

Plants with Novel Traits Working Group - Summary Report



March 4, 2008 - Ottawa, Ontario

The National Forum on Seed's (NFS) Working Group on Plants with Novel Traits (PNTs) met in Winnipeg, Manitoba on March 4, 2008. A total of 48 plant breeders, seed growers, seed distributors, crop producers, representatives of industry associations and government officials attended the meeting. The objective of the meeting was to identify opportunities for changing/enhancing/making more efficient and building synergies into the novelty assessment process for food, feed and seed. The meeting was in follow-up to the first Working Group meeting in Ottawa on March 6, 2006.

The objective of the Working Group on Plants with Novel Traits is to ensure regulations do not constitute an unnecessary barrier to innovation and commercialization for products derived through conventional plant breeding.

The Winnipeg meeting began with several presentations in the morning to set the context for the meeting. Questions and comments followed each presentation. In the afternoon, participants broke into group discussions around identifying opportunities for improving the novelty assessment process. The final part of the meeting focused on next steps.

The meeting facilitator advised the group that the Advancing Canadian Agriculture & Agri Food program (ACAAF) - under the auspicious of Agriculture and Agri-Food Canada (AAFC) - has approved and funded continuing NFS activities, including ongoing work on PNT and novelty.

Background and History

Presentation: Dale Adolphe, NFS

Mr. Adolphe gave an overview of the Working Group on PNTs since its inception. (See highlights of this presentation in Appendix 1) He described the outcomes from the March 2006 Working Group meeting with respect to greater transparency in the regulatory system; the concept of a single window for assessing novelty; the use of experience from other countries; tiered risk assessment; and, post-approval monitoring. Based on those outcomes, a report was prepared and discussed at a March 2006 NFS meeting.

A joint response from the Canadian Food Inspection Agency's (CFIA) Plant Biotechnology Office (PBO) and Feed Section (now the Animal Feed Division) and Health Canada's (HC) Novel Foods Section was received in July 2006 in the form of a letter.

Mr. Adolphe explained the ten main activities outlined in the letter and offered his view on progress that has been made to date. He pointed out that while there has been varying degrees of progress in three areas, he felt there had been no action in the other seven activity areas.

Discussion

The main area of discussion on this topic was around the degree of progress that has been made on the 10 activity areas outlined in the July, 2006 CFIA letter. It was noted during the discussion that these activity areas mainly focused on PNTs and not novel foods and novel feeds. It was suggested by the CFIA representatives at the meeting that the CFIA guidance document on novelty being developed now will in fact embrace all of the activity areas, so in that sense, progress is being made in all the activity areas. The goal is for the draft document to be available for consultation in Spring 2008.

Presentation: Dr. Stephen Yarrow, CFIA

In his presentation, Dr. Yarrow outlined the principles behind the Canadian Regulatory Framework for Biotechnology. (See highlights of this presentation in Appendix 1) Dr. Yarrow discussed the concept of novelty. He indicated this is a broad concept that built on the regulatory system already in place and applies to more than just products of biotechnology.

A key theme in Dr. Yarrow's presentation was communications. He said the government approach to novelty has not been communicated well by regulators. CFIA is trying to rectify this through participation at industry meetings, development of a guidance document on novelty for PNTs, and the future establishment of a single administrative window for plant products.

Discussion

The main area of discussion was around the definition of novelty as a product-based, versus process-based approach. The point was made that if the trigger is product-based, why is it necessary to provide process data in the regulatory package.

It was observed that many products in the Plants with Novel Traits regulatory system for environmental release are derived from biotechnology (recombinant DNA and mutagenesis), whereas many novel foods and novel feeds submissions going through the regulatory system are not derived using modern biotechnology.

The perspective from smaller breeders is that they may back away from seeking regulatory approval because of the resources required to develop a full package. As a result, this technology goes to another country where the system is perceived to be less onerous.

Novelty in a Food, Feed, Seed Context

Presentation: Dr. William Anderson, PBO, CFIA

Dr. Anderson's presentation provided an overview of the regulatory system for the environmental release of plants with novel traits in Canada. (See highlights of this presentation in Appendix 1) He referred to the new guidance document now being developed by the PBO under the Seeds Regulations. It is intended to provide more clarification to help plant developers with determining whether the environmental release of their plant is regulated. He encouraged breeders to seek advice from the PBO in the early stages of development to determine if their plant is regulated.

