Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Canadian pre-market regulatory process for novel plant products

Canada

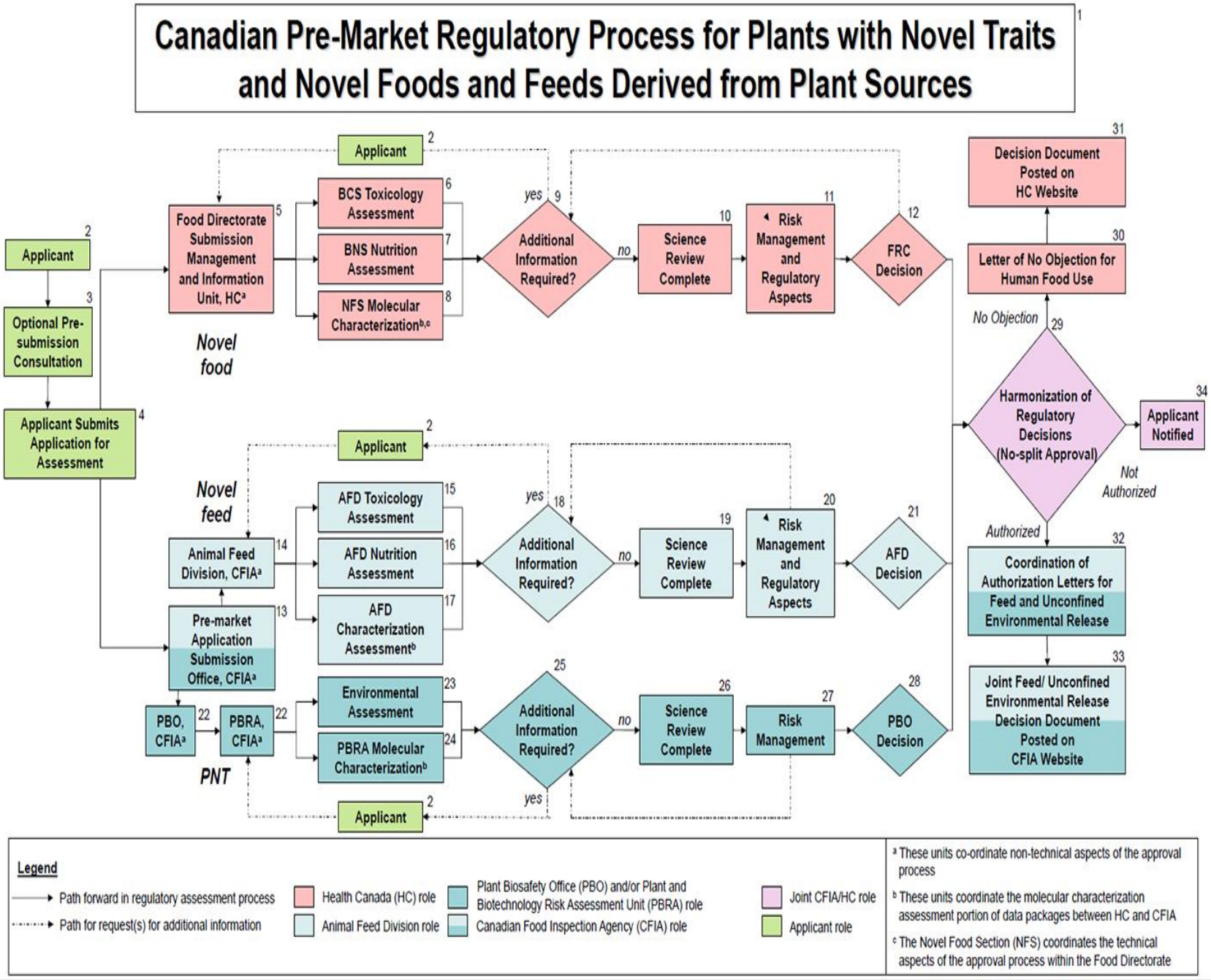
Canadian pre-market regulatory process for plants with novel traits and novel foods and feeds derived from plant sources

The information presented within this document and the associated life cycle diagram, with the same title, is intended to be used by those individuals who are seeking to increase their understanding of the regulatory process for plants with novel traits (PNTs) and novel foods and feeds derived from plant sources.

