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Issues Related to the Import and Environmental Release of Ornamental Plants with Novel Traits

Discussion Document

This discussion document was developed by the Plant
Biosafety Office of the Canadian Food Inspection Agency

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Canada 

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1.0 Executive Summary

In March 2004, the office of the Auditor General of Canada released a report on the *Regulation of Plants with Novel Traits* by the Canadian Food Inspection Agency (CFIA). In this report the office of the Auditor General recommended that the CFIA raise awareness about the regulations for ornamental plants with novel traits (PNTs) and engage the ornamental industry in developing a pragmatic way forward in this respect. The workshop scheduled for February 17-18, 2005 is the beginning of a series of activities the CFIA is committed to do in order to follow up with the recommendations made by the office of the Auditor General.

A PNT is a plant that expresses a trait not present in plants of the same species or at levels outside the range in which those traits are expressed. PNTs can be produced through a wide range of techniques including, conventional breeding, mutagenesis, cross pollination, rDNA technology, etc.

Similar to agricultural PNTs, ornamental PNTs trigger regulations under the *Seeds Act* and the *Plant Protection Act* for domestic use and importation respectively. All PNTs trigger regulatory oversight to ensure that they do not pose a greater threat to the environment than those currently in a stable population in Canada.

The CFIA recognizes that the ornamental industry is unique unto itself and that innovation is an important factor in remaining competitive. However, the CFIA also has the responsibility to consistently implement regulations for PNTs. In this respect, the CFIA is committed to work with the ornamental industry in order to develop a pragmatic way forward in regulating ornamental PNTs. The first step is to identify a mechanism or tool to assist in identifying what plants are PNTs.

2.0 Introduction

In March 2004, the office of the Auditor General of Canada released a report on the *Regulation of Plants with Novel Traits* by the Canadian Food Inspection Agency (CFIA). The report can be found at:

[http://www.oag-bvg.gc.ca/domino/reports.nsf/html/20040304ce.html/\\$file/20040304ce.pdf](http://www.oag-bvg.gc.ca/domino/reports.nsf/html/20040304ce.html/$file/20040304ce.pdf)

The report recommended that the CFIA raise awareness among plant breeders and importers of ornamental plants about the regulations for Plants with Novel Traits (PNTs). The report also recommended that the CFIA analyze and address inconsistencies with respect to implementing regulations for PNTs within Canada. Special mention on how the CFIA regulates ornamental PNTs was an area of concern for the office of the Auditor General. The CFIA is committed in following up with the recommendations of the Auditor General and has developed this discussion document to analyze the current situation with respect to ornamental PNTs and risk management.

The purpose of this discussion document is to (i) provide guidance on what constitutes a plant with a novel trait (PNT), (ii) outline the current regulatory requirements for PNTs in Canada, and (iii) initiate discussions on how to consistently implement PNT regulations within Canada with respect to ornamental plants.

A workshop scheduled for February 17-18, 2005 will provide participants with the opportunity to openly discuss current regulatory requirements for PNTs in Canada. The workshop will also provide a venue for participants to exchange valuable opinions/comments/questions on identified areas that require discussion. Proceedings from the workshop will be recorded and made available to all participants and the general public. The objectives of the workshop are to:

- 1) To raise awareness among importers and plant breeders of ornamental plants regarding the current domestic regulations for PNTs;
- 2) To raise awareness and collectively discuss criteria/information that could be used by developers/importers of ornamental plants to determine when regulatory oversight is required;
- 3) To raise awareness among regulators about the nature and complexity of the ornamental horticulture industry.
- 4) To develop an action agenda for the development of appropriate regulatory guidance.

This initiative will also inform a broader regulatory initiative addressing the import and domestic movement of PNTs within Canada.