Discussion

As with an earlier presentation, there was much discussion around the requirement on the developer to address process when the novelty definition is being depicted as product-based. Dr. Anderson explained that information about process helps regulators assess the potential for environmental impacts.

There were also questions about harmonization with regulatory bodies in foreign markets. Dr. Anderson said this has been a CFIA priority in the past few years, particularly with the United States and Mexico. Canada is also working on regulatory understandings with China and India. On the topic of imported products, one participant observed that there is a need to ensure that the trigger guidelines also apply to imports. Almost all of the new ornamentals and vegetable varieties are not developed in Canada, but are imported. The view was expressed that imported ornamentals, some of which circumvent the regulatory system when they enter Canada, may have a greater potential to impact the environment. The suggestion was made to break out the different plant groups in the draft guidance document with an annex of considerations specific to, among other products, ornamentals and forest products. A general directive with annexes that apply specifically to different crops eg: field crops, ornamentals and forestry products is, in fact, being developed.

Presentation: Lynne Underhill, Food Directorate, HC

The purpose of Ms. Underhill's presentation was to describe the scope of responsibility of HC pertaining to food, and to provide insight into the broad definition of food for purposes of regulation. (See highlights of this presentation in Appendix 1) Recognizing the food industry's desire for more guidance on novelty and the regulatory trigger, the Food Directorate of HC published revised guidelines on novel foods in 2006. They have held several workshops with the CFIA on novelty determination and submission optimization. HC is also working with CFIA on a pre-submission process for determining novelty and identifying data needs.

Discussion

Again with this presentation, there were questions about the need for data on the creation of novel food products if the regulatory trigger is product-based, not process-based. Mr. Tao, an HC representative, responded that data about product development methodology leads to a better understanding of what needs to be assessed, thus reducing data requirements and assessment time in the long term.

One participant asked whether a new food product in Canada can trigger novelty if it has had a history of safety in other countries. Ms. Underhill responded that comparability of regulatory systems between Canada and the product's country of origin is an important consideration in assessing novelty.

In response to a question, Ms. Underhill clarified that the regulatory trigger for food is novel food, not novel plant.

Presentation: Linda Morrison, Feed Division, CFIA

The purpose of Ms. Morrison's presentation was to provide insight into how the Animal Feed Division determines whether a feed product requires a mandatory pre-market assessment under the Feeds Act and Regulations. (See highlights of this presentation in Appendix 1) She referred to activities undertaken by the Division to improve stakeholder awareness regarding which feed products require a regulatory review, and, determining information requirements for submissions. As part of their activities, the Division, in collaboration with other groups such as PBO and HC, are developing checklists to help developers put together a complete submission package, hosting the second submission optimization workshops in March 2008 in Ottawa and improving the pre-consultation process for determining novelty and identifying data needs. The Division is also revising the current novel feed from plant

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sources guidelines in order to provide more clarity regarding data requirements for novel feeds submissions.

Discussion

Ms. Morrison was asked whether the Feed Section intends to develop a risk analysis process where a product can be considered not novel if it poses no risk to livestock. She responded that the trigger for novelty in feed is essentially risk-based in that if a feed product contains ingredients not on the approved list, or are not considered equivalent to an approved ingredient, they require assessment. The assessment/ evaluation for approval, or to determine equivalency, is and always has been a risk-based process to assess, analyze and manage ingredient approvals appropriately.

Presentation: Titus Tao, Food Directorate, HC and Philip Snelgrove, Feeds Section, CFIA

The intent of the presenters was to explain the assessment processes for novel foods and novel feeds derived from plant sources, and to demonstrate where there are linkages. (See highlights of this presentation in Appendix 1) The underlying themes of the presentation were that products are unique, and thus data requirements will vary; and that proponents of a product are strongly urged to consult with HC and CFIA at the earliest possible point in product development in order to determine what data is required for their product. This can help developers plan research efficiently, avoid providing too little or unnecessary information, and hasten the assessment process.

Discussion

One participant asked for clarity about the point at which novelty is no longer novelty. Mr. Tao indicated that this is an issue HC struggles with and that's why HC is working on streamlining the process to determine when a novel trait is sufficiently prevalent as to no longer be considered novel.

Some comparisons were made between the Canadian and U.S. regulatory system, with one participant suggesting that the U.S. system is quicker. Ms. Morrison responded that the U.S. process involves both federal and state regulations, whereas Canada's regulations are entirely federal. Both countries have an ingredients list that helps to determine novelty. She suggested that the U.S. process is in some ways more complex and lengthy.

