

Plants with Novel Traits

Working Group I Summary Report



06 March 2006, Ottawa, Ontario

The National Forum on Seed (NFS) convened a Working Group on Plants with Novel Traits (PNTs) following a recommendation made by the Innovation Planning Workshop last October that the regulations governing PNTs should be reviewed, clarified and possibly revised to ensure they do not constitute an unnecessary barrier to innovation and commercialization. About 40 participants, including plant breeders, seed growers, seed distributors, crop producers, representatives of industry associations and government regulatory officials, attended the first Working Group meeting in Ottawa on March 6, 2006.

Working Group Mandate

On behalf of the NFS, Dale Adolphe outlined the major issues and concerns which have been raised concerning the current PNT policy:

- It does not distinguish between types of breeding methodology.
- It leaves the developer responsible for correctly assessing “novelty” and submission requirements.
- While science based, Canada’s PNT policy is unique in the world.

He also reviewed the mandate set out for the PNT Working Group by the National Forum on Seed:

“The Working Group will focus on issues affecting conventional plant breeding, including:

- definitions and issues of clarity and understanding;
- assessments and feedback on experience with the PNT regulatory system;
- international issues and challenges.”

Background on Current Regulations

Stephen Yarrow of the Canadian Food Inspection Agency’s Plant Biosafety Office made a presentation to explain CFIA’s current PNT regulations. (See highlights of his presentation in Appendix 1.) Dr. Yarrow responded to several questions which contributed further to the Working Group’s understanding of the PNT trigger, particularly as it relates to environmental assessments.

Brian Harrison of Health Canada’s Food Directorate Novel Foods Section then explained the current process for

assessing food safety of “novel food products” not previously sold in the Canadian marketplace. (See highlights of this presentation in Appendix 1.) Although applications for novel food approvals generally come from food manufacturers and importers, Mr. Harrison indicated Health Canada is open to queries and informal consultations at early stages of novel food development.

First Table Discussion: Triggering Novelty

Working Group participants then divided into smaller groups to discuss issues and generate ideas and potential new approaches around the designation of novelty, triggering mechanisms and final regulatory decisions. (Highlights of the individual Table Group reports are summarized in Appendix 2.) Table Groups then reported in plenary and the outcomes of this wider discussion are reported below.

- There was general consensus that lack of clarity about what constitutes a “novel trait” is causing concern and is impeding investment in development of new plant varieties in Canada.
- There was strong support for the view that the degree of scrutiny under the PNT regulatory system should be more reflective of relative risk, in particular as it relates to products of conventional breeding methods.
- A consensus emerged that the current trigger for PNT regulations should be changed or significantly clarified such that specific criteria involving both risk and novelty are used to make an initial “YES or NO” determination about whether PNT regulatory requirements (full risk assessment, testing, data submissions) will apply.
- Several Working Group members took issue with the “in Canada” basis for comparison cited in CFIA’s environment and feeds directives to define a “novel trait”, suggesting this cast an unnecessarily wide net for determining novelty that would catch many products of conventional plant breeding which pose no actual threats to food and feed safety or the Canadian environment. In the course of discussions, CFIA officials clarified that the primary determinant which triggers PNT regulations from an environmental perspective is the impact of the plant

on the environment relative to its counterpart with respect to gene flow, weediness, plant pest potential, impact on non-target organisms and biodiversity (Seeds Regulation Part V). In effect, this means that most new plants produced through conventional plant breeding would not trigger PNT regulatory requirements for environmental risk assessments.

- From a scientific perspective, the Working Group concluded that the plant breeder/developer is best placed to make the initial determination of whether a novel trait exists, provided regulatory guidelines and directives offer sufficient precision on what traits merit a “novel” designation and hence require further regulatory assessment. (See previous two bullets.) However, from a liability perspective, this raises issues in the event that regulators later disagree with a breeder’s/developer’s determination that no novel trait exists. CFIA and Health Canada officials expressed willingness to be consulted when breeders/developers are assessing what regulatory requirements may apply. Several Working Group participants suggested this early-stage consultation should be documented as a record that “due diligence” has occurred.
- It was felt that it would be useful to categorize traits according to likely impacts on the five elements cited in the CFIA regulations (gene flow, weediness, plant pest potential, impact on non-target organisms, and biodiversity). It was suggested there could be a role for expert or peer committees to identify traits which pose virtually no risk in a given species, as well as those which should be subject to further assessment.
- Most participants agreed that regulatory assessments of safety for human health, feed and the environment should ideally be accessed through a “single window”.
- The majority also expressed the view that, wherever feasible and relevant, experience in other countries should be considered in the risk assessment process. It was acknowledged that this may be more difficult when assessing potential environmental impacts than food or feed safety

since environmental risks may be different in Canada than in other parts of the world.

