Submission checklist for mycotoxin detoxification agents (MDAs) feed application

The completed checklist, for mycotoxin detoxification agents (MDAs) submissions, must be included with each application for feed registration.

Indicate the submission page number corresponding to each item in the checklist; if the item does not apply, a written justification must still be provided.

Submissions received without a completed checklist will be returned.

With your submission package, you must include with the following information (mandatory)

1.1 Administrative requirements for each product

Required information	**Page number in application or Not Applicable (N/A)**
RG-1 Chapter 1: Administrative requirements for registration and approval of livestock feeds	
Application for Feed Registration and Renewal. Form Available: 1.3.1 Application for feed Registration and Renewal (CFIA/ACIA 0009)	
Total application fees (cheque, money order, Visa, MasterCard, or American Express payable in Canadian Funds) RG-1 Chapter 1: Appendix A for application fees	
For a new company or an existing company requiring changes to the signing authority list, include supporting documentation on Establishing a Company File and Signing Authority	
For a new applicant residing outside of Canada or an existing company requiring changes to the Resident Canadian Agent, , include supporting documentation and a Declaration of Resident Canadian Agent, Form II (CFIA/ACIA 1194) - PDF (101 kb)	
Cover letter and summary of the documentation included with the application, with the email address of the contact person clearly identified	

1.2 Labelling

Required information	Page number in application or Not Applicable (N/A)
Proposed Labels including all required information as per section 1.2	

1.3 Product identification and description

Required information	Page number in application or Not Applicable (N/A)
For products with deficiencies previously identified by the AFD, attach the reference number of the return letter or letter of rejection of the application and explain how you have addressed the rejection points in the new submission.	
Complete product identification and description as detailed as per Section 1.3.1	
Specify target mycotoxins and intended livestock species	
For an unapproved ingredient, information as per RG-1, Chapter 2.3	
Detailed Product Formulation: (either on a weight for weight basis or as a percentage composition) - list the amount of each ingredient by generic name as per Schedule IV or V of the Feeds Regulations, - include registration numbers for Part II ingredients or mixed feeds. Note: The source of all single ingredients listed in Schedule IV Part II must be approved and registered by AFD prior to being used in the mixed feed.	
For new ingredients, provide a detailed description of the manufacturing process	
Certificates of analysis from 3 different and recent lots of product to support the proposed label guarantees for each active ingredient	
Analytical methodology used to support the proposed label guarantees for each active ingredient, as above	
Product sample or samples, if required. The sample will be used to validate the analytical method by the CFIA laboratory. Keep a 500 g sample of the final product in stock. When the application is accepted, you will be contacted to send the sample directly to the CFIA laboratory.	

1.4 Requirements in support of product claims and other information

Required information	Page number in application or Not Applicable (N/A)
Acceptable studies in support of claims. Address all design considerations as listed in section 1.4.1	
Certificates of Analysis Analytical methodology for studies used to support the proposed label claim	
Demonstration in support of product stability and shelf life for the maintenance of the mycotoxin detoxification effects as defined in section 1.4.2	
Certificates of analysis (original and signed) for 3 recent and different lots of production of the final product to support the stability and shelf life as above. These must include three (3) CofAs at the beginning of the shelf life period and three (3) CofAs from the same three lots of the product at the end of the desired storage period. The 3 lot samples must be kept in similar storage conditions up to the proposed expiry date.	
The analytical methodology/instrumentation used for the above analyses must be included on the certificates	
Evidence to demonstrate the activity of the MDAs is not impacted during feed processing as defined in section 1.4.3. This should include Certificates of Analysis for a minimum of three (3) different lots of product.	
If CoAs are not provided, required statements added to label as per section 1.4.3	

1.5 Data requirements in support of safety

Required information	Page number in application or Not Applicable (N/A)
Description and data demonstrating the safety of the feed as noted in section 1.5. This is required for new ingredients or for a new purpose of an existing ingredient.	
If the mode of action results in any new metabolites or breakdown products, the safety of these must be demonstrated. Evidence provided as per section 1.5.1	
Scientific evidence demonstrating that the MDA does not reduce the availability of key nutrients and medications in the feed. See section 1.5.2	

Part 3: Renewals of feed registration

Required information	Page number in application or Not Applicable (N/A)
If there is a change to the product at renewal, use this checklist to describe the changes as applicable. If there is no change to the product, use the checklist for renewals available in the RG1- Chapter 1 at: Appendix B – Checklist for renewals	