3.0 Plants with Novel Traits

3.1 Novelty

For ornamental plant breeders and importers there is a market advantage to developing or importing a novel plant. As such, mechanisms such as Plant Breeders Rights (PBRs) and plant registration with the Canadian Ornamental Plant Foundation (COPF) have been introduced to create incentives for plant breeders to develop novel plants. Obtaining PBRs or registering a novel plant with COPF are only granted when the plant meets certain criteria, including novelty.

In order to determine if a plant variety is eligible for plant breeders' rights (PBR) the following criteria need to be met:

1. NEW: The sale of a candidate variety prior to application for protection is restricted. Regulations covering the sale of varieties prior to applying for protection are as follows:

Sales of Varieties in Canada - Varieties may not have been sold in Canada prior to submitting an application for protection.

Sales of Varieties outside of Canada - Varieties, excluding those of woody plants and their rootstocks, may have been sold outside of Canada for up to four years. Varieties of woody plants and their rootstocks may have been sold outside of Canada for up to six years prior to submitting an application for protection.

3. DISTINCT: A candidate plant variety must be measurably different from all other varieties which are known to exist within common knowledge at the time the application was made. Common knowledge includes varieties already being cultivated or exploited for commercial purposes in Canada and those varieties described in a publication that is available to the public.
4. UNIFORM: A candidate plant variety must be uniform in that any variation should be predictable to the extent that it can be described by the breeder. Any variations in the uniformity of a variety must be commercially acceptable.
5. STABLE: A candidate variety must remain true to its description over successive generations. The variety must be stable in its essential characteristics to the degree where further generations of seed or other propagating material exhibit the same characteristics as described in the original description for which rights were granted.

The “novelty” of a product is also used as a trigger for regulatory oversight under the *Seeds Act*. If an ornamental plant expresses a novel trait, a risk assessment on the plant is required to ensure the plant does not pose a risk to the environment, human or animal health and safety. To date, agricultural crops such as canola, corn and soybeans have been the focus of public attention due to the concerns regarding environmental, human and animal health and safety. Until recently, public concern about novel ornamental plants has been minimal. However, it is the role of the CFIA to ensure that all plants with novel traits do not pose a risk to the environment.

The following sections will help outline the current regulatory requirements for plants with novel traits, including ornamental plants with novel traits.

3.2 Regulating Plants with Novel Traits

Prior to the 1990’s, new plant varieties typically encountered regulations and standards that, depending on the species and its intended use, included plant breeders’ rights, seed crop certification and/or variety registration. These programs addressed quality, intellectual property and plant pests. However, advances in plant breeding, such as genetic engineering, raised public consciousness about environmental and food safety issues. Thus, in the 1980’s the Government of Canada consulted with all stakeholders on the development of regulations regarding products of genetic engineering. In the early 1990’s regulatory directives emerged for new plant varieties which express a novel trait to undergo pre-market assessments for environmental safety.

At that time, the *Canadian Environmental Protection Act* (CEPA) established a requirement for any person wanting to import, manufacture or sell any new substance to notify the appropriate Canadian regulatory authority so the new substance can be evaluated for potential adverse effects on the environment and human health. After extensive consultations with stakeholders the Government of Canada decided to:

Regulate based on the end-product and not on the process in which the product was produced; and

Require an assessment of risk for plants which possess characteristics or traits sufficiently different from those that are expressed in the same or similar species.

In essence, Canada adopted a product-based regulatory framework for assessing the potential risks of a novel trait on the environment, human and animal health and safety. Inherent in this approach is an understanding that the developer or importer of a plant with a novel trait has well characterized the product to ensure its safety in the marketplace. A policy decision was also made to require a risk assessment on a novel trait, assuming that a novel trait may pose a potential risk to the environment, human or animal health and safety. The rationale behind Canada’s product-based regulatory framework is that it is the final product that could be a potential risk and not the process by which the product was produced (i.e. rDNA techniques, mutagenesis, cross

pollination). As a result, all novel products whether they are developed domestically or imported into Canada are regulated based on whether they express a novel trait.

