Derived from Biotechnology. Ms Thomas also provided an overview of other international consultations including the North American Plant Protection Organization (NAPPO) Biotechnology Panel, upcoming bilateral meetings between Canadian biosafety officers and their counterparts in China and India; and consultations within the APEC's (Asia-Pacific Economic Cooperation) sub-group on Research, Development and Extension of Agricultural Biotechnology.

Dr. Bill Leask, Executive Vice-President of the Canadian Seed Trade Association (CSTA), presented the latest information on international efforts in which CSTA is involved. Because AP in seed moving internationally is one of CSTA's highest priorities, Dr. Leask said he was pleased to inform the NSF of the most recent decision of the Codex Task Force during meetings in Chiba, Japan. The current problem is a zero threshold position for those events that have been authorized in one or more countries as safe for food and feed but not in the country of import. The objectives of the Codex

recommendations are to (1) identify and incorporate into a draft annex to the Codex Plant Guideline the relevant sections of the Plant Guideline essential to the safety assessment in low level presence situations; and (2) identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it would apply, and the data necessary to conduct an assessment of food safety in the importing country. Dr. Leask said this was a very significant development in international food and feed trade because if the Codex guidelines are developed, importing governments will use them to implement risk management policies that will recognize the low level presence of events in grain shipments once the event has been authorized to be sold for seed in an exporting country to produce grain for food, feed or for processing

Dr. Leask also updated NFS members on the work of the International Seed Federation (ISF). The top priority of the IFS is to facilitate international trade of seed, and the objective of the AP consultations is to have a product containing a Genetically Modified (GM) event with an environmental assessment and authorized in the exporting country or in a country having environmental assessment procedure, accepted by an importing country where the GM event is not yet approved. Dr. Leask outlined the pillars for environmental assessment criteria, the work plan for achieving the objective, and the outreach activities that will be required.

During the NFS discussion, there was acknowledgment of the need for standard detection technology internationally, as well as recognition of the importance of a quality management approach through regulatory means to minimize the presence of AP in seed.

Decisions:

- ➔ **No more explicit work on AP needs to be done by NFS at this time; however, once the CGC project and the Agriculture Portfolio Working Group produce further information, the NFS may have a role.**
- ➔ **It was observed that the Crop-Specific Consultative Groups (CSCGs) stemming from CFIA's proposed**

Seed Program Modernization Initiative could provide advice on issues around varietal versus genetic purity.

- ➔ **The NFS confirms to the AAFC that the CGC project Creating an Environment for the Successful Commercialization of Canadian Crop Innovation is complementary to the work of the NFS and is in no way a duplication of NFS activities.**

On the second decision, the National Farmers Union (NFU) Member of NFS declined to support it, and views the CGC project as being focused on ways to facilitate the export of Canadian technologies to other countries. The Canadian Federation of Agriculture (CFA) member of NFS wished to go on the record as definitely supporting the decision as it supports producer innovation and competitiveness.

Plants with Novel Traits (PNT)

The PNT agenda item is the result of an NFS decision at its July 2006 meeting seeking an update on PNT issues "at which time a decision can be made about whether/when to reconvene the full PNT Working group to review the draft guidance document and to follow up on some of the possible areas for further discussion identified at the March (2006) meeting."

Kirsten Finstad from the Plant Biosafety Office (PBO) of CFIA presented to NFS a "pre-proposal" for the development of a guidance document on determining if a plant has a novel trait. She presented the pre-proposal essentially as a document index which included, among other subject areas:

- distinguishing between the PNT, novel feed and novel food triggers;
- providing a definition of a novel trait as per Part V of the Seeds Regulations;
- identifying responsibility areas for determining if a plant has a novel trait;
- outlining considerations and giving specific guidance for determining a newness and potential for impact on the environment;

National Forum on Seed Meeting Report - December 2006



Winnipeg December 1 2006

- exploring mechanisms for seeking advice in determining if a plant has a novel trait;
- dealing with liability and appeal mechanisms for CFIA decisions around PNTs; and,
- explaining the regulation of environmental releases for PNTs.

NFS members expressed satisfaction with the pre-proposal and congratulated CFIA on reflecting earlier NFS input.

Decisions:

- ➔ **The NFS will convene a PNT Technical Group to work with the PBO of CFIA on development of the Guidance Document.**
- ➔ **The NFS will extend an invitation to Health Canada and the Feed Section of CFIA to participate in the process.**

Issues Agenda

The NFS reviewed the issues it has dealt with during the current fiscal year, including AP, PNT, regulatory streamlining, variety names, seed standards/seed purity, and variety registration. They also considered issues which could be brought forward from now to the end of the fiscal year, and those which could be addressed in the longer time-frame to March 31, 2009 through Phase IV of the NFS funding application to ACAAF.