The life cycle diagram provides a visual representation of the process while this document elaborates on the various stages defined in the diagram. Although not all plant products will be considered novel foods, feeds and PNTs inclusively, the life cycle diagram and this document describe the situation in which a product is considered to be all three.

Acronyms

AFD – Animal Feed Division, CFIA
BCS – Bureau of Chemical Safety, Food Directorate, HC
BMH – Bureau of Microbial Hazards, Food Directorate, HC
BNS – Bureau of Nutritional Sciences, Food Directorate, HC
CFIA – Canadian Food Inspection Agency
FRC – Food Rulings Committee, Food Directorate, HC
HC – Health Canada
NFS – Novel Foods Section, within the BMH
PNT – Plant with a Novel Trait
PBO – Plant Biosafety Office, CFIA
PBRA – Plant and Biotechnology Risk Assessment Unit, CFIA
PASO – Pre-market Application Submissions Office, CFIA
SMIU – Submission Management and Information Unit, HC


Canadian Pre-Market Regulatory Process for Plants with Novel Traits and Novel Foods and Feeds Derived from Plant Sources
1
Applicant
2
Optional Pre-submission Consultation
3
Applicant Submits Application for Assessment
4
Food Directorate Submission Management and Information Unit, HC[a]
5
BCS Toxicology Assessment
6
BNS Nutrition Assessment
7
NFS Molecular Characterization[b,c]
8
Additional Information Required?
9
yes
no
Science Review Complete
10
Risk Management and Regulatory Aspects
11
FRC Decision
12
Novel food
Pre-market Application Submission Office, CFIA[a]
13
Animal Feed Division, CFIA[a]
14
AFD Toxicology Assessment
15
AFD Nutrition Assessment
16
AFD Characterization Assessment[b]
17
Additional Information Required?
18
Science Review Complete
19
Risk Management and Regulatory Aspects
20
AFD Decision
21
Novel feed
PBO, CFIA[a]
22
PBRA, CFIA[a]
22
Environmental Assessment
23
PBRA Molecular Characterization[b]
24
Additional Information Required?
25
Science Review Complete
26
Risk Management
27
PBO Decision
28
PNT
Decision Document Posted on HC Website
31
Letter of No Objection for Human Food Use
30
No Objection
Harmonization of Regulatory Decisions (No-split Approval)
29
Not Authorized
Applicant Notified
34
Authorized
Coordination of Authorization Letters for Feed and Unconfined Environmental Release
32
Joint Feed/ Unconfined Environmental Release Decision Document Posted on CFIA Website
33
Legend
Path forward in regulatory assessment process
Path for request(s) for additional information
Health Canada (HC) role
Animal Feed Division role
Plant Biosafety Office (PBO) and/or Plant and Biotechnology Risk Assessment Unit (PBRA) role
Canadian Food Inspection Agency (CFIA) role
Joint CFIA/HC role
Applicant role
[a] These units co-ordinate non-technical aspects of the approval process
[b] These units coordinate the molecular characterization assessment portion of data packages between HC and CFIA
[c] The Novel Food Section (NFS) coordinates the technical aspects of the approval process within the Food Directorate

1. Canadian pre-market regulatory process for plants with novel traits and novel foods and feeds derived from plant sources

This diagram provides general information on the steps involved in a Government of Canada review of submissions for PNTs and novel foods and novel feeds derived from plant sources and may not apply to any other novel foods or novel feeds from other sources.