3.3 Regulating based on Novelty

The product-based trigger for regulatory oversight in Canada is broader than the process-based systems currently used in many other countries. The product-based trigger used in Canada is based on risk as ***all novel traits may potentially pose risks to the environment, food or feed, regardless of the breeding method used to produce them.*** This regulatory framework for PNTs in Canada is based on science, is internationally respected and is expected to reduce regulatory burdens in the future.

Although regulation in Canada is broader than those frameworks administered in other countries, a level and scientifically consistent playing field is maintained for Canadian developers and importers of new plant varieties. For example, plant breeders have developed 3 different novel herbicide tolerant canola varieties using 1) traditional breeding, 2) mutagenesis and 3) rDNA/transgenic breeding techniques. The different breeding techniques have respectively produced an atrazine tolerant, imidazolinone tolerant, and a glyphosate tolerant canola variety. All of the novel varieties pose the same potential risk to the environment i.e. risk of increased weediness and issues regarding control of herbicide tolerant volunteers. Canadian product-based regulations ensure that all of these varieties trigger regulatory oversight and an assessment of risk is required prior to their release into the environment. The glyphosate tolerant canola is the only novel herbicide tolerant canola to trigger regulations in a process-based regulatory framework.

Plant breeders in other countries are also subject to Canadian regulations when exporting their products to Canada. Elaborating on the previous example, the novel herbicide tolerant canola developed through traditional breeding or mutagenesis, if produced in the United States, would be defined as a PNT in Canada and would trigger regulatory oversight. However, this novel canola variety would not have been regulated in the United States because regulations are based on the process used to develop the product and not the product itself.

The Government of Canada has regulated PNTs since the late 1980's, has established and maintained a science-based framework and is respected domestically and internationally for its regulatory approach to PNTs.

3.4 What is a Plant with a Novel Trait (PNT)?

The *Seeds Act* defines a plant with a novel trait as follows:

By definition a plant with a novel trait (PNT) is a plant containing a trait not present in plants of the same species already existing as stable, cultivated populations in Canada, or is present at a level significantly outside the range of that trait in stable, cultivated populations of that plant species in Canada¹.

In essence, a PNT is a plant that expresses a trait not present in plants of the same species or at levels outside the range in which those traits are expressed.

In order to determine if a plant expresses a novel trait, a significant amount of information is needed on that species. Information gathered on the stable population would determine the expression of specific traits such as yield, disease resistance/susceptibility, flower color, etc. The expression of specific traits usually fit into a defined range. This “range” differs from plant species to plant species. If a plant expresses a trait that is not present in a stable population in Canada or is outside of the normal identified range of expression, the plant would be considered a plant with a novel trait.

Furthermore, if the plant contains a new trait which is intentionally selected, created or introduced into the plant through a specific genetic change, the new plant variety may also be considered a PNT.

3.5 How to determine what is a PNT?

The determination of a PNT is done on a case by case basis depending on the plant species and trait that is expressed.

The responsibility for determining if a plant is considered a PNT rests with the importer, plant breeder or developer. The requirement for notifying the CFIA and being granted authorization to release the PNT into the environment is triggered by the presence of a novel trait in the plant. The CFIA will assist any developer, importer or plant breeder in a determination of novelty and has recently updated its Directive 94-08, entitled “Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits”, that provides guidance in determining if a plant expresses a novel trait. Current initiatives are underway to further refine the use of “novelty” as a trigger for regulatory oversight. For the purpose of this discussion document on ornamental plants, the following information will aid in the discussions on novelty at the upcoming workshop.

¹ Regulatory Directive 94-08 Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits

In order to determine whether an ornamental plant expresses a novel trait, information on the “biology” of that ornamental plant presently grown in Canada is needed. Biology is defined as the science of life and of living organisms, including their structure, function, growth, origin, evolution, and distribution. The structure and function of the plant species aids in developing expression ranges for specific traits. Developing expression ranges for ornamental plants may be quite challenging for the ornamental industry if there is a lack of information on the biology of the plant species and its interaction with the environment. In contrast, entire biology documents have been developed for agricultural crops, such as canola, soybean, flax, corn, potato and wheat and are publicly available at:

<http://www.inspection.gc.ca/english/plaveg/bio/pntchae.shtml>

The biology documents can serve as a basis for comparison when determining if a newly developed plant expresses a novel trait.

