

# National Forum on Seed Meeting Report - July 2006



Winnipeg 25-26 July 2006

The fifth meeting of the National Forum on Seed (NFS) was held at the Fairmont Hotel in Winnipeg on July 25 and 26, 2006. About 35 Forum members and observers attended. The Forum reviewed reports from the Working Groups on Variety Registration, Adventitious Presence, and Plants with Novel Traits and discussed what the next steps should be on each of these files. Members also considered what additional issues should be addressed by the NFS in the coming months and discussed future funding of the Forum.

## Variety Registration Working Group

Dale Adolphe gave a short overview of the outcomes of the fourth meeting of the Variety Registration Working Group (VRWG) which had been held in Winnipeg on April 25. VRWG IV had focused on exploring key elements of the Canadian Food Inspection Agency's Preliminary Regulatory Proposal to Modernize the Seed Regulatory Framework, in particular, the role and make-up of the proposed Crop Specific Consultative Groups (CSCGs) and how the risk-based contract registration option might operate.

While strongly supporting the CSCG concept, the Working Group raised concerns about how these consultative groups will be funded and underlined the need for them to remain focused on regulatory issues, to not add additional layers that would slow down the variety registration system, and to add value by developing consensus where changes are warranted. They also recommended that the CSCGs should report directly to the Canadian Food Inspection Agency (CFIA) and not be an offshoot of the NFS.

Most VRWG IV participants expressed support for expanding and adapting the current contract registration system using risk assessments tailored appropriately for each crop kind. There was broad agreement that contract registration shouldn't be a means to by-pass or get around merit-based variety registration, that CSCGs should play a role in identifying risk factors for their crop kind, and that a contract registration committee should be established to assess and provide advice on the control, mitigation and monitoring measures proposed by applicants.

Glyn Chancey provided an overview of the CFIA's Regulatory Proposal to Modernize the Seed Regulatory Framework, highlighting areas that have been revised to incorporate feedback

from stakeholders, including the input received from the VRWG IV meeting. With respect to the CSCGs, the CFIA proposes to officially recognize them directly, rather than having them report to the NFS. He reiterated that the CSCGs must have balanced representation from the complete value chain and adhere to the key principles for consultation advocated in the Smart Regulations initiative. For Contract Registration, the CFIA proposes to strengthen enforcement and compliance authorities to ensure appropriate risk-based measures can be taken to mitigate potential adverse effects and to enhance the monitoring capacity for contract registered varieties through developing a third party auditing program.

Mr. Chancey reported that the Regulatory Proposal would soon be released for public comment. This formal consultation phase will include an on-line e-workbook as well as stakeholder meetings. Following this process, the CFIA is planning to publish the proposed changes in the Canada Gazette Part 1 sometime in the fall. The Canada Gazette Part 2 notices should then follow in the spring of 2007, thus allowing implementation of the new regulations.

Forum members then discussed acceptance of the VRWG IV report and next steps. Some commented that more work is still needed on the scope, mandate and composition of CSCGs and to further flesh out details associated with the risk-based approach to contract registration. Ultimately, the Working Group report was accepted as fulfillment of the objectives set for its fourth meeting. CFIA officials offered to brief the Forum later this fall on the results of the forthcoming consultations, and said they would welcome any further input the NFS wished to offer on the terms of reference for CSCGs and how they should be constituted. On this last point, CFIA agreed to develop a CSCG "model" to elicit additional feedback from the NFS later this fall.

### **Decision:**

- *The Forum accepted CFIA's offer to update members on the results of the formal consultations at the fall NFS meeting. NFS members can then decide what, if anything, more needs to be addressed on this file.*

The meeting then reviewed a chronological summary of the Variety Registration Working Group process over the past two years and discussed lessons learned.

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Positive reflections included the following points:

- process was open and transparent and became more inclusive as it evolved;
- breadth of participation and different viewpoints was good;
- CFIA participation was very constructive and helpful;
- participants willing to talk issues through and some consensus was achieved;
- meeting facilitation provided structured forum for discussion and contributed to success of process.

