

# Plants with Novel Traits Working Group - Summary Report



February 27, 2009 - Calgary, Alberta

## INTRODUCTION

The National Forum on Seed Working Group meeting was held in Calgary, Alberta on February 27, 2009. The purpose of the meeting was a) to gather feedback on the draft directive, Plants Regulated under Part V of the Seeds Regulations; and b) to present the draft guidelines for the Assessment of Novel Feeds: Plant Sources (formerly DIR 95-03). It was attended by 34 participants including Forum members and observers.

## FOCUS ON THE PNT DIRECTIVE

### Review of the Draft Directive

The Plant Biosafety Office (PBO) presented the draft directive, Plants Regulated under Part V of the Seeds Regulations, to Forum members for review and feedback.

An initial draft directive was presented to the NFS in October 2008. Following review of the document, the NFS created a work group to clarify the remaining issues and uncertainties and to develop specific examples for inclusion in the directive. The document has been edited to remove duplication and improve its organization and flow. It has three main components: a) assistance in determining whether a plant is a PNT; b) descriptions of regulatory processes and the types of information required by CFIA; and c) a worksheet and some examples of plants that were, and were not, determined to be PNTs.

The directive also confirms that a plant with a trait that has been intentionally introduced is a plant with a novel trait if it meets two criteria:

- The trait is new to cultivated populations of seed of the species in Canada, and
- The trait has a potential to have a significant negative environmental effect.

The PNT directive only applies to traits in existing plant species, and not new plant species. New species are subject to other regulatory requirements. The directive also confirms that products of conventional plant breeding are unlikely to trigger PNT assessments. But some breeding objectives are more likely to trigger Part V of the Seeds Regulations including traits that significantly alter the sustainable development of a crop; produce toxic or biologically active molecules that are intended for pesticidal, pharmacological, or industrial uses; or increase plant fitness in a crop for which Canada is a centre of diversity. The Plant Biosafety Office is prepared to issue a

letter to confirm an assessment made by a proponent if the proponent is able to submit sufficient information.

Forum members sought clarification around the terminology used to describe a plant that has been assessed and determined not to be a PNT. CFIA's current approach is to label all plants that trigger Part V to be PNTs.

Forum members were asked to identify the elements that they liked in the revised directive. They identified the following elements:

- The revised directive is a substantial improvement over the first draft in terms of clarity, simplicity and usability. The focus on PNT triggers is very welcome.
- The upfront and conspicuous statement that in order to trigger PNT regulations, the plant must contain a trait that is both new, and has the potential for a significant negative impact on the environment is welcomed and very important.
- Important clarifications incorporated into the new draft include clarification of Canada's product-based approach in the international context; and that conventional breeding is not likely to trigger PNT assessment.
- The addition of the worksheet is valuable.
- The commitment of the Plant Biosafety Office to provide a letter confirming the determination by the proponent is a very positive step. The fact that the CFIA is developing a "reasonable service standard" that includes timelines for letters like these is appreciated.

Participants provided the following recommendations for enhancement of the directive:

- Better coordination between PBO, AFD and Health Canada is needed. The adoption of a one-window approach to determining whether a product is novel or not is desired. Such an approach should be clearly outlined in the Directive along with an explanation of the novelty triggers and processes related to food, feed and the environment. Glyn Chancey, Executive Director of the Plant Health and Biosecurity Directorate, CFIA spoke about the single window approach within his directorate and the Grains Innovation Roundtable. He noted the importance of creating an enabling regulatory environment in the long-term as well as the necessity

to continue moving forward in the short-term as regulatory change is undertaken.

- Further clarification of the path forward is required (e.g., statement of issues that have been resolved; indication of issues still to be resolved).
- Further consideration of how the PBO will define a sustainable management system and how this determination will be made is recommended.
- Additional clarification is required in the directive to clarify how exemptions related to seed grown prior to 1996 will be applied. Examples would be welcome.
- There is a need for further evolution to exempt products based on experience.
- It was noted that as proponents make determinations of whether a particular product is novel, it is possible for different proponents to make different determinations of 'novel' for a similar product. This raises the issue of whether and how determinations can be challenged or questioned. The practice of issuing confirmation letters from PBO would help avoid this issue as would the implementation of a single window approach.
- Biology documents are useful sources of supporting information; reference to these documents should be included in the directive.
- The following editorial comments were received:
  - Date the document.
  - Section 2.1 (first line, first paragraph): Capitalize "part".
  - Section 2.1 (first bullet): Remove "of seed" from the sentence.
  - Section 2.3.3 (first line, first paragraph): Modify to read "conventional plant breeding".