As the CFIA moves forward in applying consistent regulatory oversight on all plants with novel traits, including ornamental, horticulture and forest trees, information regarding the biology of the plant species will aid the developer, importer or plant breeder in the determination of novelty.

3.6 Other Factors that may help in Determining whether a Plant Expresses a Novel Trait

Breeding Objectives

Another factor that could help plant breeders and importers of ornamental plants in determining if a plant expresses a novel trait is to look at the breeding objectives for the plant species. If the breeding objectives are concentrated on introducing traits that have never been expressed in a stable population of that plant species, it is likely that the plant would express a novel trait in Canada. For example, the introduction of stress tolerance, salt tolerance, cold tolerance or different flower color would likely produce a plant with a novel trait, if those traits have never been expressed in that plant species before in Canada or if these new traits are significantly outside the known ranges in Canada.

Novel Germplasm

The introduction of a trait from wild biotypes or from germplasm originating outside of Canada, is more likely to produce a PNT than conventional breeding with germplasm already in use in the Canadian environment. It is possible that the traits expressed in the germplasm originating outside of Canada would not already be present in a stable population in Canada as breeders are using this germplasm to access new traits. Thus, if those novel traits are introduced into an established plant in Canada, the resulting plant would likely express a novel trait. A risk assessment on the plant would be required to ensure that it does not pose a risk to human health or the environment.

4.0 Current Regulatory Requirements for PNTs

The Plant Biosafety Office (PBO) within the Canadian Food Inspection Agency (CFIA) has the responsibility for regulating all PNTs, including ornamental PNTs in Canada under the *Seeds Act* and *Seeds Regulations Part V*². The CFIA is also responsible for the importation of ornamental PNTs under the *Plant Protection Act*³.

For traditional plants that express a novel trait and are intended for food or feed use, the Government of Canada requires that food safety and animal feed safety assessments are carried out under the Food and Drugs Act and the Feeds Act for PNTs prior to being granted unconfined release into the environment. However, ornamental PNTs that are not intended for food or feed use will not be required to undergo food safety and animal feed safety assessments.

4.1 Seeds Act

As mentioned above, the responsibility for determining if an ornamental plant is considered a PNT rests with the importer, plant breeder or developer. The requirement for notifying CFIA and being granted authorization to release the PNT into the environment is triggered by the presence of a novel trait in a plant.

Once the plant breeder or importer determine that the plant expresses a novel trait they are required to submit an application to the PBO to release the PNT into the environment under confined conditions. The PBO will review the submission and either authorize the confined release of the PNT or not authorize its release into the environment. PNTs authorized for release into the environment under confined conditions have to abide by certain regulations which include, but are not limited to, restricting the acreage of production, imposing conditions such as reproductive isolation, restricting the use of harvested material and restricting the production of specific plants in the field plots in subsequent growing seasons. The confined field trials are used to gather information on the effects of the PNT on the environment. The data gathered from the confined field trials will inform a decision on whether the PNT will be authorized for *unconfined environmental release*.

Information gathered during the confined release stage on potential changes in weediness/invasiveness, gene flow, plant pest properties, impacts on other organisms and impact on biodiversity will inform the determination on whether the PNT poses a threat to the environment. After the risk assessments have been completed, the PBO will either authorize the

² *Seeds Act and Regulations*: <http://laws.justice.gc.ca/en/S-8/> and <http://laws.justice.gc.ca/en/S-8/C.R.C.-c.1400/>

³ *Plant Protection Act*: <http://laws.justice.gc.ca/en/P-14.8/>

PNT for unconfined environmental release, authorize the PNT for unconfined release subject to specific conditions (e.g. geographical restrictions), or refuse to authorize the environmental release of the PNT or request further information from the developer to aid in the assessment of risk.