Suggested improvements included:

- move the process along faster and sharpen the focus of Working Group meetings;
- purpose of meetings must be clear and Management Committee should help Working Groups to stay on track with their mandate;
- need to ensure there's enough meeting time for Working Groups to do their job properly;
- make more effort to address issues that affect attendance (funding, lack of interest among parts of value chain, scheduling meetings well ahead).

**Decision:**

- *Continue to follow the VRWG model with other working groups, incorporating suggested improvements to make the process more expeditious and efficient.*

### Working Group on Adventitious Presence

Bill Leask reviewed the outcomes of the Adventitious Presence Working Group held in Ottawa on March 7, 2006. He also briefed the Forum about the work of the International Seed Federation's AP Working Group, of which he is a member.

The Forum had accepted the AP Working Group report at its March 23 meeting and forwarded it to the CFIA, Health Canada and the Portfolio Working Group on Adventitious Presence. In mid-July, a coordinated written response was received from CFIA's Plant Biosafety Office, Feed Section and Plant Production Division. Krista Thomas made a presentation summarizing the regulators' response, which included an overview of current Canadian regulatory AP initiatives.

It was noted that the first meeting of the NFS' AP Working Group had been a valuable forum to raise awareness among stakeholders of the complexity of this issue and that it provided a basis for furthering government-industry dialogue and integrated approaches.

Canadian regulators have been exploring new approaches to address unapproved events. These include harmonization of international regulations, mutual recognition of foreign reviews and actions to reduce the potential for AP occurrences. The two options which biosafety regulators view as most promising in the short-term are Standard Operating Procedures (SOPs) and International Regulatory Relationship Building. CFIA and Health Canada have committed to publish their SOPs for unapproved materials that have entered Canada. In this context, they plan to further explore a tiered approach to managing the risks posed by unapproved events. Canadian regulators will continue to build relationships with their counterparts in key countries and to try to create mechanisms for internationally harmonized approaches to AP.

The CFIA presentation stressed that no single option will fully address AP concerns, but several may be useful components of an overall approach to managing AP.

Ms Thomas flagged CFIA reservations about setting threshold levels for safety purposes, both because there is no mechanism to say that a certain percentage of AP is "safe" while a slightly higher percentage is not, and because regulators don't have the resources to set up a testing program to ensure that any established threshold levels aren't being exceeded. Canadian officials continue to work both bilaterally and in international fora to pursue standard operating procedures for risk assessments and enforcement actions.

The Canadian and international regulatory policy landscape for unapproved events will continue to evolve. CFIA officials promised to keep the NFS updated and to continue to consult on possible new approaches. The regulators' response letter also encouraged the NFS to continue its AP work and consider broadening its efforts to explore export aspects of the AP issue.

Forum members expressed appreciation for the government's response and voiced support for CFIA and Health Canada efforts

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in Codex and other international fora. Members discussed whether a further mandate should be given to the Working Group to discuss AP issues related to Canadian exports and/or liability aspects of unapproved events which occur within Canada. Dennis Stephens apprised the Forum of an AP-related initiative that the Canada Grains Council is proposing to undertake; while not specifically focused on seed sector interests, this multi-stakeholder work would address the export side of AP and could include liability concerns as well. Several members spoke in favour of plugging seed industry concerns into the Grains Council initiative rather than reviving the AP Working Group at this point.

## **Decision:**

- *The NFS will work with the Canada Grains Council (CGC) initiative, inputting seed perspectives as appropriate. The Forum will maintain a 'watching brief' on the AP topic and will schedule updates at the next meeting and future meetings in order to track progress of the CGC work as well as international developments.*

## Working Group on Plants with Novel Traits (PNTs)

Dale Adolphe reviewed the outcomes of the PNT Working Group which had met in Ottawa on March 6. This Working Group had come up with suggestions for improving the 'triggering' process for regulation of PNTs, including greater transparency, an appeal mechanism, a two-stage determination process, a proposal for tiered risk assessment, and a single window access for food, feed and environmental risk assessments.