For simplification, some steps that are not specific to PNTs and novel foods and feeds from plant sources in the regulatory process are not included in this diagram. For example, novel foods and novel feeds may require additional review for health or efficacy claims during the evaluation phase and post-approval, PNTs may also be subject to variety registration.

2. Applicant

The applicant is the entity representing the novel product in the Canadian regulatory framework. The term applicant and petitioner are interchangeable. For example, the applicant may be a plant breeder, importer or manufacturer of the product.

Under the Feeds Act and Food and Drugs Act, the applicant must be or have a Canadian agent who will assume legal liability for the novel product. For authorization for environmental release, a Canadian agent is not required.

The applicant is also responsible for considering novelty of the product based on the Feeds Act, Seeds Act, and the Food and Drugs Act and identifying their products to the appropriate regulators. If an applicant is uncertain whether a product is novel, Health Canada (HC) and the Canadian Food Inspection Agency (CFIA) offer an optional novelty determination consultation.

If additional information is required to complete a food, feed, and/or environmental safety assessment (see boxes 9, 18, and 25), the applicant can respond by contacting the Submission Management and Information Unit (HC), or communicating directly with the risk assessors (CFIA).

To protect the applicant's confidential business information, the CFIA's Animal Feed Division (AFD) also requires that applicants establish a company file with the Division containing a signing authority list. The list will contain the names of the persons who will be authorized to sign applications, discuss applications, and correspond with the AFD.

3. Optional pre-submission consultation

Pre-submission consultation, an optional step in the current regulatory framework, is available as a forum for potential applicants to discuss their products with regulators prior to making a submission. Pre-submission consultation provides the applicant an opportunity to:

- present an overview of their regulatory submission
- ask specific questions regarding the content of their regulatory submission
- receive clarity on the data and/or information requirements specific to the individual product
- clarify the regulatory requirements, policies and administrative processes when applicable
- clarify expectations for data quality and fit for purpose and the use
- elaboration of scientific rationale

This practice often reduces the number of requests from regulator(s) for either clarification or additional information that might otherwise have been required in order to complete a safety assessment and

reach a decision. HC and the CFIA have developed a guidance document for pre-submission consultation that is intended to provide new applicants with more information. It is available on the Pre-submission consultation procedures for novel foods, novel feeds and plants with novel traits web page or by contacting the addresses listed below.

Applicants wishing to consult with regulators should contact either HC or the CFIA to arrange for a pre-submission consultation meeting. Regulators from all relevant groups will be present, regardless of whether this service is accessed via HC or via the CFIA.

For Novel Foods:
Submission Management and Information Unit
Food Directorate, Health Products and Food Branch, Health Canada
251 Sir Frederick Banting Driveway
Postal Locator: 2202E
Ottawa, Ontario K1A 0K9
Phone: (613) 960-0552
Fax: (613) 946-4590
Email: hc.smiu-ugdi.sc@canada.ca

For PNTs and Novel Feeds:
Pre-market Application Submissions Office
Canadian Food Inspection Agency
59 Camelot Drive
Ottawa, Ontario K1A 0Y9
Website: Pre-market Application Submission Office
Email: cfia.paso-bpdpm.acia@canada.ca

4. Applicant submits application for assessment

The applicant must make three separate applications for the assessment of a PNT and of the novel foods and novel feeds derived from plant sources:

- one to the Plant Biosafety Office (PBO) for unconfined environmental release of the PNT
- one to the AFD for feed use and
- one to HC's Novel Foods Section (NFS) for food safety

The CFIA's PBO is responsible for the regulation of PNTs in Canada with regard to environmental safety under the authority of Part V of the Seeds Regulations. A PNT is a plant that contains a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health. These traits can be introduced using a variety of different techniques including genetic engineering, mutagenesis, and conventional breeding techniques.

Before a PNT can be authorized for unconfined environmental release, a determination on the risk to the environment is required. The criteria for an environmental release assessment are outlined in the CFIA's Directive 94-08 (Dir94-08): Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits.

