

APPENDIX I
WORK SHEET: DETERMINATION IF A PLANT IS A NOVEL FEED SOURCE

As stated in the *Feeds Regulations*, all feeds must be safe and efficacious. One way a proponent of a plant can demonstrate due diligence in this regard is to characterize their plant in terms of:

- compositional parameters;
- levels of endogenous allergens, toxins and anti-nutrients; and
- other factors that affect feed safety.

Knowledge of the general characteristics of the plant will aid proponents in determining novelty as they work through the following worksheet.

It will also be helpful for proponents to consider the breeding history prior to starting the worksheet:
In general conventional breeding with germplasm in cultivation in Canada will not typically result in a novel feed. Enhancing a trait in cultivated species by introgressing genes from wild biotypes or using germplasm from outside Canada may result in a novel feed.

Describe any new characteristic or any existing characteristic of the plant that has been modified:

Plant genus and species:
Common name of plant:

1. Is it likely that this plant, or parts or products from it, will be fed to livestock?

If the answer to question 1 is no, then STOP - the plant is not a feed, and thus is not regulated under the Feeds Act and Regulations. If the answer is yes, then continue.

2. Is the plant listed as an approved feed ingredient in Schedule IV or V of the *Feeds Regulations*?

If the answer to question 2 is no, then the plant is a novel feed source, and will require a pre-market assessment by the Animal Feed Division. If the answer is yes, novelty has not been triggered under this consideration; please continue.

3. Will the use of this plant, either as a single ingredient feed or as part of a complete feed:

3a) be different from previous use of the unmodified conventional crop in Canada? (e.g., feed now intended as an energy source where it was previously a protein source)?

3b) change the amount of the plant incorporated into a given livestock species diet (e.g., rapeseed vs. canola)?

3c) result in changes to ration formulation¹?

3d) allow the use of different feed processing techniques?

If the answer to any part of question 3 is yes, the plant likely does not meet an existing ingredient definition²; please contact the Animal Feed Division as the plant may require a pre-market assessment. If the answer is no, novelty has not been triggered under these considerations; please continue.

4. Has the plant been modified such that:	
4a) it exhibits a characteristic that was not previously found in the unmodified conventional crop in Canada ³ ?	
4b) it no longer exhibits a characteristic that was previously found in the unmodified conventional crop in Canada?	
4c) an existing characteristic (including compositional parameters ⁴) has been modified such that it now falls significantly outside the typical range for the unmodified conventional crop in Canada (beyond incremental improvements historically made to the crop)?	
4d) there is a difference in bioavailability of a given compound?	
5. Is a new compound produced by the plant?	
6. Have levels of endogenous allergens, toxins or antinutrients been altered ⁵ ?	
<i>If the answer to any of questions 4-6 is yes, or the answer is unclear, please contact the Animal Feed Division, as the plant may be a novel feed source and may require a pre-market assessment. If the answer is no, novelty has not been triggered under these considerations; please continue.</i>	
7. Are you planning on making nutritional or efficacy claims associated with your product?	
<i>If the answer to question 7 is yes, please contact the Animal Feed Division. Registration of this claim is required, since all feed claims must be registered.</i>	
Conclusion:	
If your responses to any of the considerations above indicate that you have developed a plant that is, or may be, a novel feed, or if you require further guidance, please contact the Animal Feed Division as the plant may require pre-market assessment.	

¹ An example of a change to ration formulation would be the use of corn modified to contain high lysine, which results in a decreased need for supplemental lysine in feed rations.

² Single ingredient feeds must be defined and labelled appropriately for consumer protection. The ingredient definition is an accurate description of the feed and its approved purpose.

³ New characteristics may include agronomic characteristics that affect safety and efficacy.

⁴ Compositional analysis to support novelty determinations should focus on those plant parameters that could reasonably be expected to be affected by the modification. For example:

- for imidazolinone herbicide tolerance resulting from mutations in the ALS genes, characterize the branched chain amino acids (valine, leucine, isoleucine) which are catalyzed by the AHAS enzyme
- for drought tolerance, characterize the drought stress metabolites associated with the drought tolerance
- for intentional modification of the fatty acid profile, characterize the fatty acid profile to determine if parameters are still within the typical range, and in addition, characterize other compositional parameters (e.g., fat content) that may be affected due to changes in metabolic pathway

⁵ Proponents should focus on endogenous allergens, toxins or antinutrients in the plant that could reasonably be expected to be affected by the modification.