- While endorsing that it is appropriate for government regulators to make approval decisions based on risk assessments, participants indicated that greater transparency and an appeal mechanism are desirable.

Second Table Discussion: Tiered Risk Assessment

Following lunch, participants reviewed the outcomes of their morning discussion on an improved process for designating novelty, and then broke into Table Groups to discuss the potential value of a tiered risk assessment process and whether bio-industrial plant products unfit for food or feed uses should be eligible for approval for non-food/feed uses. (See highlights of Table Group discussions in Appendix 2.) In the course of the subsequent plenary discussion, Working Group participants elaborated the following elements of a model, two-step process which could be used for regulating potential PNTs.

- The current PNT regulatory process should be divided into two stages. First determine if the prospective new plant material is novel and whether it needs to be subjected to an actual risk assessment. If not, it should not be identified as a PNT nor trigger PNT regulatory requirements. CFIA guidelines and directives should reflect this so as not to encompass new plants that pose no risk to the environment in terms of the five elements listed in the regulation (gene flow, weediness, plant pest potential, impact on non-target organisms and biodiversity).
- If risk assessment is warranted, use a tiered system that gears information and data requirements to the level of perceived risk. Separate assessments may be required for environmental, health and feed impacts, but a single window for coordination of submissions would ease regulatory burden.
- There was recognition that creating tier distinctions to stream approvals implies effort by the regulator and industry to establish and describe appropriate

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risk “categories” and create transparent requirements for each tier.

- There may be some scope for split approvals of PNTs for non-food uses (feed, bio-industrial products), provided segregation and containment are feasible, that Health Canada is consulted, and that appropriate restrictions and risk mitigation measures are applied.
- Existing risk assessment criteria being used by CFIA and Health Canada appear appropriate, but data exemptions and requirements should be made transparent and be tiered according to potential hazards and probable exposure to harm.

Plenary Discussion: Post-approval Monitoring

The question of post-approval monitoring of PNTs was discussed in plenary with the following outcomes.

- There is no general requirement for monitoring, but if the risk assessment identifies a particularly serious hazard, a stewardship and reporting requirement might be included as a condition of approval.
- Any post-approval surveillance program would have to be worked out when agreeing to a conditional approval, so it would be on a case-by-case basis.
- There are practical limits to what the developer could control or report on, as well as potential resource limitations for CFIA in enforcing compliance.

Possible Areas for Further Working Group Discussion

Participants then considered whether the PNT Working Group needed to further explore some of the concepts and approaches that had been developed during the day and whether there were other topics it should address. The following areas were cited as possibly meriting further work:

- how to further internationally recognized risk assessment processes for rDNA products

- more detailed plan for tiered risk assessment approach
- appeal mechanism(s)
- appropriate role for expert committees
- more detailed criteria for initial yes/no decision on novelty.

It was agreed that further work would be dependent on a response from regulators on what is do-able and reasonable, and that it might be appropriate for the Working Group to proceed in an iterative fashion.

Next Steps

- A summary report of the proceedings of this Working Group meeting was prepared and submitted to the National Forum on Seed at its March 23 meeting in Winnipeg.
- CFIA officials undertook to provide a written response, incorporating input from Health Canada as well.
- The National Forum on Seed will then decide on the merits and timing of another Working Group meeting.

