AG PROVISION LLC

Supplier cGMP Audit Questionnaire

Supplier Certification

Supplier Name			
Supplier Physical Address		Site Phone Number	
		Supplier Web Address	
Primary Contact			
Contact Address		Contact Phone Number	
		Contact E-mail	
Items(s) Supplied			
Company Description (including list of goods/services provided)			

Supplier Certification:

I certify that the information provided in response to the questions posed is true, accurate, and complete. I further understand that the responses provided will form part of the basis of the decision to approve my firm as a foreign supplier and those responses will form part of the legal relationship between our companies. In the event that the responses provided to this questionnaire prove not to be accurate, we may consider such responses to be cause for reevaluating, or terminating, a trade relationship. Where appropriate we may also seek suitable legal recourse.

I understand that Ag ProVision will take appropriate corrective actions, up to and including supplier disqualification and discontinuation of use and return of the listed items, if the items supplied are determined to be adulterated or misbranded, until the cause of non-compliance, adulteration, or misbranding has been adequately addressed.

Signature _____ Printed Name _____ Date _____

Title _____

Supplier cGMP Audit Questionnaire

Ag ProVision Determination

Ag ProVision Determination:

_____ is ☐ is not ☐ approved as a supplier for Ag ProVision.

Teena F Middleton, Ph.D

Signature *Director of Technical & Regulatory Affairs* Date

Supplier Verifications Activities (if any) to be performed to verify that the hazards requiring controls have been significantly minimized or prevented[1]:

Procedures/Preventive Controls agreed upon should the verification activities reveal that the hazards have not been appropriately controlled:

Date of Required Supplier Re-evaluation[2]: _____

[1] Serious/life threatening hazards will require annual on-site audits to verify control activities

[2] Must be performed at least every three years or whenever significant changes occur

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Instructions for Completion

Background: As of May 31, 2017, the FDA Food Safety Modernization Act (FSMA) rule on Foreign Supplier Verification Programs (FSVP) requires that importers must have a FSVP in place for each food/feed and the foreign supplier of that food/feed which verifies that the food/feed imported into the United States has been produced in a manner that meets U.S. safety standards (80 FR 74225). This requirement for verification can be fulfilled by review of evidence demonstrating that the food/feed is produced according to current Good Manufacturing Practices (cGMP) for animal feed (21 CFR 507/Guidance for Industry #235), by conducting a hazard analysis for each imported food/feed to identify if known or reasonably foreseeable hazards requiring controls are associated with the product, and then, if determined to be necessary, establishing preventative controls and/or supplier verification activities to reduce the probability of the hazard occurring or the severity of the hazard should it occur.

We request your assistance in both providing evidence of your compliance with cGMP for animal feed production and in performing a hazard analysis for each food/feed product you supply to Ag ProVision. Evidence of compliance with cGMP can be provided either by 1) responding to questions A.1. through H.8. in the attached questionnaire, 2) supplying audit reports and/or certifications from third-party certification bodies which provides similar information, or 3) supplying a summary report prepared for this purpose. Information sufficient for us to conduct a hazard analysis can be provided by 1) responding to questions I.1. through I.7. in this same questionnaire and 2) completing the Hazard Analysis Form in Appendix One for each food/feed ingredient. Alternatively, information can be supplied from an internal or third party hazard analysis previously conducted by your facility.

Instructions for Completing the Questionnaire: Please answer all questions that are applicable to your company operations or provide alternative documentation as suggested in the background section. Where appropriate, check where indicated. Please denote questions not applicable as "N/A". Attach additional documentation (including Standard Operating Procedures, flow diagrams, forms, etc) if preferred to provide alternative or more complete information than form space allows.

On our part, we understand that your responses to some of the questions may involve disclosure of information that your firm may consider commercially sensitive. We commit that the information provided will only be used by personnel at Ag Provision and its owner companies for the sole purpose of making decisions on the approval of your company as a foreign supplier. Further, we will not disclose to any other party, except as might be required by law, any information disclosed by you in your responses.

A responsible official of the company who has the authority and knowledge to confirm the accuracy of all responses must sign the supplier certification on the cover of this survey. Please return an electronic version of the completed survey within three weeks of its receipt.