## Review of Worksheets (Appendix 1 and Appendix 2)

The PBO provided an overview of Appendices 1 and 2 of the revised directive. The template in Appendix 1 (page 11) is provided to assist a proponent (e.g., plant breeder, importer) in determining whether a particular plant is a PNT. It was designed as a tool; its use is not mandatory

Forum members were asked to discuss whether the examples are helpful to understand due diligence considerations in assessing environmental safety issues and in understanding when to contact the PBO. As noted above, participants found the inclusion of the worksheets and examples in the Directive to be extremely useful overall and suggested that similar worksheets should be developed for food and feed. They agreed that the examples are helpful in clarifying due diligence considerations.

They suggested that the worksheets (as well as the Directive) should include recognition that a range of literature resources could be used as supporting documentation (e.g., peer-reviewed literature, biology documents, unpublished experimental data, 'authoritative literature', etc.). The worksheet examples would also benefit from the inclusion of some additional explanation of the rationale used to reach a particular conclusion.

The conclusions in any particular example should clearly state whether or not a proponent needs to contact PBO and whether other regulators (i.e., food, feed) must be contacted. It would also be useful to provide an overview of PBO's assessment process following the submission of a work sheet.

In some cases, new information could emerge after a determination has been made that a particular plant is not a PNT. This could raise the possibility that the plant may be a PNT. If this were the case, the proponent would be responsible for informing PBO of the new information thus initiating a new review of the product.

Overall, Forum members were pleased with the range of the examples provided but suggested that Appendix 2 should be updated on a regular basis to include new, challenging (e.g., low phytate barley), controversial (e.g., fatty acid composition changes) and/or unusual examples as they arise. Examples of novel food and feed, ornamentals and unregulated traits/characteristics as well as examples where it was decided that a plant was not a PNT should also be included. An searchable electronic database could be used to store examples and sample confirmation letters.

Industry Experience with Non-rDNA HT Crops: BASF Canada Dr. Kent Jennings, BASF Canada provided an overview of his company's experience with novelty determination for non-rDNA herbicide tolerant crops. He outlined the process by which they prepare regulatory packages for food, feed and the environment.

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### FOCUS ON GUIDELINES FOR THE ASSESSMENT OF NOVEL FEEDS: PLANT SOURCES

#### Overview of the Guidelines Document

The Animal Feed Division (AFD) provided an overview of the process used to develop the Guidelines for the Assessment of Novel Feeds: Plant Sources.

First, a summary of the initiatives that led to the reorganization and amalgamation of existing guidance which included the novel feed guidelines was presented. As part of the Paper Burden Reduction Initiative (PBRI), the AFD made the following considerations around projects: streamlining, while maintaining integrity, impact to industry and government as well as project timeline. This resulted in the reorganization and amalgamation of numerous documents into one central Regulatory Guidance document, the Regulatory Guidance: Feed Registration Procedures and Labelling Standards. The aim was to reduce duplication and repetition and improve user-interaction. The Guidelines for the Assessment of Novel Feeds: Plant Sources (formally Dir 95-03) are included in this document in Chapter 2.

The AFD also addressed issues that the NFS raised regarding de-authorization, heirloom varieties, when novel is not novel and due diligence surrounding novelty determinations and answered several questions from Forum members.

A member asked how an heirloom is determined (e.g., by age, deregistration, lack of use). AFD considers exposure to livestock and relies on the proponent to make a case as to whether or not the plant has been grown continuously. The AFD might also refer a proponent to OECD consensus documents to determine the parameters for a specific plant. Clarification was sought around de-authorization in situations where a producer begins selling a feed that the original applicant has ceased distributing. The importance of stewardship of information was noted; multiple parties might be responsible should any information come to light that challenged the safety or efficacy of that novel feed.

AFD then addressed the topic of novelty determination. The trigger for regulation under the Feeds Act and Regulations was outlined and existing materials created by the AFD to help proponents in novelty determinations were presented. Forum members were asked to comment on whether this material was sufficient, whether more guidance was required,

and if so, what type of guidance would be most meaningful to novel feed developers.

The regulatory trigger for feed is novelty, not risk; that is, "any feed that is new (i.e., not listed in the Schedules) or has been modified such that it differs from conventional parameters, is required to undergo a pre-market assessment". Any potential risk (e.g., safety and efficacy) is determined during the assessment of the product. Other resources could also be used to determine novelty (e.g., OECD consensus documents, scientific literature, producers' knowledge, peer-reviewed literature and/or information from the International Life Sciences Institute). Consultation between the proponent and AFD is optional but encouraged, especially for those who are working through the process for the first time.