APPENDIX 1

Highlights of Stephen Yarrow Presentation (CFIA Novelty Regulations)

- Assessments for new plants and plant products required under Canadian Environmental Protection Act are carried out by CFIA using authorities under existing legislation (Seeds Act and Feeds Act).
- Trigger for assessment is novelty of the product rather than means by which it's produced.
- Under Seeds Regulation Part V, a plant with a "novel trait" is defined by the impact of the plant on the environment, relative to its counterpart, with respect to 5 elements: gene flow, weediness, plant pest potential, impact on non-target organisms and biodiversity.
- Current regulatory directives of CFIA state that a "novel trait" is one not present in plants of the same species already existing as stable, cultivated populations in Canada, or present at a level significantly outside the range of that trait in stable, cultivated populations of that plant species in Canada. Examples given for novel traits not present were herbicide tolerance and insect resistance, while significantly outside the range was further elaborated as being an incremental increase in the trait beyond historical trends, such as rust resistance way beyond previous breeding improvements.
- Most products of breeding programs, including many products of mutagenesis, would not be considered PNTs. More than 50 PNTs have been approved to date.
- The Plant Biosafety Office has been working with crop industry to develop "more prescriptive" guidance to help developers determine the potential of new plants being considered to have a novel trait.

Highlights of Brian Harrison Presentation (Novelty Food Regulations)

- Under the Food & Drugs Act and Regulations, notification is required prior to sale or advertising of a "novel food"—i.e. onus is on food manufacturer or importer to trigger process.
- Health Canada conducts safety assessment for each novel food before it can be marketed, requesting info from applicant as required.
- Health Canada's definition of a novel food is:
 - a) a substance with no history of safe use as a food;
 - b) a food manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and that causes the food to undergo a major change;
 - c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that it has characteristics not previously observed, or no longer exhibits characteristics previously observed, or has characteristics outside the range normally anticipated.
- Health Canada endeavors to respond within 45 days for low risk novel food applications, and within 90 days when fuller assessment work is required.
- Assessments are comparative, looking at differences in a novel food compared to a counterpart already in the market. In order to determine potential food safety risk, the assessment may involve looking at areas such as molecular biological data for genetically modified crops, food composition, nutritional information, and potential for new toxins and allergic reaction.
- Evidence of safe food use may come from outside Canada.
- More than 80 novel foods have been approved since 1994. No applications have been rejected, but a

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number have been voluntarily withdrawn by petitioners as they could not meet Health Canada criteria. Examples of novel foods which have undergone successful assessments:

No history of safe use as a food

- Trehalose
- Vegetable diacylglycerol (DAG) oil

Manufactured using a process not previously applied to that food

- UV light treatment of apple cider
- Omega 3 enhanced pork

Food derived from genetically-modified organism

- Imidazolinone tolerant wheat
- Insect resistance corn (Cry3Bb1).

APPENDIX 2

Observations and Suggestions from Table Discussions

(The following notes summarize points raised during discussion in small groups and include comments and perspectives not endorsed by the Working Group as a whole.)

Clarity/Definitions

- Require concrete definition or list of “traits” that are considered for specific crops; perhaps not all traits need to be considered; for example, should colour, size and shape be novelty triggers if they don't pose any risks to human health, animal feed and the environment?
- Maybe plant breeders should look at the Seeds Regulation which sets out five areas of potential environmental impact (gene flow, weediness, etc.) before they focus on the Environment and Feeds Directives definition of a “novel trait”.
- Also need clarity about when “novelty” ends.
- There should be a recognition of the risk associated with a trait. A better understanding of which traits are higher risk should be communicated—e.g. lentils are not overly competitive and pose less risk of weediness.
- There is need for documents describing current traits of species—i.e. a baseline.
- If plant used widely in other parts of world without ill effect, why should it be subject to PNT regulations in Canada?
- Issue of how much work has to be done to back up decision—paper rationale or lab/field study, and whether this could vary depending on risk.
- Currently the plant breeder determines novelty. (Note: There could be confusion as to whether it is the breeder or the individual/company/organization commercializing the variety who is responsible. It may be clearer to refer to “the developer” or to breeder/developer.)
- Assuming there are clear regulations/guidelines, the developer can identify PNTs and can bring forward an argument as to novelty or lack of it.
- Should formalize process for determining PNT status and make it more like the novel foods prenotification process. Using that approach, research exemptions could be applied for early plant breeding stages.
- Initially, developer should assess whether novel trait exists and make submission; second step would be regulator decision, based on submission, taking account of risk (could consider third party information).
- May be a role in approval process for an expert or recommending committee of some sort. Talked about using a panel of peers—processors, pathologists, geneticists, farmers. Variety Registration recommending committees are already in place for some commodities. Some novel traits may be obvious, but if breeder/developer has questions then could go to committee. Some participants expressed concern about letting others make this call. It was also noted that developers may not wish to disclose the trait to others at an early stage; if they self-determine, and deal only with the relevant agency in cases of uncertainty, it would not become public. Others thought expert committees should not be part of the novelty determination process but could play a role in developing lists of traits and assessing general risks associated with them.
- A tiered system based on risk and science would be helpful. Ranges of novelty need to be defined on the basis of risk.

