

Adventitious Presence Working Group I Summary Report



07 March 2006, Ottawa, Ontario

Following a recommendation from the Innovation Planning Workshop held last October, the National Forum on Seed (NFS) convened a Working Group on Adventitious Presence (AP) which met in Ottawa for the first time on March 7, 2006. About 50 participants attended, including plant breeders, seed growers, seed distributors, crop producers, representatives of various industry associations and government regulatory officials.

Working Group Mandate

On behalf of the NFS, Bill Leask outlined the main issues which have given rise to the creation of the Working Group:

- As a function of the grain handling system world-wide and the number of new varieties being developed, there is a growing likelihood of rDNA events approved in a producing/exporting country finding their way into a country where the event is not yet approved.
- A zero-tolerance policy does not provide tools to manage AP.
- How can we expect importing countries to allow an AP tolerance in Canadian exports when Canada itself does not allow it?

Dr. Leask also reviewed the mandate set out for the AP Working Group by the Forum, which is:

“To identify options/make recommendations for regulatory or industry measures that would further the interests of the seed sector and Canadian agricultural producers.”

The scope of work for the Working Group was clarified as follows:

- The focus is on importation of GM events which are unapproved in Canada but approved in the exporting country.
- Explore options to manage low levels of AP.

- The starting point is “seed” and the policy and regulation that impacts breeding, production and trade.
- The challenge for the Working Group is to identify and explore options which:
- recognize the regulatory competence and hence decisions of other countries;
- Balance trade facilitation with environmental protection.

In response to questions, Dr. Leask further clarified that the AP Working Group would not, at this time, be discussing non-GMO Plants with Novel Traits (PNTs), nor approved events in Canada which have not been approved in countries Canadian producers want to export to. He explained that the scope of Canadian regulations being looked at includes food and feed safety as well as environmental protection, and that “unapproved in Canada” is meant to refer to events/products which have not yet been assessed and approved, or which have been assessed and rejected—in either case, there would be zero tolerance for their adventitious presence in Canada under current regulations.

Background on AP Portfolio Working Group

Krista Thomas, of the Canadian Food Inspection Agency's Plant Biosafety Office (CFIA-PBO), made a presentation to inform participants about the activities of the federal government's AP Portfolio Working Group which was set up about a year ago. (See Highlights of her presentation in Appendix 1.) Ms Thomas, who is co-chair of this Working Group, outlined some of the regulatory challenges related to AP, including the difficulty in assessing risk (using the classic formula Risk = Hazard x Exposure) and taking appropriate action in the case of unapproved events for which hazard has not previously been identified.

Questions followed about what happens now when an unapproved product is discovered coming into Canada

and how quickly risk assessments can be done. Brian Harrison, of Health Canada's Food Directorate, explained that as with any food contamination event, this would be treated as a priority and an initial response regarding potential harm to human health would be forthcoming within 24-48 hours. Bill Anderson, of CFIA-PBO, added that CFIA would apply its general policy on unapproved events and pointed out that there are currently no provisions that would target or exempt AP occurrences. Industry representatives expressed appreciation for the open and informative responses provided by government officials and welcomed their active participation in the forthcoming dialogue on ways to deal with AP challenges.

Table Group Discussions on Managing Imports

Participants then broke into smaller groups to discuss issues and options for managing imports of products which may contain low levels of rDNA/transgenic products approved in the exporting country but not yet approved in Canada. (See Appendix 2 for summary of comments and suggestions reported by Table Groups.) Plenary discussion followed. While Working Group participants were in full agreement that AP was an important issue that needs to be addressed, there was divergence on the priority of options to address current regulatory challenges. The following summarizes some broad conclusions, as well as points of significant interest that might warrant further discussion:

- There was general agreement that there should be some room to recognize science-based regulatory competencies in other countries and a consensus that Canada's approach to AP tolerances in imports should take full account of risk implications.
- Many participants saw an opportunity for Canada to be a leader internationally in acknowledging the

difficulties with maintaining and enforcing zero tolerances and proposing possible solutions.