The Forum had accepted the PNT Working Group report at its March meeting and forwarded it to the CFIA and Health Canada for their consideration. A joint response was received from the Plant Biosafety Office and Feed Section of CFIA and the Food Directorate of Health Canada. Krista Thomas made a presentation highlighting the main points of that response. She reiterated the explanation of the novelty trigger for environmental safety assessment as per Part V of the Seeds Regulations which had been given at the Working Group meeting and which rests on both the "newness" of the trait in question and the plant's potential impact on the environment. She also re-confirmed CFIA's willingness to assist plant developers in ascertaining whether a potential new variety may be subject to regulation.

The Plant Biosafety Office, in consultation with other regulators within CFIA and at Health Canada, is now drafting a document to further clarify the trigger for regulatory oversight under the Seeds Regulations, and to address other concerns raised by the PNT Working Group. Officials plan to consult with industry on this draft guidance document by early 2007. In the meantime, direct consultation with the separate regulatory sections (Plant Biosafety Office, Feeds Section and Novel Foods Directorate) is required since regulatory triggers and information requirements vary among them and their respective programs may be impacted.

Discussion focused on how NFS might assist with the development of the guidance document and whether it would be helpful to convene a second Working Group meeting or have a small number of NFS members provide input on an early draft of the CFIA document. It was suggested that a technical sub-committee of the PNT Working Group could be struck to help clarify the type of information that plant breeders and others in the seed sector would like to see in the document. Harmonization of regulatory requirements and/or single window access was also flagged as a priority.

## **Decisions:**

- *The Management Committee will draft a letter from the NFS to thank officials of the three regulatory areas for their prompt and constructive response and to compliment them for their efforts to address PNT concerns in a coordinated and collaborative manner.*
- *A small group (technical committee) will be struck to provide further input to the Plant Biosafety Office as the guidance document is drafted and refined. Forum members should advise the Management Committee if they wish to be directly involved in this work.*
- *An update on PNT issues will be included on the agenda for the next Forum meeting, 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 meeting.*

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## Issues Agenda

To ensure NFS activities reflect sector priorities and concerns, the Forum's governance process requires an annual opportunity for stakeholders and regulators to submit issues for consideration as priorities for future NFS work. In response to a call letter sent earlier this summer, 19 issues were identified. The Executive Committee pre-screened the issues submitted to assess whether they met the following criteria:

- issue is related to/affects seed policy and/or regulation;
- is of interest to both the value chain and regulators;
- is appropriate to the role and work of the NFS; and,
- is not a duplication or conflict with the mandate of other bodies.

Most of the issues did meet the criteria and meeting attendees were asked to prioritize the ones they believed would merit early action. CFIA officials added four additional topics to the list. The Secretariat tabulated the results of the prioritization exercise and reported that the leading issues appeared to fall into three clusters: (1) Modernization of Seed-Related Acts and Regulations, (2) Technical/Regulatory aspects of the current Seeds Act, and (3) Innovation.

Within these groupings, specific areas of concern were discussed, including:

- the need to have a horizontal review of the Seed, Feed and Grain Acts and Regulations with a view to identifying inconsistencies and facilitating development and production of value-added products;
- the need to review variety de-registration procedures;
- desirability of a timely review of Grade Tables and the Weed Seeds Order;
- non-Canadian seed being blended with Canadian seed, then labeled as "Product of Canada";
- use of variety names on common seed;
- potential changes to the Licensed Sampler Program;
- the future of grade-based seed certification programs;
- re-evaluation of the scope of the PNT definition;
- need for better knowledge and understanding of policy and regulations affecting GURTs (Genetic Use Restriction Technology, often referred to as 'terminator' technology);
- desirability of changing the basis of comparison used to determine what constitutes a "novel feed";

- value of further exploring incentives and disincentives that would affect investment in innovation, as well as possible enhancements to intellectual property protection to ensure value chain participants can capture the added value associated with innovation in plant breeding and seed production.