Process to Determine Novelty

- Need to create more certainty in the process.

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- Regarding environmental risk assessment requirements, process needs to distinguish between introduction of a crop species not currently "in Canada" and introduction of a new trait in a species that is currently "in Canada" (where there is already an "in Canada" history of potential environmental impact—weediness, plant pest potential, etc.).
- Perhaps rDNA should trigger novelty regulation regardless of whether the process yields a GM variety without "novel" characteristics.
- Should have a single desk approach to determine if a trait or event is novel (food, feed and environmental assessments); a "Smart Regulation" process could make this workable.
- (Note: Challenge would have to be based on scientific data. Health Canada process for novel foods allows re-opening application if new information available.)
- Appeal mechanism could also permit challenge by a third party.

Liability

- Breeder/developer currently appears to bear liability, but it should be shared by the regulators if due diligence has been done properly and in good faith. Unexpected reactions could occur and harm the environment. Liability issues are another argument in favour of having more formal process and written responses from government regulators.

"In Canada" Comparisons

- Vast majority of germplasm being used in Canadian plant breeding originated outside Canada. There may be a need for an "in Canada" perspective when assessing risks to our environment for introduction of a new species, but since a record already exists for potential environmental impacts of species already cultivated here, it's not clear that an environmental impact assessment would be warranted for most "novel traits" introduced in those species. Even for species not cultivated in Canada, global data and information may have some relevancy and should be taken into account.
- Suggest removing "in Canada" provision for crops with history of safe use.

Transparency/Appeals/Challenge by Third Parties

- Would like to see written response from CFIA on novelty inquiries. Also, need to decide whether information used by regulator in determination of novelty is public information, recognizing that this could impact confidential business information.
- Should be a process defined for developers to challenge CFIA decisions.

Tiered Risk Assessment: How it Might Work

- Current PNT risk assessment is qualitative; to tier the system means to quantify it. There is an appetite to be able to offer tiers as an option. The same level of safety remains the bottomline.
- First, need "tighter" definition of "novel" that would only encompass new traits that pose significant potential risk. The risk involved should determine the rigor of assessment; things that don't pose risk should not be subject to PNT regulations.
- Once novelty is established, proceed with tiered risk assessment. Having tiers would require definitions/descriptions of the categories of risk. Environmental impact assessments would have to be done for all PNTs; some will need food safety and/or feed safety assessments as well. Goal is to address real risks; data requirements should be geared to those risks—e.g. if another herbicide tolerant canola was being assessed, could be exempt from non-target organism info requirements.
- CFIA and Health Canada already do tiered risk assessment de facto when posing questions and requiring data, and can presumably allow exemptions from certain requirements based on sound scientific

rationale. Difficulty is to make the process more transparent, clear and concrete (not subjective).

- Perhaps benefits should also be factored into risk assessments on a case-by-case basis.

What about Bio-industrial Products?

- Non-food crop production examples already exist, such as ethanol and molecular farming.
- Plant Biosafety Office currently requires information re: accidental human, livestock or wildlife consumption.
- Plants not intended for food use wouldn't be subject to novel food approval, but Health Canada should be consulted in the process of determining whether a product poses too much risk for release into the environment.
- Should adopt same risk calculation ($\text{Risk} = \text{Hazard} \times \text{Exposure}$) now used in compliance field. The potential harm of the product must be considered first and foremost (hazard), but risk of exposure should be considered as well—e.g. probability of biological “escapes”, probability of consumption.
- Segregation from other varieties and food crops is primary issue. If it can be isolated and handled separately, then could be approved just for the intended use. Perhaps approvals could include restrictions based on risk considerations—e.g. containment, acreage limitations, testing and monitoring requirements. (Note: Opinions were also expressed to the contrary—e.g. that there should be no “split decisions” when approving new plants or that approvals for new plants destined for industrial bio-products should not be permitted within food crop species.)