Please attach/enclose the following items:

- Product Label (facsimile) and Product Safety Data Sheet (Required for each item supplied)
- Index of Standard Operating Procedures (SOPs) relevant to this product (Highly Recommended)
- Any Quality Systems Certifications or Reports (ISO, FAMI-QS, cGMP, ISFSF, SFSF, etc.) (Required if Applicable)
- Copies of inspection reports from US or foreign regulatory authorities (Required if Applicable)
- Company Organization Chart, including warehousing, manufacturing, packaging, and quality control/assurance (Recommended)
- A schematic layout of the facility, with details on the layout locations applicable to this product (Recommended)
- Flow chart describing the manufacturing process (Recommended)
- Statement of conformance with current Good Manufacturing Practices in 21 CFR 507 (for non-medicated feed ingredients) and/or 21 CFR 225 (for medicated feed ingredients) (Recommended)

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Supplier cGMP Audit Questionnaire

cGMP Compliance

A. FACILITY OVERVIEW

1. Is this company a division or subsidiary of another company? ☐ Yes ☐ No ☐ N/A
   If yes, please provide the name of the parent company and reporting relationship:

2. Are you the manufacturer, repackager, or distributor of the listed items? (check all that apply)
   ☐ Manufacturer ☐ Repackager ☐ Distributor

3. Please provide information on the number of employees that work at the supplying site in the following areas:

Management:	
Professional/Technical:	
Quality Assurance/Quality Control:	
Direct Labor:	
Mechanical Repair:	

4. Is the site registered with the US Food and Drug Administration under any of its programs?
   ☐ Yes ☐ No If yes, facility registration number: _____
   If yes, date of last inspection: _____ Summary of results of last inspection:

5. Is there an implemented quality system at the production facility? ☐ Yes ☐ No
   If yes, please describe, including any certifications (example: ISO 9001):

   _____

   _____

6. Does your firm have a formal auditing program to compare performance to quality system requirements? ☐ Yes ☐ No If yes, please check all programs in place:
   ☐ Internal ☐ Vendor ☐ Customer ☐ Third Party
   ☐ Other (please describe): _____

   _____

   _____

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cGMP Compliance

7. Are follow up actions as a result of the audit confirmed to be completed as scheduled?
   ☐ Yes ☐ No If yes, please describe how they are confirmed:

8. Are there written procedures for investigations of variances in procedures? ☐ Yes ☐ No
   If yes, please describe the steps taken when variances are identified:

9. Briefly describe your supplier verification program:

10. Briefly describe the sampling and testing of the final product for release:

11. Are there written procedures to assure that Out of Specifications (OOS) test results are investigated, assessed, documented and reviewed? ☐ Yes ☐ No ☐ N/A If yes, please describe the steps taken when a raw material or finished product fails to meet specifications, including product disposition requirements:

12. Briefly describe your program for preventing physical contamination during production:

13. Please describe your system for assigning lot/batch numbers or production control numbers. Include information on how this system affords traceability and supports product recalls:

14. Does your firm have written procedures for formally addressing customer complaints, up to and including recalling products? ☐ Yes ☐ No ☐ N/A If yes, please describe or attach a copy of the relevant procedure(s):

B. cGMP TRAINING AND QUALIFICATIONS (21 CFR 507 Subpart A & F)

1. Are all employees that manufacture, process, pack or hold animal food qualified to perform their assigned duties? ☐ Yes ☐ No	If yes, how does management ensure they are qualified?
2. Are records maintained of employee's education, training, and/or experience which document that they are qualified to perform their assigned duties? ☐ Yes ☐ No	If yes, please describe the nature of these records?
3. Is the responsibility to ensure that individuals are qualified to perform their assigned duties clearly assigned to supervisory personnel? ☐ Yes ☐ No	If yes, how is this assignment documented?

4. Do all employees that manufacture, process, pack or hold animal food receive training in the principles of animal food hygiene and animal food safety? ☐ Yes ☐ No	If yes, how is this training provided and how often is refresher training provided?
5. Are indelible records maintained which identify the facility, the date the training occurred, the name and signature of the person performing the training, and the list of persons trained that document the training in the principles of animal food hygiene and animal food safety for all employees that manufacture, process, pack or hold animal food? ☐ Yes ☐ No	If yes, are these records maintained for at least two years after they were prepared?
6. Does management ensure that all persons working in direct contact with animal food or animal food contact surfaces conform to hygiene practices that protect against the contamination of animal food? ☐ Yes ☐ No	If yes, please provide examples of methods/requirements utilized (such as removing jewelry, storing of personal belongings, use of hair nets, etc.).