## *Decisions:*

- *It was agreed that a technical Working Group would be formed to look into and make recommendations on possible improvements in current standards under the Seeds Act related to the Licensed Sampler Program, the Grade Tables and Weed Seeds Order, and the rules for Product of Canada labeling.*
- *A consultant will be hired to look horizontally at current federal Acts and Regulations governing seed, feed and grain in order to identify inconsistencies or other elements which may be impeding potential value added production opportunities. The consultant's work will then be passed to a technical Working Group which will determine areas that may warrant further action.*
- *A one-day symposium will be organized prior to the next NFS meeting to raise awareness and understanding of GURTs and the regulatory environment surrounding them. The Forum can then discuss what next steps, if any, it might take regarding GURTs.*
- *Forum members agreed that a further NFS discussion was required to map outstanding issues related to Innovation and decide on next steps.*
- *CFIA will draft an issues paper outlining concerns and potential actions related to variety de-registration. This paper will be brought to the Forum for discussion.*
- *CFIA will develop a similar paper on the use of variety names on common seed for discussion at the fall NFS meeting.*

## Funding and the Path Forward

Dale Adolphe explained that the NFS submission for interim funding from Agriculture and Agri-Food Canada's ACAAF program is still under review. It is hoped that approval will be forthcoming in September. The Canadian Seed Growers' Association is working

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out bridge financing in the meantime. A fourth ACAAF funding submission is currently being drawn up by the NFS Management Committee; however, this will likely be the last time the Forum can draw on this funding source, so a longer-term sustainable funding option is required.

From the inception of the National Forum on Seed (2004-05 fiscal year) until June of 2006, total expenditures have been about \$644,000. Costs for an average Forum meeting are about \$32,000 and Working Group meetings come in at about \$26,000.

Clyde Graham, from the Canadian Fertilizer Institute, made a presentation about the Canadian Fertilizer Products Forum (CFPF) which is being proposed for the fertilizer sector. They are forecasting an \$800,000 budget for two years and are seeking ACAAF funding of \$500,000 for project activities including research, communications, policy development and consensus building. CFPF membership would be drawn from a range of agricultural, agribusiness, environmental and municipal associations. Government departments and agencies as well as universities and other bodies may be ex-officio members of CFPF. The Canadian Fertilizer Institute will act as the "proponent" and implementer of the initiative, as well as handling the secretariat role in order to keep down overhead costs. Mr. Graham said they believe their approach is a "flexible, cost-effective way to set up a group like this". Some NFS members expressed interest in the CFPF model, especially the proposed communications activities.

Regarding longer-term NFS funding, there was discussion about the possibility of the Forum receiving some form of ongoing support from the CFIA since NFS is contributing to their policy development process. CFIA officials indicated any financial support would be contingent on meeting the standards set for advisory bodies, including a requirement for presenting recommendations as well as conforming to financial and administrative requirements.

#### **Decision:**

- *The Management Committee, with input from CFIA, will develop a proposal for a longer-term self-funding model for discussion at the next Forum meeting.*

#### Governance Issues

A suggestion was made, in the interests of transparency, to include a list of participants with Working Group reports. There was discussion of the wider context of attendance (about 250 organizations notified, specific invitations sent to some), privacy concerns, and whether individuals should be named or just the organizations they represented. Concern was expressed about having governance issues raised and debated in the context of other agenda items, with no advance notice.

#### **Decision:**

- *A list of attendees (names and affiliations) will be included with all future Working Group and Forum meeting reports. An explanatory note, describing the breadth of organizations made aware of these meetings through notices or special invitations, will be included.*
- *Governance issues will be a standing agenda item for future NFS meetings.*

The format for the July Forum meeting (spread over two days) was discussed. Some preferred this timing, while others—a slight majority—said they favoured a one-day meeting. An evaluation form was distributed to gather feedback on this and other aspects of the July meeting.

#### Next Meeting

The next Forum meeting will be convened in late October or early November. Agenda items at that time are expected to include:

- update from CFIA on results of formal consultations on its Proposal to Modernize the Seed Regulatory Framework;
- updates on Canada Grains Council AP project and any international developments;
- update on PNT issues; discussion and decision on whether to reconvene PNT Working Group;
- discussion of next steps regarding GURTs, variety deregistration and use of variety names on common seed; and,
- budget update and proposal for longer-term funding.