- As a first step, there was agreement that it would be useful to formalize and make transparent the current risk assessment process regulators are using for unapproved events.
- There was agreement that it would be desirable for developers to pro-actively seek Canadian approval for events/products likely to be imported here. As well, there was some appetite for having Canadian regulators pro-actively assess risks for likely imports and determine how these would be handled. However, practical considerations (e.g. commercial strategies, confidentiality of data, costs for "pre-approval assessments", scarce regulatory resources) may limit the potential benefits of these options.
- Working Group participants would like to see regulators create/assign categories of risk to traits in order to achieve a transparent, predictable, action-based system that would facilitate imports of products not approved for production in Canada.
- In the longer term, most participants felt Canada should move toward some level of mutual recognition of approvals in other countries, beginning with bilateral negotiations and pursuing Codex standards or other international conventions to establish a sound scientific basis for recognizing equivalency of approval decisions in other jurisdictions.
- On the question of "de minimus" levels of AP, there was interest in developing a way to establish AP tolerance levels for imported products/events provided approval in the exporting country is based on relevant risk assessments and scientifically sound approval process. Nonetheless, as an interim

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measure, participants expressed a preference for placing emphasis on pursuing bilateral and multilateral agreements on standards for acceptable approval processes rather than working on “de minimus” AP tolerance levels. It was noted that establishing “de minimus” tolerances would have monitoring and compliance implications, including costs.

Table Group Discussions on Options for De Minimus AP Tolerance:

After lunch, participants reviewed the key outcomes of the morning session and then resumed Table Group discussions, considering what kind of framework would be needed if de minimus tolerance levels for AP were to be established. (See Appendix 2 for summary of Table Group comments and suggestions. The following points summarize the conclusions reached in plenary when outputs of the Table Groups were shared:

Category A

- There was general consensus that if an imported product were going to be grown in Canada, the unapproved event would need full approval (Canadian approval system or formal acceptance of equivalence of risk assessment and approval process in other country).
- To ensure a continued high level of environmental protection, rigorous case-by-case risk assessments, possibly using a tiered approach considering both hazard (potential harm) and exposure (probable extent of harm) would be required before any acceptable AP tolerance levels could be established for seed imports. However, it was noted that there are instances where low AP levels in seed shipments would not pose significant risks (e.g. where AP is of

a species or variety that will not reproduce itself or cannot compete effectively with the imported seed).

Category B

- If the imported product/event is intended for feed, food or further processing and it has received unconditional approval in another country, some de minimus AP tolerance level could be acceptable.
- It was acknowledged that Category B may pose some challenges regarding acceptance by trading partners to whom Canada exports grains and oilseeds, and regarding necessary compliance measures, regulatory resources and issues of liability. It was suggested that, where warranted, compliance measures (to minimize risk or spillage or other forms of release to the environment) be negotiated as conditions of import.

Next Steps:

- A summary report of the proceedings of the Working Group meeting was prepared and submitted to the National Forum on Seed for consideration at its March 23 meeting in Winnipeg.
- A written report or submission would then be conveyed to the AP Portfolio Working Group and CFIA officials agreed to come back to the NFS and Working Group with views and reactions from the Portfolio and Health Canada.
- The Working Group would meet again as appropriate to focus on areas where regulators indicate further work would be productive.

APPENDIX 1

Highlights of Krista Thomas Presentation (AP Portfolio Update)

- Agriculture and Agri-Food Canada (AAFC) and Canadian Food Inspection Agency (CFIA) hosted stakeholder workshop in February last year to explore AP issues in seed, grain and oilseeds sectors and possible government/industry approaches to managing AP. Focus was on approved events in Canada and importing countries.
- Defined Adventitious Presence as: “the unintended, technically unavoidable presence of genetically engineered material in an agri-food commodity.”
- Workshop resulted in recommendations on issues such as managing AP in seed, developing agreements on thresholds for AP along the value chain, harmonizing international standards for sampling and testing, and trying to establish international standards or tolerances for low levels of unapproved events.
- AP Portfolio Working Group struck to follow up on four thematic blocks:
 - Purity and Testing
 - Best Practices
 - Safety Assessments and Approval of New Products
 - Information Sharing and Education.
- A number of next steps have been identified and follow-up actions have been or are being undertaken by AAFC, CFIA and the Canadian Grain Commission. Examples include:
 - September '05 Workshop on Seed Certification and Modern Biotechnology;
 - proposed definitions for standards, thresholds and tolerances;
 - Best Practices pilot project with mustard seed industry;
 - Canadian regulators discussion on approaches to deal with unapproved events in Canadian environment, food or feed;
 - study of international AP regulatory requirements.
- AP Portfolio Working Group will release a report on its activities later this spring. Meanwhile it continues to explore options for managing asynchronous approvals, managing AP throughout the value chain, and making linkages to related initiatives such as CFIA's review of PNT import policy and the Seed Regulatory Framework Modernization Project.

