Readiness Audit for Food Safety Modernization Act
Preventive Controls for Animal Food Rule.

Facility: ___________________ Auditor:___________________ Date of Audit: __________

Preliminary Questions

Number of employees: _______ Annual tonnage: _________ Annual Sales: __________

Hours and days of activity: _______ Is the facility a designated importer subject to FSVP? Yes No

Which of the following are the compliance dates for this facility (CGMP and Food Safety Plan)?

9/19/16 and 9/18/17  9/18/17 and 9/17/18  9/17/18 and 9/17/19

Owner, Operator, or Agent-in-Charge: ________________ Management: ________________

What are the raw materials/ingredients used?

____________________________________________________________________________________

Finished animal foods that are manufactured, processed, packed, or held at facility: ________________

____________________________________________________________________________________

Largest suppliers: _____________________________________________________________________

Largest customers: ________________________________________________________________

Summary of recent customer complaints: ________________________________________________

Are individuals engaged in manufacturing, processing, packing, or holding animal food trained for:

Their assigned duties in a way that results in safe animal food? □ Yes □ No

The principles of animal food hygiene and animal food safety? □ Yes □ No

Are there records to demonstrate the animal food hygiene training? □ Yes □ No
<table>
<thead>
<tr>
<th><strong>507.14 Personnel</strong></th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes □ No (1) Does management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food?</td>
<td></td>
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<tr>
<td>□ Yes □ No (2) Is adequate personal cleanliness maintained?</td>
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<td>□ Yes □ No (3) Are hands washed thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination?</td>
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<td>□ Yes □ No (4) Are jewelry or other objects that might fall into animal food, equipment, or containers removed and/or secured?</td>
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<tr>
<td>□ Yes □ No (5) Are clothing and other personal belongings stored in areas other than where animal food is exposed or where equipment or utensils are cleaned?</td>
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<tr>
<td>□ Yes □ No (6) Are any other necessary precautions taken to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.</td>
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<thead>
<tr>
<th><strong>507.17 Plant and Grounds</strong></th>
<th>Comments</th>
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<tbody>
<tr>
<td>□ Yes □ No 7) Are the grounds around an animal food plant under the control of the management of an establishment kept in a condition that will protect against the contamination of animal food?</td>
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<tr>
<td>□ Yes □ No 8) Is equipment stored, litter and waste removed, weeds and grass within immediate vicinity of facility cut so they do not constitute an attractant, breeding place or harborage for pests?</td>
<td></td>
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<tr>
<td>□ Yes □ No 9) Are driveways, yards, and parking areas maintained so they do not constitute a source of contamination in areas where animal food is exposed?</td>
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<tr>
<td>□ Yes □ No 10) Are areas that may contribute to the contamination of animal food adequately drained?</td>
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<tr>
<td>□ Yes □ No 11) Is waste treated and disposed of so that it does constitute a source of contamination in areas where animal food is exposed?</td>
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</tr>
<tr>
<td>□ Yes □ No 12) Is the plant suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials?</td>
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<tr>
<td></td>
<td>Yes</td>
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<tr>
<td>13</td>
<td>Does the plant provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment?</td>
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<tr>
<td>14</td>
<td>Is the plant constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination?</td>
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<tr>
<td>15</td>
<td>Does the plant provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors (e.g. steam) and fumes in areas where they may contaminate animal food and in a manner that minimizes the potential for contaminating animal food.</td>
</tr>
<tr>
<td>16</td>
<td>Does the plant provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned?</td>
</tr>
<tr>
<td>17</td>
<td>Does the plant provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation to protect against the contamination of animal food in case of glass breakage?</td>
</tr>
<tr>
<td>18</td>
<td>Does the plant protect against animal food stored outdoors in bulk from contamination by any effective means, including using protective coverings where necessary and appropriate, controlling areas over and around the bulk animal food to eliminate harborages for pests, and checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food?</td>
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</table>