C. cGMP FACILITIES AND GROUNDS (21 CFR 507.17)

1. Are the grounds in the vicinity of the facility maintained in a manner that will not harbor pests or otherwise contribute to the contamination of animal food? ☐ Yes ☐ No	If yes, please describe your program.
2. Is there adequate space between equipment, walls, and stored materials to allow for cleaning to prevent harborage of pests or contamination from dirt or accumulated product? ☐ Yes ☐ No	If yes, please describe your policy.

3. Does plant design and construction prevent drips or condensate from becoming a source of contamination? ☐Yes ☐ No	If yes, how are any identified leaks/condensates addressed?
4. Are all light bulbs, fixtures, skylights, or other glass items suspended over exposed animal food shatter-resistant to protect against contamination from glass breakage? ☐Yes ☐ No	
5. Are any ingredients stored outside? ☐Yes ☐ No	If yes, please describe the steps taken to prevent spoilage or contamination.

D. cGMP Sanitation (21 CFR 507.19)

1. Are all utensils and equipment cleaned, maintained, and stored in a manner which protects against contamination of animal food? ☐Yes ☐ No	If yes, please describe your program standards.
2. Are toxic materials (cleaning compounds, sanitizing agents, and other chemicals used for laboratory or facility operations) identified, used, and stored in a manner that protects against the contamination of animal food, animal food contact surfaces, or animal food packaging materials? ☐Yes ☐ No	If yes, please describe your policy.

3. Are toxic materials such as fertilizers and pesticides stored only in areas where animal food is not manufactured, processed or exposed? ☐Yes ☐ No	If yes, please describe how physical separation or physical barriers are determined to be sufficient to prevent contamination of animal food.
4. Are pesticides used in the plant only under precautions and restrictions that will protect against the contamination of animal food, animal food contact surfaces, and animal food packaging materials? ☐Yes ☐ No	If yes, please provide examples of precautions or restrictions to their use.
5. Is a pest control plan in place that includes regular monitoring for the presence of pests and measures to exclude pests to protect against the contamination of animal food by pests? ☐Yes ☐ No	If yes, please briefly describe key components of your plan.
6. Is trash handled so that it does not attract pests or contaminates animal food, animal food-contact surfaces, or animal food packaging materials? ☐Yes ☐ No	If yes, please provide examples of trash management practices.

E. cGMP Water Supply and Plumbing (21 CFR 507.20)

1. Is water pressure sufficient to easily rinse debris and soap from hands, equipment, utensils, and food-packaging materials? ☐Yes ☐ No	

2. Is the water monitored to ensure that it does not contain contaminants that might adulterate the animal food? ☐Yes ☐ No	If yes, please provide information on the biological and chemical contaminants monitored.
3. Is the plumbing system designed, installed, and maintained to avoid being a source of contamination to the animal food, water suppliers, equipment, or utensils? ☐Yes ☐ No	
4. Is any sewage plumbing installed over areas where it could contribute to animal food contamination? ☐Yes ☐ No	If yes, please provide information on the techniques employed that prevent condensate or drips from contaminating animal food.
5. Are there any backflow or cross-connections between discharge pipes and pipes that carry water for animal food or animal food manufacturing? ☐Yes ☐ No	If yes, please briefly describe key components of your remediation plan.
6. Does the sewage system have sufficient capacity to handle the amount of sewage and liquid waste generated? ☐Yes ☐ No	If yes, please provide estimated volume of sewage produced daily.
7. Are toilet facilities clean and maintained so that they are not a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials? ☐Yes ☐ No	
8. Are hand-washing facilities provided as part of the toilet facilities? ☐Yes ☐ No	

9. Are additional hand-washing facilities provided in other key areas? ☐ Yes ☐ No	If yes, please provide examples of operations in which the need for additional hand-washing facilities were identified.

F. cGMP Equipment and Utensils (21 CFR 507.20)

1. Are all plant utensils (shovels, scoops, etc.) designed and constructed so as to be completely cleanable? ☐ Yes ☐ No	If no, are disposable utensils employed during operations where cleaning is difficult?
2. Is equipment designed so that it does not leak lubricants, fuel, contaminated water, or other liquids into the animal food or onto animal food-contact surfaces? ☐ Yes ☐ No	
3. Is equipment used in the manufacturing, processing, packing, and holding of animal food installed to facilitate cleaning and maintenance of the equipment and adjacent spaces? ☐ Yes ☐ No	If yes, please describe your installation policies that allow for sufficient space to allow for cleaning, maintenance, and pest control around each piece of equipment.
4. Do animal food-contact surfaces contaminate the animal food? ☐ Yes ☐ No ☐ N/A	If no or N/A, please describe how animal food-contact surfaces are selected and maintained to prevent contamination.
5. Are freezers and/or cold storage compartments used to hold animal food at your facility? ☐ Yes ☐ No	If yes, please describe the temperature measuring device installed and the manner in which the temperatures are monitored.