Decisions:

To March 31, 2007:

- ➔ **The NFS will convene a working group to provide documentation on guidelines, roles and responsibilities related to CSCGs as input into the CFIA consultation process in support of the Seed Program Modernization Initiative. This input will be provided on or prior to February 28, 2007 via the CFIA web site which has been created to facilitate transparent, inclusive consultations.**

- ➔ **As per the decision reflected earlier in this Report, the NFS will create a PNT Technical Group to work with the PBO of CFIA on development of the Guidance Document.**

The Management Committee will take steps to plan these two working groups on behalf of NFS.

After March 31, 2007:

- ➔ **Consistent with decisions taken at the NFS meeting in July 2006, the longer term work of the Forum will be determined at the next meeting of the NFS based on ACAAF funding decisions in the interim.**

Governance

Governance is a standing agenda item at NFS meetings. No governance issues were raised over the course of the December 1st meeting. A participant did share that the open, inclusive process whereby NFS members and observers are provided with an opportunity to share views and discuss views is appreciated.

Funding and the Path Forward

A decision on Phase III funding from the ACAAF was imminent as of the December NFS meeting. The Phase IV funding application has been submitted and is now under review. This proposal would take the NFS funding to March 31, 2009. The Phase IV funding application contains a proposed initiative on self-funding to sustain NFS after March 31, 2009.

With regard to the Phase II ACAAF funding agreement which expired in June 2006, the audit is now complete. A summary of expenses was tabled at the meeting.

Winnipeg December 1 2006

Next Meeting:

The next Forum meeting will be convened in March. Agenda items at that time are expected to include:

- Report from the NFS working group on its input into the CFIA consultations on guidelines, roles and responsibilities related to CSCGs.
- Status report on the NFS Technical Group on PNT with respect to development of a Guidance Document.
- Update on the CFIA consultations on its Seed Program Modernization Initiative
- Update on Phase III and Phase IV funding applications
- Work plan for 2007/2008



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Meeting Participants

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Bouvier	Helene	OTA Canada, MOMA Trade
Brechka	Monica	Catholic Women's League Association
Brown	Doug	AAFC
Bukusu	Pierre	Conseil des appellations agroalimentaires du Québec (CAAQ)
Campbell	Alan	BrettYoung
Carrier	Les	Manitoba Metis Federation
Demeke	Tigst	Canadian Grain Commission
Dewar	Denise	Crop Life Canada
Dion	Jacques	Registered Seed Establishment
Doyle	Monty	National Forum on Seed
Drost	Wilhelmina	CFIA
Duke	Louise	CFIA
Edney	Michael	PRRCG
Enns	Art	Grain Growers of Canada
Finstad	Kirsten	CFIA
Fossay	Chuck	Keystone Agricultural Producers
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Holtman	John	VITA Health
Holtlander	Cathy	Saskatchewan Organic Directorate
Hornford	Robert	BASF
Jahn	Wendy	CFIA
Johnston	Andrea	Agriculture and Agri-Food Canada
Koekman	Koekman	Agriculture and Agri-Food Canada
Krahn	Allison	Saskatchewan Pulse Growers
Kristianson	Johanne	Agriculture and Agri-Food Canada
Lanoie	Daniel	Union des producteurs agricoles

Last	First	Organization
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Leslie	Mike	Alberta Barley Commission
Lewis	Frank	CFIA - Ottawa Lab
Lindo	Jennifer	CFIA
Love	Rick	Agricore United
Mader	Charlene	CFIA
Magnan	Andre	University of Toronto
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O'Connor	Laurel	University of Saskatchewan
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Pauker	Peter	CFIA
Pearson	Cindy	CFIA - Seeds Section
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Reimer	Bill	CFIA
Reisner	Barry	CSGA
Rossnagel	Brian	University of Saskatchewan
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Sharrat	Lucy	CBAN
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Smith	Dan	Monsanto Canada Inc.
Stephens	Denis	Canada Grains Council
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Thomas	Krista	CFIA
Townsend	Patty	CSTA
Tranberg	Janice	Ag-West Bio Inc.
Waterer	John	Cargill
Wilson	Warren	National Forum on Seed
Witbeck	Bill	Association of Alberta Coop Seed Cleaning Plants c/o Alberta Ag Field Crop Development
Young	Terry	Alberta Barley Commission
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Total Number of Participants: 79