If the scientific risk assessment displays that the PNT should pose no greater risk to the Canadian environment compared with its counterpart currently cultivated in Canada, the PNT will be authorized for unconfined environmental release. Essentially, no greater regulatory oversight is required if the PNT poses no greater risk to the environment than its counterpart.

To date, the CFIA has authorized the following PNTs for unconfined release into the environment: corn, canola, flax, lentils, potatoes, soybeans, sugar beet, and wheat. These PNTs have been developed either through somaclonal variation, recombinant DNA technology, or chemically induced seed mutagenesis. To view the entire list of the crop trait variations please see:

<http://www.inspection.gc.ca/english/plaveg/bio/pntvcne.shtml>

An important element for the ornamental industry to consider when submitting an application for environment release is the amount of information that is required to prove that the ornamental PNT does not pose a greater threat to the environment than its conventional counterpart. Certain information requirements may be waived by the CFIA if it determines that the information in question is not relevant to a particular PNT's environmental safety assessment. The developer or plant breeder making the submission must provide a valid, scientific rationale (supported by appropriate data and/or literature references) why the CFIA could waive the information requirements and still make a decision to authorize the environmental release of the ornamental PNT. For example, an argument could be made by the developer or importer that an ornamental PNT in which the stable population does not survive in the Canadian environment would require less extensive information on the environmental interactions.

4.2 Plant Protection Act

The *Plant Protection Act* regulates the importation of plants into Canada in order to prevent the importation, exportation and spread of pests injurious to plants within Canada. Ornamental PNTs have the potential to be a plant pest and therefore imports of ornamental PNTs are regulated under the *Plant Protection Act*.

All imports of ornamental PNTs are required to have a Permit to Import, issued by the Plant Health and Production Division, in order to enter Canada, regardless of regulatory decisions by other authorities outside of Canada. Conditions are placed on the import of PNTs which are outlined in the Permit to Import. To date, all imported PNTs are required to enter into containment facilities as they are considered to be a potential plant pest. Once the PNT is in

Canada, developers or plant breeders must abide by the *Seeds Act* and *Regulations* if they want to release the PNT into the environment.

For example, an importer that wants to import a geranium that expresses a novel trait (e.g. disease resistance) into Canada must obtain a Permit to Import from the CFIA. The Permit to Import will be granted under the condition that the novel geranium enters into a contained facility. If the importer wants to release the novel geranium into the environment an environmental risk assessment is required as defined by the *Seeds Act* and *Regulations*.

5.0 How to Manage Consistent Program Delivery and Regulatory Oversight

The CFIA:

Recognizes that the exposure, intended use, breeding objectives and biology for ornamental plants are different than agricultural products;

Understands that innovation in the ornamental industry is an important factor in remaining competitive and is dependant on developing novel plants.

Recognizes that the ornamental industry and the federal government have to work together to develop a sustainable and workable framework for regulating ornamental PNTs.

The Government of Canada has a strong regulatory framework for agricultural PNTs. To date, the Government of Canada has authorized the environmental release of approximately 58 PNTs in either corn, soybeans, canola, flax, potatoes, wheat, sugar beet and lentils. Experience and knowledge of these agricultural plant species has led to the development of an effective and efficient regulatory system for importers and developers of these products.

In contrast, there has been relatively little experience in regulating the import and environmental release of ornamental PNTs in Canada. Chapter four (4) of the March 2004 report from the Auditor General recommended that:

1. The CFIA should more formally and more systematically identify the environmental safety issues related to the environmental release of ornamental PNTs.
2. Based on the environmental safety issues, the CFIA should develop appropriate approaches for its assessment and regulation of environmental releases of ornamental plant species with novel traits.