Presentation: Dr. William Anderson, PBO, CFIA

Dr. Anderson said he recognizes the importance of a government-wide approach to industry on seed, feed and food regulation. (See highlights of this presentation in Appendix 1) He described the Increasing Transparency and Efficiency in the Regulatory Assessment of Novel Products (ITERANP) initiative, which involves projects such as the Saskatoon and Ottawa workshops on optimizing submission quality. The Ottawa workshop will be an opportunity for industry to comment on new information pieces developed by CFIA and HC such as pre-submission consultation standard operating procedures (SOPs) and data package life-cycle diagrams.

The concept of a single administrative window for regulated plant products is being explored. Among the outcomes of the window would be to enhance transparency and regulatory predictability for industry, and improved timely commercial access to safe products.

Discussion

There was general agreement at the meeting that the single window is a helpful idea. There were questions around which products would use the single window and which would not. Dr. Anderson responded that the intent of the single window is not to funnel all products through it and that most plant products developed by traditional research most likely would not use the window. Rather, the intent of the single window is to be more explicit and transparent about how different government departments work holistically on regulatory assessments.

Some participants, particularly plant breeders, expressed frustration about the manner in which organizations were contacted for the March 2008 submission optimization workshop in Ottawa, as many at the meeting were not aware of it.

Building Synergies

The basis of the group discussion was the list of 10 activity areas identified by the PBO in consultation with the Feed Section and HC, in a letter of July, 2006.

1. Clarify newness and environmental safety linkages.
2. More clearly define and interpret the novelty trigger.
3. CFIA draft of a guidance document on novelty.
4. Recognize early consultation as due diligence.
5. Explore the concept of a single window approach.

6. Recognize other countries' data.
7. Develop an appeal mechanism.
8. Recognize scientific rationale in lieu of *de novo* data.
9. Clarify the no split decision policy.
10. Commit to working with stakeholders.

Participants were asked to focus their discussion on these questions:

- Is this a complete list?
- If not, what other activities need to be added?
- Can you prioritize these activities?

Overall, there was general confirmation that the list is valid. Some points of emphasis were suggested for some of the activities, and several new activities were suggested. The points of emphasis around the existing list follows:

Novelty trigger (2):

- There were differing views around whether it would be useful to drop the idea of novelty, as opposed to clarifying it. Some said the current definition is impeding innovation. In Canada, the definition was constructed around the product of plant breeding, while the definition in other countries is generally around rDNA.
- There should be clarification on the impact on international marketing of calling a product novel. The comment was made that the current definition has much ambiguity.
- The term "new" rather than novel might work better for food and feed. Novelty carries the perceptual baggage of transgenic in the plant breeding community. New feeds and foods are subject to a safety assessment; this is a fundamental difference from seed where the product is subject to an assessment if it contains a trait that is new and has the potential to have an impact on the environment.

Guidance Document (3)

- The group would welcome appendices for different crop types in the PNT guidance document.
- The earlier a breeder or developer can know whether their product will be regulated, the better. It is helpful to know when the product is still in development what specifically might trigger regulatory oversight.

- There needs to be greater transparency in determining the type of data needed for assessing a product.
- Potential impact on the environment is where CFIA puts its regulatory emphasis for regulating the environmental release of plants with novel traits, so there needs to be caution about being solely rDNA-focussed with the trigger mechanism.

Due diligence (4)

- It was emphasized that early consultation should be seen as due diligence.

Single Window (5)

- As part of this project, there should be a support system for shepherding a developer through the regulatory system.
- There was concern that the single window approach might mean a product that triggers only one or two pieces of regulatory legislation might be subject to assessment under all regulatory legislation. CFIA assured that the objective of single window is a single point of contact. It is not being designed to push a product unnecessarily into a regulatory process.
- A participant suggested that a single window should mean that one set of documents goes to three groups, instead of three sets of documents, one to each group.

Other countries' data (6)

- As science and processes are constantly evolving, we need a regulatory system that will allow Canada to be competitive and to introduce new products in a timely fashion.
- The term alignment is a more accurate and palatable definition in working with other countries. Rather than harmonization of regulations, Canada has been working with trading partners on aligning processes. A participant noted that it would be desirable, if feasible, to go further than aligning processes to include the alignment of items such as maximum acreage restrictions around confined trials between countries as currently they are not the same.