### 507.19 Sanitation

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>19</td>
<td>Are buildings, structures, fixtures, and other physical facilities of the plant kept clean and in good repair to prevent animal food from becoming adulterated?</td>
<td></td>
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<tr>
<td>20</td>
<td>Are animal food-contact and non-contact surfaces of utensils and equipment cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials?</td>
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<tr>
<td>21</td>
<td>When necessary, is equipment disassembled for thorough cleaning?</td>
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<tr>
<td>22</td>
<td>When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet-cleaned, are the surfaces, when necessary, be thoroughly dried before subsequent use?</td>
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<tr>
<td>□ Yes □ No</td>
<td>23) In wet processing of animal food, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, are all animal food-contact surfaces cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated?</td>
<td></td>
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<tr>
<td>□ Yes □ No</td>
<td>24) Are cleaning compounds and sanitizing agents safe and adequate under the conditions of use?</td>
<td></td>
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<tr>
<td>□ Yes □ No</td>
<td>25) Are only the following toxic materials used or stored in the plant area where animal food is manufactured, processed, or exposed: • Those required to maintain clean and sanitary conditions; • Those necessary for use in laboratory testing procedures; • Those necessary for plant and equipment maintenance and operation; and • Those necessary for use in the plant’s operations?</td>
<td></td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>26) Are the toxic materials described above identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials?</td>
<td></td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>27) Are other toxic materials (such as fertilizers and pesticides not above not stored in an area of the plant where animal food is not manufactured, processed, or exposed?</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>507.20 Water Supply and Plumbing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes □ No</td>
<td>28) Is water safe for its intended use and drawn from an adequate source?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>29) Is running water at a suitable temperature and pressure?</td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
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<tr>
<td>-------------------------------------------------------------------------</td>
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<tr>
<td>30) If is water reused, is it safe for its intended use and not add contamination?</td>
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<tr>
<td>31) Does plumbing carry sufficient amounts of water for intended use?</td>
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<tr>
<td>32) Does plumbing sufficiently carry sewage and liquid waste from the facility so it is not a source of contamination?</td>
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<tr>
<td>33) Does plumbing provide sufficient floor drainage?</td>
<td></td>
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<tr>
<td>34) Does plumbing ensure no backflow from piping system empty wastewater or sewage near areas of manufacturing or animal food?</td>
<td></td>
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<tr>
<td>35) Does the facility provide employees with accessible toilet systems that are kept cleaned and well-maintained?</td>
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<tr>
<td>36) Does the plant provide hand washing facilities to prevent employees’ hands from becoming a potential source of contamination?</td>
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<tr>
<td>507.22 Equipment and Utensils</td>
<td>Comments</td>
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<tr>
<td>-------------------------------</td>
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</tr>
<tr>
<td>□ Yes □ No 37) Are all equipment and utensils designed and constructed of such material and workmanship to be adequately cleaned and properly maintained?</td>
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</tr>
<tr>
<td>□ Yes □ No 38) Are all equipment and utensils designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminates?</td>
<td></td>
</tr>
<tr>
<td>□ Yes □ No 39) Is equipment installed to facilitate the cleaning and maintenance of the equipment and adjacent spaces?</td>
<td></td>
</tr>
<tr>
<td>□ Yes □ No 40) Are all animal food contact surfaces made of nontoxic materials that withstand the environment of their use, the action of animal food, and the action of cleaning compounds, cleaning procedures, and sanitizing agents?</td>
<td></td>
</tr>
<tr>
<td>□ Yes □ No 41) Are all holding, conveying, manufacturing, and processing systems designed, constructed, and maintained in a way to protect against the contamination of animal food?</td>
<td></td>
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<tr>
<td>□ Yes □ No 42) If freezers and cold storage compartments are used to hold animal food, are they fitted with accurate temperature-measuring devices?</td>
<td></td>
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<tr>
<td>□ Yes □ No 43) If there are instruments and controls used in measuring, regulating, or recording temperature or other conditions to control or prevent the growth of undesirable microorganisms, are they accurate, precise, adequately maintained, and adequate in number for their designated uses?</td>
<td></td>
</tr>
<tr>
<td>□ Yes □ No 44) Is compressed air or other gas mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment used in such a way to protect against the contamination of animal food?</td>
<td></td>
</tr>
<tr>
<td>507.25 Plant operations</td>
<td>Comments</td>
</tr>
<tr>
<td>-------------------------</td>
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<tr>
<td>□ Yes □ No</td>
<td>45) Is all animal food accurately identified?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>46) Are all animal food-packaging materials safe and suitable?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>47) Is the overall cleanliness of the plant under the supervision of one or more competent individuals assigned responsibility for this function?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>48) Are adequate precautions taken so that plant operations do not contribute to contamination?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>49) Are chemical, microbial, or other testing procedures used where necessary to identify sanitation failures or possible animal food contamination?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>50) Is all animal food that becomes adulterated rejected, treated, or processed to eliminate adulteration, or disposed of in a manner that protects against the contamination of other animal food?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>51) Is all animal food manufacturing, processing, packing, and holding conducted under conditions and controls necessary to minimize the potential for growth of undesirable microorganisms to protect against the contamination of animal food?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>52) Are shipping containers and bulk vehicles holding ingredients examined upon receipt?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>53) Are all raw materials cleaned as necessary to minimize contamination?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>54) Are all raw materials and other ingredients stored in a way that protects against contamination and deterioration?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>55) Are ingredients susceptible to mycotoxins used in a proper manner?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>56) Are all raw materials or other ingredients that must be frozen, kept frozen and thawed properly?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>57) Is all animal food maintained, manufactured, and packaged under conditions which minimize the potential for the growth of microorganisms?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>58) Is work-in-process and rework handled to protect against undesirable microorganisms?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>59) If water activity or pH are used to prevent the growth of microorganisms, are they used properly?</td>
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<tr>
<td>□ Yes □ No</td>
<td>60) If ice is used, is the water it was made from safe for use?</td>
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<td></td>
<td>507.27 Holding and distribution</td>
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<tr>
<td>□ Yes □ No</td>
<td>61) Is animal food held in appropriate places that protect from the contamination of pests, chemicals, and other products?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>62) Are unpackaged or bulk animal foods held to protect cross-contamination?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>63) Are shipping containers (bulk trucks, tote bags, paper or plastic bags, etc.) designed, constructed of appropriated material, and maintained to protect against contamination?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>64) Are containers properly clean?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>65) Are containers inspected to protect cross-contamination before loading?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>66) Do the animal food labels follow AAFCO suggestion which contains the instructions of safely using and intended animal species?</td>
</tr>
<tr>
<td>□ Yes □ No</td>
<td>67) Do you accept returned products to your facility? If yes, do you have procedure to control them (Who will decide whether to accept or reject? Where are they placed? Who will justify the corrective action for them?)</td>
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<tr>
<td>CGMP Compliance Summary</td>
<td></td>
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<tr>
<td>Number of Compliance (Yes Boxes Checked)</td>
<td></td>
</tr>
<tr>
<td>% Compliance (of 67)</td>
<td></td>
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</tbody>
</table>