The CFIA's AFD regulates all livestock feeds, including novel feeds, under the authority of the Feeds Act and Regulations. All new feed ingredients including novel feeds from plant sources are evaluated

and regulated in the same manner. Any feed ingredient that is new (that is, not already listed in the Feeds Regulations), or has been modified such that it differs significantly from a conventional ingredient, is required to undergo a pre-market assessment and approval.

The purpose of all feed assessments is the same: to ensure that the feed ingredient is safe (in terms of animal health, human health via food residues and worker/by-stander exposure, and the environment) and effective for its intended purpose prior to marketing.

The evaluation also ensures that the feed is accurately defined in the Feeds Regulations and is labelled appropriately for its safe, effective use and for consumer protection. Information on the criteria for a novel feed assessment can be found in the Guidelines for the Assessment of Novel Feeds: Plant Sources, which is section 2.6 of the AFD's Regulatory Guidance: Feed Registration Procedures and Labelling Standards document.

HC is responsible for verifying that all novel foods are safe prior to their entering into the Canadian food system. Division 28 of the Food and Drugs Regulations requires that the organization wishing to sell the product make a notification to HC prior to the marketing or advertising of a novel food. Information on the criteria for a novel food assessment can be found in HC's Guidelines for the safety assessment of Novel Foods (2006).

5. Food Directorate Submission Management and Information Unit, HC

The Submission Management and Information Unit (SMIU) is responsible for communicating with applicants, and receiving and tracking the progress of all pre-market notifications, including novel foods derived from plant sources and other submissions in the Food Directorate (excluding food-like natural health products, natural health products in food formats, packaging and incidental additive submissions). This provides for a single window approach to submission reviews.

SMIU distributes the submission material to the Bureau of Chemical Safety (BCS), the Bureau of Nutritional Sciences (BNS), and the Bureau of Microbial Hazards (BMH).

6. BCS toxicology assessment, HC

The BCS is responsible for the evaluation of chemical, toxicological and allergenic considerations.

7. BNS nutrition assessment, HC

The BNS is responsible for the evaluation of nutritional considerations, including the review of compositional data for the novel food in comparison with its conventional counterpart.

8. NFS molecular characterization, HC

The NFS of the BMH is responsible for the evaluation of genetic and microbial considerations. Also, the NFS coordinates the technical aspects of the pre-market safety assessment across the three bureaus of the Food Directorate.

9. Additional information required, HC

If, following a review of all submitted information, one or more bureaus have questions and/or require clarification of information submitted, the SMIU (or the NFS) will send a letter on their behalf to the applicant outlining these questions and/or requests for clarification.

10. Science review complete, HC

Information requirements have been met and any outstanding requests for further information and/or clarification have been satisfied.

11. Risk management and regulatory aspects, HC

Based on the determinations of the safety assessment, appropriate risk management recommendations would be added, as well as ensuring its agreement with other applicable regulatory aspects.

12. Food Rulings Committee decision, HC

At the completion of the safety assessment, a document is drafted to summarize the scientific reviews conducted by the relevant bureaus of Food Directorate. In the case of novel foods derived from plant sources, it is drafted by the NFS and is presented to the Food Rulings Committee (FRC) for consideration and decision. This Committee is chaired by the Director General of the Food Directorate and consists of Food Directorate senior management and representatives from the CFIA (Note: the composition of the Food Rulings Committee may change according to the specific novel food proposals that are being presented).

In the event that the scientific reviews conducted by the Bureaux conclude that the product cannot be considered safe for consumption as a food, this determination would also be brought to the FRC. Also, where applicants are not able to provide data or a valid scientific rationale required to reach a conclusion about the safety of a product, they may choose to withdraw the submission prior to presentation to the FRC.