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Appeals (7)

- Any appeal process should ensure that the appeal does not go to the same people who made the original decision.

Working with stakeholders (10)

- Improved communication and education is a key goal and regulators are committed to continuing to work with regulated parties.
- It is important for product proponents to know what data may be required while the product is still in development.

During the plenary, additional activities were identified:

- Participants suggested that all activities on the list should be completed by the end of 2008 with the exception of the appeal mechanism, which will take longer. The definition of "complete" is that the activity should be either done, or done and ongoing.
- There should be clarification around when a novel trait is no longer novel.
- Actual cases should be made available where products have been successful in the regulatory process and where they have not. This would be an excellent education tool for breeders and the industry.
- Within the organic movement there is growing interest in heritage varieties. In some cases, these varieties have not been in use for decades. There needs to be clarity around whether they would trigger novelty.
- Can pre-consultation occur to determine whether a product will trigger novelty? CFIA indicated that this has been done in the past on several occasions. With the development of SOPs for pre-submissions consultations the process will be more transparent in the future.
- The treatment of socio-economic considerations and whether, or not, that treatment exists needs to be clear in the risk assessment process.

The Path Forward

Next Steps

Following table discussions, the group engaged in a plenary to identify next steps.

1. The NFS will review this Summary Report at its next meeting April 9, 2008 in Winnipeg. Subsequently, it will be provided as guidance from NFS to CFIA and HC.
2. Guidance document:
 - The goal for the guidance document on PNTs being developed by CFIA is for it to be available in the Spring of 2008 for consultation. It was suggested by a participant that consultations go beyond an on-line approach. An online consultation would allow all stakeholders have a full opportunity to participate. It was suggested that the consultation timeframe should be short initially, but subject to continuous evolution. The NFS, Canadian Seed Growers Association and Canadian Seed Trade Association could be helpful in the process of encouraging stakeholder comment on the document.
 - In addition to the PNT guidance document, a broader document that incorporates trigger guidance on food and feed should be developed.
 - The guidance document should provide examples of actual submissions, both successful and unsuccessful, as learning tools for breeders and product developers. A web-based decision tree also could be a helpful education tool.
 - Regarding the definition of novelty, it was suggested that a regulatory impact assessment might be a means toward changing the definition.
3. The SOPs, checklists and other information material will be tabled for discussion and comments at the submission optimization workshop March 18-19, 2008 in Ottawa.
4. The Animal Feed Division is working to enhance and clarify guidelines for feed. These will be ready by the end of 2008. This should not be viewed as a change in the guidelines, but rather as a clearer explanation of them.

5. The single window approach is now at the senior management discussion stage of CFIA. Participants recommended that the approach be implemented by the end of 2008. Some meeting participants cautioned against casting the net too widely as the process could become bogged down. Many submissions from feed and food do not have a biotech component and therefore should not go to the single window.
6. Participants acknowledged the progress CFIA and HC have made in improving communication with stakeholders, and underscored the need for continuous improvement in this area. In particular, there needs to be better communication between regulators and small breeders who may currently perceive that the regulatory system is too burdensome.
7. It was widely commented that progress in all of the activity areas identified in this Summary Report should be reported, possibly in the form of a report card. There was general consensus that if this is done, the Working Group should not have to meet again.

Closing

A key message in the closing discussion was about the need for better communication at all levels. While much of the discussion during the meeting was around communication between regulators and industry, the view was also expressed that the general public, particularly consumers, need to better understand the interconnectivity of the regulatory process and Canada's economy. Another view was that the messages are getting out and public perception and understanding, particularly around biotechnology, is improving.

Ms. Underhill from HC assured the group that the messages of the Working Group had been heard. She said the meeting was productive and HC wants to continue to be engaged in working with stakeholders to make improvements. Ms. Morrison of CFIA said the meeting was helpful in clarifying that the expectation of the Working Group is that guidance on novelty should include food and feed, not just seed. She emphasized the importance for developers to consult with regulators as early as possible to assess whether novelty might be triggered and if so, what data may be required. Dr. Yarrow of CFIA concurred that the ideas raised at the meeting were very useful; they provide guidance for future work.

APPENDIX 1

Highlights of Dale Adolphe presentation (Background and History)

The first PNT Working Group meeting was held in Ottawa March 6, 2006. Participants included plant breeders, seed growers, seed distributors, producers, industry associations and government regulatory officials.