6. Does your facility use instruments or controls to measure conditions that control or prevent the growth of undesirable microorganisms in animal food? ☐Yes ☐ No ☐ N/A	If yes, please briefly describe the calibration and maintenance procedures for the instrumentation.
7. Is compressed air (or other gas under mechanical pressure) used to clean animal food-contact surfaces or equipment? ☐Yes ☐ No	If yes, pleases describe your policies to prevent the compressed air from blowing dirt, debris or other contaminants into the animal food or onto food contact surfaces.

G. cGMP Plant Operations (21 CFR 507.25)

1. Is compliance of the facility with the cGMP requirements of 21 CFR 507 (subpart B) for manufacturing, processing, packing, and holding operation assigned as a management responsibility? ☐Yes ☐ No	If yes, briefly describe the system of oversight and checks that ensure that the physical facilities meet the cGMPs and that the individuals working at the plant comply with the cGMPs as they perform their duties.
2. Are procedures in place that require verification that equipment and automated systems are performing correctly before operations begin? ☐Yes ☐ No	If yes, briefly describe the system of oversight, records, and checks in place that ensure that performance is appropriate (accuracy verification of scales, visual checks, calibrations, etc.).
3. Is all animal food, including all raw materials, rework, and finished animal food, accurately identified so that animal food is not commingled, substituted, or incorrectly formulated in a manner that results in adulterated animal food? ☐Yes ☐ No	If yes, briefly describe your physical and/or electronic means for their identification.

4. Is the condition of shipping containers, bulk packaging, and/or bulk vehicles holding raw materials examined upon receipt to determine whether their condition could have contaminated the animal food? ☐Yes ☐ No	If yes, please briefly describe the procedures taken at receiving.
5. Are all raw materials examined to ensure that they are suitable for manufacturing and processing into animal food? ☐Yes ☐ No	If yes, what are your raw material testing/examination procedures for any raw materials used to manufacture the items supplied.
6. Are ingredients stored in containers designed and constructed to protect against contamination and deterioration? ☐Yes ☐ No	
7. Are animal food-packaging materials safe and suitable? ☐Yes ☐ No	If yes, please describe how the packaging protects the animal food by preventing contamination from the environment and how it helps minimize product deterioration.
8. Are chemical, microbial, or extraneous-material testing procedures used to identify sanitation failures or possible animal food contamination? ☐Yes ☐ No ☐ N/A	If yes, please describe the testing procedures employed (examples include residue testing, microbial evaluations, use of magnets).
9. Are all manufacturing, processing, packing, and holding processes conducted under the conditions and controls necessary to minimize the potential for growth of undesirable microorganisms and/or to prevent product decomposition/deterioration? ☐Yes ☐ No ☐ N/A	If yes, describe the conditions and controls utilized for the items supplied.

10. Are procedures in place to ensure that adulterated animal food is rejected, disposed of, or reprocessed to eliminate the adulteration? ☐ Yes ☐ No	

H. cGMP Holding and Distribution (21 CFR 507.27)

1. Is animal food held for distribution under conditions that will protect it from contamination and minimize deterioration? ☐ Yes ☐ No	If yes, briefly describe the conditions under which the items supplied are held for distribution.
2. Are the containers used to hold the animal food before distribution designed and constructed of appropriate material, cleaned as necessary, and maintained in a way that protects against contamination? ☐ Yes ☐ No	If yes, briefly describe the container system for the item(s) supplied prior to distribution and how the container system achieves the intended goals.
3. Is the animal food labeled with information and instructions for safely using the product for the intended animal species? ☐ Yes ☐ No ☐ N/A	If no or N/A, briefly describe why this information is not required for the item(s) supplied.
4. Does the animal food labeling include warning or caution statements for some species for which the food is not intended or for an intended species if not used properly? ☐ Yes ☐ No ☐ N/A	If no or N/A, briefly describe why this information is not required for the item(s) supplied.
5. Is the shipping container/vehicle visually examined prior to loading to determine whether its condition could potentially lead to the contamination of the animal food? ☐ Yes ☐ No	If yes, what are your procedures in the event the condition of the shipping container/vehicle are unacceptable?