### Food Safety Plan

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tbody>
<tr>
<td>Has the Owner, Operator, or Agent-in-Charge signed and dated the food safety plan?</td>
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<tr>
<td>Does the Food Safety Plan identify the plant or facility?</td>
<td></td>
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<tr>
<td>What are the known or reasonably foreseeable hazards?</td>
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<tr>
<td>Are the other known or reasonably foreseeable hazards adequately controlled through prerequisite programs and/or CGMP?</td>
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<tr>
<td>If yes, are there adequate records to support the sufficient control of the hazard?</td>
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<tr>
<td>Explain:</td>
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<tr>
<td>Are there hazards requiring a preventive control?</td>
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<td>If yes, describe:</td>
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<tr>
<td>Are there monitoring procedures and records?</td>
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<td>Method:</td>
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<td>Frequency:</td>
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<tr>
<td>Are there corrective action procedures and records?</td>
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<tr>
<td>Identify and correct the problem:</td>
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<td>Reduce likelihood that the problem will recur:</td>
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<tr>
<td>Evaluate affected animal food for safety:</td>
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<tr>
<td>Prevent affected animal food from entering commerce, if necessary:</td>
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<tr>
<td>Reanalyze the food safety plan, if necessary:</td>
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<tr>
<td>Is there validation to support the preventive control?</td>
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<tr>
<td>Explanation:</td>
<td></td>
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</tbody>
</table>
Is there verification to support the preventive control?  

Yes  
No  
n/a

Calibration: __________________________________________________________

Product Testing: ______________________________________________________

Environmental Monitoring: _____________________________________________

Review of monitoring/corrective action records within 7 working days: ________________

Review of verification records within a reasonable time: ________________

Does the facility have a recall plan?

- Assigns responsibility for all procedures
- Includes procedures to directly notify consignees
- Includes procedures for notifying the public, if necessary
- Includes procedures for how to conduct effectiveness checks
- Includes procedures for how to appropriately dispose of animal food