In response to questions around the relationship between feed and PNTs, the nature of the three regulatory triggers that govern food, feed and the environment was described. Each of these have different triggers that are found in different legislation, with different regulations and statutes. Therefore, they cannot be addressed or managed in the same way. NFS members appreciated the distinction as described and encouraged AFD, PBO and Health Canada to include such an explanation in all their guidance documents on this topic.

Forum members suggested regulatory amendment as a means of including risk assessment in the novel feed trigger. This would further align the process for feed with Health Canada and PBO. In response, AFD noted that Health Canada considers any rDNA modification to be novel. AFD is not considering regulatory change at this time.

Overall, Forum members encouraged AFD to consider the following additions and revision to the Directive:

- Include clarification of the trigger for novel feed; that is, if a product is not listed in the Schedules, or has been modified such that it differs from conventional parameters, it is considered to be novel and is required to undergo a pre-market assessment. Novel feed is not subject to the same pre-1996 exemption that exists for plants regulated under Part V of the Seeds Regulations.
- The Guidelines would benefit from the addition of worksheets and examples (i.e., similar to the approach taken by PBO for Part V of the Seeds Regulations). Examples should be simple, clear and concise; they

could include a carryover of examples from the PBO guidance as well as examples where novel feed is triggered but a PNT is not. Further guidance from the Animal Feed Division is also needed to clearly articulate the thought process for determining novelty.

- Development of examples and worksheets should be conducted in consultation with proponents. Thus, Forum members recommended the creation of a small working group. The following individuals volunteered to participate in such a group: Simon Barber, Ann de St Remy, Jennifer Elliott, Dorothy Murrell, Joseph Nyachiro, Randy Preater, Blaine Recksiedler and Terry Young.
- NFS members also recommended the development of a coordinated approach (a "single window") between AFD, PBO and Health Canada. This would initially require consistent formatting, terminology and documentation between the assessment processes and guidance undertaken by each group. In the long-term, a single access point could be developed by which proponents could access the assessment processes necessary for food, feed and environmental considerations.
- NFS members raised some sensitivity to the term "novel" and pointed out that the term has negative connotations in an international setting (i.e., the perception of "novel" is that it is the same as "genetically modified organism") and encouraged the AFD to use the word "new".
- The issuance of letters of confirmation to confirm determinations would be useful for proponents. The AFD noted that they are working in collaboration with PBO and this will be done.
- Regular consultation with the seed industry and developers was recommended. In addition, Forum members encouraged further efforts from government to raise awareness and educate industry and stakeholders about the process for assessing novel feeds from plant sources.
- Some Forum members encouraged further guidance to ensure that public breeders are given assistance to

ensure that their crops are not disadvantaged by lack of resources and expertise to prepare submissions for the assessment of new crops (they noted that private sector companies are better equipped to manage the regulatory process than public breeders).

- Overall, the language in Appendix 2 could be clearer and more direct.
- Some members suggested removing Section 8 of the Guidelines as it relates to environmental safety triggers. AFD pointed out that this section is included to comply with the requirements under the Feeds Act and Regulations which is scheduled under the Canadian Environmental Protection Act (CEPA).

Some of the suggestions raised by NFS members could require regulatory change:

- The Schedules are out of date and need to be updated as soon as possible. AFD noted that this work is underway.
- NFS members suggested regulatory amendment as a means of including the concept of risk in the novel feed trigger. This would further align the process for feed with PBO. It was noted by a Forum member as well as AFD, that the main purpose of the Feeds Act and Regulations is safety and efficacy. This is the case for all feeds including novel feeds. It was noted that the regulatory oversight of novel feeds is the same as for any other feeds covered under the Feeds Act and Regulations.

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## NEXT STEPS

The Directive: Plants Regulated under Part V of the Seeds Regulations will be revised and posted online for further consultation.

The feedback received from Forum members would be used to enhance novelty guidance in regards to novel feeds.

The AFD will consider creating a working group to further inform the development of guidance; CFIA will contact the individuals who volunteered to participate on this working group. In addition, comments on the document, including the Guidelines for the Assessment of Novel Feeds, can be submitted in writing to: [AFD-DAA@inspection.gc.ca](mailto:AFD-DAA@inspection.gc.ca).

The next meeting of the National Forum on Seed will be held in Ottawa on March 19-20. This will be last meeting of the NFS under Phase IV of ACCAF funding.