There were numerous outcomes from the 2006 meeting. The plant breeder is in the best position to make the initial determination of whether novelty exists. CFIA and HC showed a willingness to be consulted early on whether novelty exists. Regulators should categorize traits according to likely impacts on gene flow, weediness, plant pest potential, impact on non-target organisms and biodiversity. Greater transparency and an appeal mechanism would be desirable. Ideally, a single window for assessing novelty should be accessible for food, feed and environmental risk assessments. Experience in other countries should be considered in the risk assessment

process. Other outcomes included proposals for tiered risk assessment and post approval monitoring.

A report on the meeting was discussed by the NFS March 2006. Subsequently a CFIA response incorporating HC input was received in July 2006 in the form of a letter. Subsequently, ACAAF approved Phase IV NFS activities, including further work on the PNT and novelty issue.

The letter focused on the issue of what triggers novelty. PBO acknowledged that clarifying the linkage of newness and environmental safety would be positive. PBO agreed the novelty trigger should be more clearly defined, and indicated it was drafting new guidance to the industry. CFIA indicated it was exploring options for documenting consultations early in the development stages as due diligence. There was a willingness among PBO, the Feed Division and HC to explore a single window for products that trigger novelty. While environmental

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safety assessments must continue, PBO can take into account relevant and appropriate data from other countries. The appeal mechanism is being reviewed. The letter further indicated that information requirements can, in some cases, be met by valid scientific rationale in lieu of actual *de novo* data. The no split approval policy was clarified. PBO stated its commitment to working with stakeholders in further developing regulations to facilitate innovation.

The presentation listed the undertakings in the letter as a series of ten activity areas. This formed the basis for discussion throughout the Working Group meeting on how progress can be made between now and the end of 2008.

Highlights of Stephen Yarrow presentation (The Government of Canada Approach)

Canada's regulatory framework was established through agreement among federal regulatory bodies and was announced in 1993. It sets out six key guiding principles. Following these principles, regulations were developed that incorporated the concept of novelty as a regulatory principle.

Novelty is a broad concept and applies to traditional products, products of modern biotechnology, and products derived through innovative means. In the case of feeds and foods, the concept of novelty was built on the regulatory system already in place. In the case of PNTs, new systems were developed.

Three pieces of legislation must be considered before releasing a new plant and plant-derived products into the Canadian market. Canada has an integrated regulatory system that recognizes the product's lifecycle (environmental release, food use, feed use).

CFIA and HC appreciate there are concerns about the impact on innovation of regulating novel products. Departments are working to rectify this through participation at industry meetings, development of new documents (i.e.: guidance document on novelty) and other activities aimed at reducing the regulatory burden (i.e.: single administrative window).

Highlights of William Anderson Presentation (Context: PNTs)

Regulating the environmental release of PNTs in Canada involves several Acts. Prior to environmental release, notification of the following types of plants are required: PNTs not previously authorized in Canada; plants with more than one previously-authorized trait stacked through conventional breeding in a new combination; previously-authorized PNTs for which authorization was granted to an entity other than the entity currently in control of the variety; and, plants expressing a previously-authorized trait where conditions were imposed on the release.

A PNT is defined as a plant into which a trait has been intentionally introduced; and where the trait is new to cultivated populations of the species in Canada, and has a potential to affect the specific use and safety of the plant with respect to the environment and human health. The method used to introduce a new trait is not a factor in determining whether a plant has a novel trait.

It is the responsibility of the proponent wishing to release a plant into the environment to determine if it has a novel trait.

A trait may be considered new if it previously has not been observed in distinct, stable populations of that species in Canada, or if it is a quantitative trait that lies statistically significantly outside the range observed for that trait in that species in Canada.

When assessing potential for environmental impact, proponents should consider weediness potential, potential for gene flow and consequence, plant pest potential, potential impacts on non-target organisms, and other potential impacts on biodiversity.

The draft guidance document on novelty will provide more clarification to plant developers on how to determine whether the environmental release of their plant is regulated under Part V of the Seeds Regulations. A series of sector-specific technical appendices will provide more technical guidance with respect to determining whether a plant has a novel trait (proposed appendices are agricultural and field crops; forest trees; ornamental, fruit and nut trees; herbaceous and shrubby ornamental plants; turfgrasses).