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cGMP Compliance

6. Is any returned animal food identified, segregated, and assessed prior to dispositioning (discarded, reworked, or redistributed)? ☐Yes ☐ No	If yes, please briefly describe the conditions under which any of the supplied items would be discarded, reworked, or redistributed following return.
7. Is unpackaged or bulk animal food held in a way that could result in unsafe cross contamination with other animal food? ☐Yes ☐ No ☐ N/A	If no, please describe how your bulk holding procedures prevent cross contamination.
8. Are any of the supplied items human food by-products that were originally held at and distributed by a human food facility before their intended use as an animal food? ☐Yes ☐ No	If yes, please provide documentation that the items supplied are subject to and in compliance with all applicable regulations.

Supplier cGMP Audit Questionnaire

I. FSVP Hazard Analysis

1. Has a Hazard Analysis considering each of the following factors been conducted for each of the items supplied to determine if any risks and/or hazards are associated with the listed items?
   a. Formulation of the food ☐ Yes ☐ No
   b. Condition, function, design of the establishment and equipment ☐ Yes ☐ No
   c. Raw materials and other ingredients ☐ Yes ☐ No
   d. Transportation practices ☐ Yes ☐ No
   e. Harvesting, manufacturing, processing, and packaging procedures ☐ Yes ☐ No
   f. Packaging and labeling activities ☐ Yes ☐ No
   g. Storage and distribution ☐ Yes ☐ No
   h. Intended or reasonably foreseeable use ☐ Yes ☐ No
   i. Sanitation, including employee hygiene ☐ Yes ☐ No
2. Were any known or reasonably foreseeable risks and/or hazards identified for each of the items supplied based on this hazard analysis? ☐ Yes ☐ No ☐ Only for _____
   a. If "Yes", please provide the information requested in items A – D for each hazard identified in Appendix One, including the known or reasonably foreseeable hazards associated with each item , classifying each hazard as a Biological (B), Chemical (C) or Physical (P) hazard. Duplicate Appendix One as necessary to address each item supplied and associated hazards identified. Attach additional sheets as necessary.
3. Has an assessment of the probability that the hazard will occur been conducted? ☐ Yes ☐ No
   a. If "Yes", classify the probability that each identified hazard will occur as "A", "B", "C", or "D" and note where requested in Appendix One (probability classifications defined in note "[2]" in Appendix One as well as in Appendix Two rubric).
4. Has an assessment of the severity of the illness or injury if the hazard was to occur been conducted? ☐ Yes ☐ No
   a. If "Yes", classify the severity of each identified hazard as "I", "II", "III", or "IV" and note where requested in Appendix One (probability classifications defined in note "[3]" in Appendix One as well as in Appendix Two rubric).
5. Record the combined probability and severity code for each identified hazard in the appropriate locations in Appendix One (Example: "I-A").
6. List in the appropriate location in Appendix One any additional controls recommended beyond the prerequisite (cGMP) controls that are in place to reduce or eliminate either the probability that the hazard will occur or the severity of the illness or injury should the hazard occur.
7. What verifications are you proposing for the item supplied to ensure that the controls put in place are appropriate to control the identified hazards (please specify for each hazard identified)?

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Appendix One

Hazard Analysis

Item Supplied:

Item Hazard Number	1	2	3
Known or Reasonably Foreseeable Hazard Identified			
Hazard Classification (B, C, P)[1]			
Prerequisite programs and/or controls in place that reduce or eliminate the hazard			
Activities which verify that the controls in place are effective at reducing or eliminating the hazard			
Classification of the probability that the hazard will occur in the absence of additional controls[2]			
Classification of the severity should the hazard occur[3]			
Combined probability and severity classification[4]			
Recommended additional controls to reduce the probability of the hazard occurring or the severity of the hazard should it occur			

[1]B=Biological, C=Chemical, and P=Physical

[2]A=Immediate danger that the hazard will occur; B=Probably will occur in time if not corrected; C=Possible to occur in time if not corrected; and D=Unlikely to occur, may assume hazard will not occur.

[3]I=Imminent and immediate danger of death or severe illness. Likely to impact humans and animals; II=Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible human impact; III=Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans; IV=Illness or injury is minor. Possible to impact animals, unlikely to impact humans.

[4]I-A through IV-D from Hazard Evaluation Rubic

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Appendix Two

Hazard Evaluation Rubric

	Severity	High (I)	Medium (II)	Low (III)	Very Low (IV)
Probability		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
High (A)	Immediate danger that the hazard will occur	I-A	II-A	III-A	IV-A
Medium (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
Low (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
Very Low (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

Critical: Additional controls required
Moderate: Additional controls may be required
Negligible: No additional controls necessary