13. Pre-market Application Submissions Office, CFIA

The Pre-market Application Submissions Office (PASO) is the single location to submit applications for PNTs and novel feeds derived from plant sources, as well as other plant and feed submissions, to the CFIA. One of the purposes of PASO is to promote consistency of administrative functions among programs. Once a novel livestock feed or environmental release submission is received, PASO conducts basic administrative tasks and then passes the files on to the AFD or PBO, respectively.

Additionally, AFD conducts a preliminary screen of the file in order to verify that all information needed for review has been received and makes a decision regarding acceptance of the file for review which is communicated to PASO. PASO then completes the remaining administrative tasks for the file. If the file has been accepted for review, the file is entered in the queue and given to AFD evaluation officers assigned to the file.

14. Animal Feed Division, CFIA
Data packages are received by an administrator in the AFD and then distributed to the appropriate evaluators for review. Each evaluator assesses a submission according to his/her own expertise (for example, animal nutrition, toxicology, molecular biology) but all evaluators work collaboratively to assess the submission and make a decision regarding authorization.

15. Toxicology assessment, AFD
The AFD reviews the toxicity and allergenic potential of the novel feed, including livestock exposure, consideration of the transfer of contaminants to foods of animal origin, and occupational/by-stander exposure.

16. Nutrition assessment, AFD
The AFD reviews all information submitted regarding the nutrient and anti-nutrient composition of the novel feed in terms of safety and nutritional efficacy as a livestock feed. This unit also considers if the novel feed will have any impact on conventional livestock feeding practices and assesses any nutritional claims associated with the novel feed.

17. Characterization assessment, AFD
The AFD reviews any information submitted regarding the development of the novel plant, characterization of the novel trait(s) in the novel plant, and other information submitted in support of safety and efficacy of the novel plant that requires expertise in molecular biology and protein characterization.

The evaluation officer assigned to conduct the characterization assessment also coordinates the technical aspects of the pre-market safety assessment across the different evaluation disciplines of the AFD and acts as a point of contact with HC and the PBO in coordinating the final decision for authorization of the novel plant.

The AFD lead evaluator shares responsibility with the Plant and Biotechnology Risk Assessment Unit (PBRA) for reviewing the method of detection and identification if applicable by the CFIA for PNTs and novel feeds from plant sources and for coordinating writing of the decision document once the final decision for authorization of the novel plant has been made.

18. Additional information required, AFD
If, following a review of all submitted information, the AFD has questions and/or requires clarification of information submitted, a letter will be sent to the applicant outlining these questions and/or requests for clarification. In some cases, for example, potential residues in foods of animal origin resulting from consumption of a novel feed from a plant source, the AFD may seek an opinion from an appropriate regulatory agency, such as Health Canada.

19. Science review complete, AFD
Submitted information has been reviewed by AFD and the applicant has had the opportunity to respond to all outstanding requests for further information and/or clarification. AFD proceeds with the decision-making step, including risk management, based on the available information.

If information is incomplete and will not be available in a timely manner, or the applicant is unable to substantiate safety and efficacy of their product(s) under review, AFD cannot conclude its assessment and the file will be closed. Risk management and regulatory aspects (see below) may also be considered during the science review. Refer to section 21.

20. Risk management and regulatory aspects, AFD

Risk management consists of imposing conditions required for the safe and efficacious use of a novel feed for livestock, as identified during the science review. Risk management is not needed or appropriate for all novel feeds, that is, if they meet a definition in Schedules IV or V of the Feeds Regulations. AFD also considers whether novel feeds from plant sources meet the definitions and requirements of feeds as listed in Schedule IV of the Feeds Regulations, of if a new definition for the novel feed is to be created or an existing one modified.

21. AFD decision, AFD

Once all evaluators within the AFD have finished assessing a submission according to their own expertise, all evaluators work collaboratively to reach a joint decision based on all the evidence included in the submission, and recommends appropriate risk management options as necessary.

22. PBO reviews and submits request to PBRA, CFIA

The PBO coordinates the review process, determines the level of assessment required and seeks science advice from the PBRA as required in order to make a decision on the product. It also determines and imposes the appropriate risk management conditions on products.