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APPENDIX 2

Observations and Suggestions from Table Discussions Working Group on Adventitious Presence

(NOTE: 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.)

Options for Managing Imports:

- Distinction should be made between approving product/event for full production in Canada, versus allowing a low level AP of that material to enter.
 - Short-term, Canada may continue to be reactive in responding to unapproved events, but longer term should have more proactive/formal approach. Case-by-case reactive risk assessments will tax Canadian regulatory resources and it will be increasingly difficult to keep pace as trade expands. Conversely, greater certainty on how import shipments will be handled/regulated will facilitate trade.
 - Recognizing equivalency of regulatory decisions of other countries (full approval) could yield efficiencies, particularly for food and feed safety assessments, but Canada would have to assess both competency and relevance—e.g. smaller economies may not possess adequate capacity/resources to support strong, science-based regulations; environmental review conducted in another country might not be applicable to Canadian environment; different food consumption patterns and allergy issues might limit equivalency of human health assessments.
 - Start discussions/negotiations with major trading partners (e.g. U.S., Brazil, Argentina, Seed Association of the Americas) and expand as possible to trading blocks and eventually international agreements. At same time, Canada could support work towards Codex standards for AP. Synchronized global approvals would be hardest option to achieve, but offers most comprehensive solution for the future.
- Other option is to create approval process for AP up to a de minimus level for events/products not approved in Canada. Could create a list of events approved in other countries that would have pre-approved de minimus levels. This could be one standard level for all crops and traits or established on case-by-case basis, tiered according to level of risk.
 - There is an opportunity for Canada to “lead by example”. On other hand, having Canadian AP thresholds before these are accepted in other countries could affect ability to export.
 - Might want to consider encouraging developers to seek full approval in all countries where product/event likely to be exported or to at least seek Canadian approval where export to Canada is probable.
 - Interim option might be to proactively do toxicity/allergenicity evaluations and/or other risk assessments when rDNA products/events are approved in U.S. and possible importation to Canada can be foreseen. However, this option poses potential problems re: volume of assessments and access to commercially confidential material if developer not seeking Canadian approval.
 - Could focus on proactive safety reviews for plant materials with low levels of new protein or begin with materials that pose low hazards and low probability of exposure—i.e. pre-approval of less risky products/events. Alternatively, might wish to focus scarce regulatory resources on assessments of higher risk events/products.

- Having AP thresholds implies having testing to see if they are being met and those tests would have to be acceptable for both imports and exports. "Conditional approvals" may have appeal, but raise specter of extensive testing and reporting requirements.
- Might look to Pest Management Regulatory Agency who are beginning to recognize assessments done in other countries.
- Monitor shipments to ensure de minimus tolerance levels not exceeded. (Will require sampling protocol.) Internal audits suggested as other approach to enforcement.
- Perhaps exporter could be obligated to meet Canadian import requirements and submit proposed detection method.

Elements of Framework for De Minimus AP Tolerance:

- Acknowledge potential for AP related to unapproved events. However, to fall within framework for "de minimus" AP tolerance, product/event must be approved by a recognized authority somewhere (using process that is internationally acceptable).
- Should be tiered approach to risk assessment, by species and by trait. Tolerance levels should be related to risk, with greatest area of risk being used to set the bar. Both hazard and exposure should be considered.
- Concern was expressed that even at very low percentage levels, the "absolute" level of AP material would be large in an average grain shipment.
- Expert committees could be used to establish practical thresholds and tolerance levels. Tolerances could/should be linked to good agricultural practice.
- Risk introduced should be no greater than current levels and consistent with existing domestic framework.
- De minimus levels must be detectable within scientific levels of certainty. Standards must be linked to internationally accepted methodologies and validated tests. (Could perhaps focus on protein rather than a whole grain or DNA basis.)
- Framework will require distinctions depending on intended use (food or feed vs. seed). Would need different rules for seed vs. grain because seed would have greater potential environmental impact. Could perhaps use system similar to MRL for pesticides.
- More work will be needed to determine the regulatory and monitoring capacity required. Legislative change required to have enforcement capability.
- Over time, should seek to harmonize AP tolerance levels with trading partners. Considerable regulator-to-regulator work would be required to gain understanding, confidence and acceptance.
- Given high costs of all this risk assessment and testing, one Table Group felt it would be preferable to concentrate on an approval equivalence framework rather than a de minimus framework.