As such, the CFIA is committed to identify potential environmental risks and subsequently develop consistent risk management procedures for the environmental release of ornamental PNTs. Recognizing that it is the mandate of the CFIA to protect the environment from plants with novel traits, invasive plants and plant pests, the CFIA needs to develop a pragmatic regulatory framework for the ornamental industry which is consistent with current regulations for PNTs.

In order to develop a pragmatic regulatory framework for ornamental plants with novel traits, CFIA is committed to working with key stakeholders to minimize the cost and regulatory burden these regulations may impose. As such, the workshop on February 17-18, 2005 will focus on exchanging information and ideas on how to proceed in this respect. The following section outlines some of the challenges that the CFIA needs to address at the present time.

5.1 Current Challenges

Most plant breeding programs for ornamental plants are focused on developing a novel plant variety. The existence of Plant Breeders Rights (PBR) in Canada and the Canadian Ornamental Plant Foundation (COPF) encourage innovation in this respect. These novel plant varieties may be PNTs and thus trigger regulations under the *Plant Protection Act* or the *Seeds Act*. The existing challenge for the CFIA is to provide guidance to importers and plant breeders on how to determine if the ornamental plant is a plant with a novel trait. The challenge for the ornamental industry is to actually determine if the plants express a novel trait.

The first question that needs to be answered is:

What information is known about the biology/agronomy/taxonomy of the plants that are imported or developed in Canada?

Collecting or gathering baseline data on ornamental plants that may be considered PNTs would aid both developers and plant breeders in determining if the ornamental plant expresses a trait which is either not present in a stable population or is expressed outside the normal trait range.

Once a plant breeder has determined that the ornamental plant is a PNT and they are planning to release it into the environment, the plant breeder is required to submit an application to the CFIA for authorization for confined or unconfined release. Information requirements may differ depending on the plant species. Furthermore, if the plant breeder can provide a valid, scientific rationale as to why specific information on the PNT and its interaction with the environment is not necessary, the information requirement may be waived by the CFIA.

An importer of ornamental plants must also determine if they are importing an ornamental PNT. If this ornamental PNT is not destined for release into the environment the importer does not need to submit an application to the PBO of the CFIA for authorization for environment release. On the other hand, if the ornamental PNT is destined for release into the environment, the

importer must submit an application for environmental release. Again, if the plant breeder can provide a valid, scientific rationale as to why specific information on the PNT and its interaction with the environment is not necessary, the information requirement may be waived by the CFIA.

Are there any valid, scientific reasons why specific information requirements that show that an ornamental PNT does not pose a risk to the environment could be waived by the CFIA i.e are there any plants that could be exempted from going through the environmental risk assessment using the criteria in the Seeds Regulations Part V?

Some plant breeders register their novel plants with COPF or obtain plant breeders rights through the CFIA. Information is required to prove that the plant is new, uniform, distinct and stable. In order to minimize the regulatory burden on developers and importers of PNTs could PBRs, plant registration with COPF or other mechanisms currently in place assist in the determining whether an ornamental plant expresses a novel trait and/or the environmental risk of such an ornamental plant?

Are there any existing mechanisms, such as PBRs or plant registration with COPF that would aid in the determination of novelty and/or understanding the environment risk of an ornamental PNT?

6.0 Conclusion

As outlined above the current regulatory framework for PNTs poses specific challenges for the ornamental industry. However, the CFIA has the mandate to ensure that all PNTs do not pose a threat to the environment. As such, the workshop on February 17-18, 2005 will allow federal officials to gain further information about the ornamental industry and will provide stakeholders in the ornamental industry with relevant information on the current regulations for ornamental PNTs. This workshop is the first step in determining how to proceed in regulating ornamental PNTs. The workshop is expected to generate a common understanding of the regulations for ornamental PNTs, identify where further information is needed on ornamental plants, and generate an action agenda for both stakeholders and government officials to fulfill upon completion of the workshop.

The CFIA is committed to working with all stakeholders from the ornamental industry to develop a pragmatic way forward in regulating ornamental PNTs.