23. Environmental assessment, PBRA

The PBRA reviews environmental safety information provided by the applicant to the PBO according to the criteria set out in Directive 94-08, and provides guidance on the product back to the PBO.

The PBRA reviews information addressing the five “pillars” of the environmental safety assessment:

- potential for increased weediness/invasiveness
- potential for gene flow and its consequences
- potential for the PNT to become a plant pest
- potential impacts on non-target organisms and
- potential impacts on biodiversity

When risks are identified by the safety assessment process, the PBRA also provides scientific advice related to risk management.

24. Molecular characterization, PBRA

The PBRA conducts a molecular characterization of the PNT (in co-operation with the Molecular Unit of the AFD and HC’s Bureau of Microbial Hazards).

25. Additional information required, PBRA
If, following a review of all submitted information, the PBRA has questions and/or requires clarification of information submitted, a letter will be sent directly to the applicant outlining these questions and/or requests for clarification.

26. Science review complete, PBRA
Information requirements have been met and any outstanding requests for further information and/or clarification have been satisfied.

27. Risk management, PBO
Risk management imposes guidelines on the use of the PNT such that identified potential risks to the environment are mitigated. Risk management may not be required or appropriate for all PNTs, but some PNTs (particularly insect-resistant and herbicide-tolerant PNTs) may require a stewardship plan. The PBO and PBRA share this role.

28. PBO decision, PBO
Taking into consideration the science advice provided by the PBRA and any other relevant factors, the PBO is responsible for decision making on the authorization of a PNT for unconfined environmental release, along with any risk management conditions, as required (for example, insect resistance management and/or herbicide-tolerance management plans).

29. Harmonization of regulatory decisions (no-split approval policy), CFIA/HC
When a plant is considered to be a PNT and a source of a novel food and a novel feed, regulatory decisions regarding the use as a novel feed, novel food and environmental release will be coordinated and harmonized to minimize the potential for unapproved products to enter the Canadian environment or food or feed supplies. Once regulatory decisions have been harmonized, the CFIA and HC will each send a letter to the applicant and post a decision document on their respective websites.

30. Letter of no objection for human food use, HC
If the food rulings proposal and the conclusion that the food is safe for consumption are found acceptable by the Committee, the applicant is notified in writing that, based on the evaluation of the submitted data, Health Canada has no objection to the sale of the novel food product as human food in Canada as specified in the notification.

31. Decision document posted on HC website, HC
In order to maintain a transparent approach, yet respect the confidential business information contained in a submission, a general summary document is drafted which describes the product and summarizes the information collected to demonstrate its safety.

This summary is prepared according to the appropriate sections of the Guidelines:

- Development and Production
- Product Information
- Dietary Exposure

- Nutritional Data
- Toxicology Data

The applicant is given an opportunity to review this document and provide comments. The novel food decision document is subsequently made available on the Novel Foods page of the Health Canada website.

32. Coordination of authorization letters for feed and unconfined environmental release, CFIA
A harmonized regulatory decision to authorize a PNT for release into the environment and as a source of a novel feed results in authorization letters being issued from the PBO and AFD [of the CFIA] to the applicant. These letters will outline any conditions associated with the authorizations.

33. Joint Feed/unconfined environmental release decision document posted on the CFIA website, CFIA
In order to maintain a transparent approach, yet respect the confidential business information contained in a submission, a general summary document is drafted which describes the product and summarizes the information assessed during the submission review. This summary is prepared according to the appropriate sections of the CFIA's pertinent regulatory guidance. The applicant is given an opportunity to review this document and provide comments. The novel feed/PNT decision document is subsequently made available on the CFIA's website.

34. Applicant notified CFIA/HC
If CFIA and HC reach a harmonized regulatory decision to refuse the authorization of a PNT for release into the environment and as a source of a novel feed or food, a letter describing the decision will be sent to the applicant by each respective group.