Highlights of Lynne Underhill Presentation (Context Food)

The globalization of the food supply and the rapid advances in food science and technology have resulted in the introduction of foods not previously available in Canada. HC is responsible for establishing standards and policies governing the safety and nutritional quality of all food, including novel foods, sold in Canada.

The Novel Foods Regulation under the Canadian Food and Drugs Act requires notification of a potentially novel food prior to sale or advertising. The requirement to notify includes: 1. a substance with no history of safe use as food; 2. a food that has been 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; or 3. a food that is derived from a plant, animal or micro-organism that has been genetically modified such that it exhibits characteristics that were not previously observed in that plant, animal or micro-organism; it no longer exhibits characteristics that were previously observed; one or more characteristics of it no longer fall within the anticipated range. It is the third category of Novel Food that is most applicable to the plant breeding community.

Since 1994 HC has issued letters of no objection to the sale of over 100 novel foods. In the past, the majority of these have been foods derived from rDNA crops. More recently, the number of non-rDNA, non-plant submissions is increasing.

HC is mindful of the need to maintain and strengthen the risk-based approach to allocating regulatory resources to the pre-market assessment of foods. To that end, revised guidelines were published in 2006, submission optimization workshops have been organized, formalized tiered assessments have been put in place for familiar products; a formalized pre-consultation process is being developed.

The goals of Food Regulatory Modernization are to provide petitioners with more timely requests for additional information; increase co-ordination within the Food directorate, and improve the quality of submissions.

Highlights of Linda Morrison Presentation (Context: Feed)

Any feed ingredient is required to undergo a pre-market assessment if it is new, or has been modified such that it differs from conventional parameters. Newness can be determined by referring to the list of approved ingredients in Schedules IV and V of the Feeds Regulations. Assessment may be required for feed ingredients that are derived from new processing techniques; that have changes in intended uses, that have new characteristics, or that have significantly modified endogenous characteristics.

The purpose of feed assessments is to ensure the feed is efficacious for the intended purpose, and safe for animal health, human health and the environment. As well, feed assessments ensure that the feed is defined appropriately in the Schedules, and labelled appropriately in terms of safety and consumer protection.

The feed assessment process begins with an optional but highly recommended pre-consultation. This is followed by administrative requirements, pre-screening to ensure the file is complete, review and decision-making.

In order to improve the process, the Animal Feed Division has been collaborating with PBO and HC on submission optimization workshops. CFIA is also formalizing the pre-consultation process, developing checklists for guidance on data package requirements, and making more user-friendly the guidelines for feed.

Highlights of Titus Tao and Philip Snelgrove Presentation (Assessment: Food and Feed)

The key assessment principle is tiering of data, that is, the degree of scientific support required is adjusted based on the complexity/familiarity of the product. Other assessment principles are: Products are considered on a case-by-case basis; valid scientific rationale can be used in place of data or to bridge data; the sum of the overall data provides context for determining efficacy and safety; the assessment considers the likelihood that unintended effects may be present; and comparators must be appropriate. Proponents are encouraged to consult with HC and CFIA to determine what data is required for their product.

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The presenters outlined the eight general considerations for assessing whether a product meets the “bar of safety”.

- History of safe use
- Dietary exposure
- History of organisms
- Characterization of the derived line in relation to parental varieties
- Genetic modification considerations
- Nutritional considerations
- Toxicological and allergenicity considerations
- Chemical considerations

Highlights of William Anderson Presentation (Context: Single Window Approach)

CFIA is working with HC toward increasing regulatory transparency and efficiency. Applicants have raised concerns regarding the turnaround times for review of data packages for safety assessments of PNTs, novel feeds and novel foods. CFIA and HC are endeavouring to enhance industry’s understanding of the regulatory process and information requirements.

To that end, they have developed workshops on optimizing data packages. Information pieces have been developed to increase understanding and transparency: pre-submission consultations, SOPs, data package life-cycle diagrams, and checklists and companion documents.

Pre-submission consultations provide a forum for potential applicants to discuss their products with regulators.

Navigating and addressing regulatory requirements for innovative plant products intended for the marketplace can be time consuming and costly for companies. CFIA and HC recognize that in some cases, regulatory oversight is approached from a stove-pip perspective. The plant single window initiative will lead to a single administrative window for regulated plant products requiring safety and efficacy evaluations.

The desired outcomes of the single window are: enhanced transparency and regulatory predictability for industry; a co-ordinated approach to regulatory oversight; reduced administrative burden on industry; and, improved timely commercial access to safe, efficacious products.