Submission Checklist for Modified Fatty Acid Single Ingredient Feeds

Note: Submissions received without the completed checklists will be returned.

Administrative requirements: (Please refer to Administrative Requirements for Registration and Approval of Livestock Feeds):	**Included (Y), or Not Applicable (N/A)**
New companies must include:	
Signing Authority and/or corporate documents	
Declaration of Resident Canadian Agent (required when the product is being imported)	
All submissions must include:	
Cover Letter (detailing purpose of product, any requested change(s) if product is already registered and please include the e-mail address of the authorized representative)	
Completed *Application Form for Feed Registration or Renewal* (CFIA/ACIA 0009;One (1) application form per product is required)	
Application fees (cheque, money order, Visa, MasterCard, or American Express payable in Canadian Funds). **New Applications:** Ingredients not listed in Schedule IV (Code 3256, Category 3); New sources of existing Part II ingredients (Code 3255, Category 2); Mixed feeds claiming/highlighting registered sources of modified fatty acid single ingredient feeds (Code 3253, Category 2) **Significant Changes to an existing registration (requiring efficacy and/or safety):** Modified Fatty Acid Single Ingredient Feeds (Code 3255, Category 2) Mixed feed containing registered sources of modified fatty acid single ingredient feeds (Code 3253, Category 2) **Renewal of Registration:** Modified Fatty Acid Single Ingredient Feed or Mixed feed containing registered sources of Modified Fatty Acid Single Ingredient Feeds (Code 3259) Note: Any proposed changes made to the original registration require, in addition to the renewal application, an application to the AFD for significant change or administrative amendment. Note these two requests are to be made on the same application form, and will necessitate payment of the corresponding fee for the evaluation of the revised product label in addition to the renewal fees.	

As applicable	
Supporting documentation for any changes in signing authority	
New Declaration of Resident Canadian Agent form if any changes to Canadian Agent	
If a review of your product has been performed previously by the AFD and the file was closed due to deficiencies identified, please enclose a copy of the return letter with the new application and detail in the cover letter how deficiencies were addressed	
Modified Fatty Acid Single Ingredient Feeds	
Proposed Label (3 copies)	
Ingredient Identification and Characterization	
• A proper characterization of the modified fatty acid single ingredient feeds (specifications of the fatty acid source).	
• Clear identification of the origin of the fatty acids (i.e., are obtained from edible vegetable oil and/or are a by-product of vegetable oil manufacturing).	
• Identification of the plant species (e.g., corn, soy, palm, etc.) that the fatty acids source originated from.	
• Indicate the grade of the final product that is destined for use in livestock feeds.	
Manufacturing Process	
• Flowchart/diagram of the manufacturing process	
• Detailed written description of the manufacturing process including the origin/source and specifications of each raw material, and the specifications of any processing aids, catalysts, carriers, anti-oxidants, etc. Specific details about each biological, chemical or physical processing step are required	
• Product formulation and amount or percentage of all raw materials used in the manufacturing of the final product	
Certificates of Analysis and Analytical Methods	
• Original and signed certificates of analysis from three different and recent production lots of the final product in support of the proposed label guarantees and the complete fatty acid profile, and the analytical methodology/instrumentation used for each analyte.	

• Original and signed certificates of analysis for three different and recent production lots of the final product for known contaminants (e.g., pesticide residues, heavy metals including arsenic, aluminium, lead, cadmium, chromium, residual solvents if used in the manufacturing process). The analytical methodology/instrumentation used and limit of detection/limit of quantification must be noted.	
• Original and signed certificates of analysis for three different and recent production lots of the final product for the seven (7) dioxin congeners, ten (10) furan congeners and twelve (12) dioxin-like PCB congeners are to be submitted with the application. The analytical methodology/instrumentation used and limit of detection/limit of quantification must be noted.	
Reference Sample	
• A reference sample (50 grams) is required for all new modified single ingredient feeds not listed in Schedule IV or V of the *Feeds Regulations*.	
Data Requirements for New Modified Single Ingredient Feeds and/or New Feed-Related Purpose	
Three (3) scientific studies (per target livestock species) are required to support the intended purpose of the new modified fatty acid single ingredient feed or an existing modified fatty acid ingredient with a new purpose.	
Data Requirements to Support Feed-Related Label Claims	
Rumen Bypass Claims • A minimum of one (1) acceptable (*in situ* or *in vivo*) scientific study (per target livestock species) is required to support rumen bypass claims.	
Production Claims • Three (3) scientific studies per target livestock species (e.g., three dairy cattle feeding studies) are required to support livestock performance claims associated with the modified fatty acid single ingredient feeds in question, when used at the inclusion rates specified on the proposed label.	
Mixed Feeds Containing Registered Sources of Modified Fatty Acid single Ingredients	
Proposed Label (3 copies)	
• Label must include a complete list of all ingredients listed in Schedule IV or V of the *Feeds Regulations*, including the registration number for Part II ingredients. **Note: The source of the modified fatty acid single ingredient must be approved and registered by AFD prior to being used in the mixed feed.**	

Product Formulation	
• Product formula listing the amount or inclusion rate of each ingredient used	
Applications for Feed Registration Renewal	
Single ingredient feeds: • Original and signed certificates of analysis for three different and recent production lots of the final product for the seven (7) dioxin congeners, ten (10) furan congeners and twelve (12) dioxin-like PCBs for each final product. The analytical methodology used and limit of detection/limit of quantification must be noted.	
• Original and signed certificates of analysis for three different and recent production lots of the final product known contaminants (e.g., heavy metals (including arsenic, lead, aluminium, chromium, mercury and cadmium, and residual solvents if applicable).The analytical methodology used and limit of detection/limit of quantification must be noted.	
• A signed statement that the manufacturing process has not changed and all raw materials (source and origin of fatty acid source), all processing aids, carriers, catalysts, anti-oxidants, etc. have not changed since the original approval.	
Mixed Feeds: • A copy of the current product formulation.	