REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000
(Version 5.1, 10/01/2007; FDA/CVM, HFV-230, www.fda.gov/cvm/Documents/BSE_V42.pdf)

FEI#:

Firm (Legal) Name:

Firm (Physical) Address:

Firm City:

Firm State: Zip Code: Phone #:

GPS Coordinates of Inspected Site:

Date Current Inspection Ended:

Lead Investigator:

Lead Affiliation ***(check one):***
- ☐ Federal
- ☐ State Agency, *(name)*

FDA District Office:

Name and title of persons(s) interviewed:

Name and title of most responsible person at this site:

Operational Status: ***(Check only one)*** (See **Instructions**)
- ◯ Operational
- ◯ Seasonal
- ◯ Inactive
- ◯ Out of Business

[If firm is OOB, Skip ALL Sections!]

☐ Information above includes changes to firm's name and/or address

Section 1 - Complete for ALL firms

1. a) Type of firm inspected? (*Check ALL that apply*)

- ☐ Renderer
- ☐ Protein Blender
- ☐ Transporter (Hauler)
- ☐ Distributor/Retailer
- ☐ Feed Mill (FDA Licensed)
- ☐ Feed Mill (not FDA Licensed)
- ☐ Pet Food Manufacturer
- ☐ Animal Feed/Pet Food Salvager
- ☐ On-farm Feed Mixer
- ☐ Feeder of Ruminants
- ☐ Human Food Processor
- ☐ Other:

b) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of ruminant animals? ◯ Yes ◯ No

c) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of non-ruminant animals? ◯ Yes ◯ No

d) Is the firm aware of the BSE rule, 21 CFR 589.2000? ◯ Yes ◯ No

2. Does the firm receive feeds or feed ingredients that contain or may contain prohibited material (PM) ***(Check only one)*** ◯ Yes ◯ No
- ☐ YES, but PM is Only in Retail Pet/Lab Feed

---

a) If Question 2 is **"YES, but PM is only in Retail Pet/Lab Feed"** or **"NO,"** check all of the following that describe voluntary safeguards the firm has in place to assure they do not receive prohibited material.

- ☐ Written assurance from supplies that they no longer manufacture/distribute any products containing prohibited materials
- ☐ Written assurance from transporters that they do not transport products containing prohibited materials
- ☐ Written assurance from transporters that they utilize dedicated transport equipment OR utilize clean-out measures that adequately prevent commingling or cross-contamination
- ☐ Written procedures for the label review of incoming materials
- ☐ Uses only vegetable source proteins and uses no animal proteins
- ☐ Uses animal proteins only from exempted sources
  Check all that apply: ☐ blood ☐ milk ☐ "plate waste" ☐ porcine ☐ equine ☐ fish ☐ gelatin
- ☐ Testing of incoming materials, *(please describe)*
- ☐ Other, *(please describe)*

[If Q2 = "No" or if Q1a) is only "Feeder of Ruminants", skip to Section 3] ----------

b) If **Question 2** is either "**YES, but PM is Only in Retail Pet/Lab Feed" or "YES"**, is imported prohibited material (not originating in the United States) used?

◯ Yes ◯ No ◯ Unkown

Please list the country/ies of origin for the imported prohibited material,

3. Is the received product containing prohibited material intended **ONLY** for further distribution? ◯ Yes ◯ No

4. Does the firm manufacture or process products containing prohibited materials? ◯ Yes ◯ No

5. Are the received feeds or feed ingredients containing prohibited materials (referred to in **#2** above) labeled with the caution statement, "**Do not feed to cattle or other ruminants**"? (***Check only one***)

☐ PM is Only for Rendering ☐ PM is Only for Retail Pet/Lab Feed ◯ Yes ◯ No

Section 2 - Complete for ALL firms EXCEPT: Firms that are ONLY Q1a) Firm Type = "Other" OR Firms that are ONLY Q1a) Firm Type = "Feeder of Ruminants"

6. Are the outgoing feeds or feed ingredients containing prohibited materials labeled with the caution statement, **"Do not feed to cattle or other ruminants"**? ***(Check only one)***

☐ No Outgoing Feeds/Ingredients containing PM ☐ PM is Only in Retail Pet/Lab Feed ◯ Yes ◯ No

7. Describe records the firm maintains in tracking prohibited materials throughout their receipt, processing and distribution:

a) Date of receipt **or** purchase **or** sale **or** delivery	◯ Yes	◯ No
b) Name and address of the seller	◯ Yes	◯ No
c) Name and address of the purchaser	◯ Yes	◯ No
d) Identification of the product	◯ Yes	◯ No
e) Quantity	◯ Yes	◯ No
f) Copies are available for inspection and copying	◯ Yes	◯ No
g) Are **ONLY** retail feed sales involved?	◯ Yes	◯ No
h) Are **ONLY** retail feed sales of pet food involved?	◯ Yes	◯ No

8. a) Does the firm manufacture, process, blend, repackage, or transport BOTH products containing prohibited materials AND products containing only non-prohibited materials?

◯ Yes ◯ No

b) Does the firm manufacture, process, blend, repackage, or transport **BOTH** products containing prohibited materials **AND feeds or feed ingredients that may be used for ruminants?**

◯ Yes ◯ No

9. a) If the answer to Q8a) is "NO," then SKIP to Question 10.

If the answer to **Q8a)** is "**YES**", does the firm have a system in place to avoid commingling and cross-contamination? ◯ Yes ◯ No

b) If the answer to **Q8a)** is "**YES**," check **ALL** of the following that describe the measures the firm has in place to avoid commingling or cross-contamination.

☐ Sequencing of feeds
☐ Flushing the system, (*please describe*)
☐ Written sequencing and flushing procedures
☐ Documentation maintained of sequencing and flushing
☐ Flushed materials discarded or labeled with the caution statement
☐ Physical clean-out (e.g. vacuuming, cleaning)
☐ Dedicated equipment used for prohibited materials
☐ Product containing prohibited material is always in packaged form when in the firm's possession
☐ Other, (*please describe*)

10. Please describe any additional safeguards the firm has in place to assure that prohibited material are not shipped to ruminant feeders, ***(If none, please enter "None")***

Section 3 - SKIP this section if the firm is ONLY marked as: Q1a) Firm Type = "Other" OR Q1a) Firm Type = "Transporter (Hauler)"

11. a) Are any incoming feeds or feed ingredients transported in bulk form? ◯ Yes ◯ No

b) Are any incoming feeds or feed ingredients transported in packaged form? ◯ Yes ◯ No

c) Does the firm utilize **its own** transportation vehicles for the delivery of any bulk incoming feeds or feed ingredients? ◯ Yes ◯ No

d) Does the firm utilize **other firms'** transportation vehicles for the delivery of any bulk incoming feeds or feed ingredients? ◯ Yes ◯ No

e) If 11(d) is "**YES**," do **ALL** inbound transporters provide written assurance that they utilize dedicated transport equipment OR utilize measures that adequately prevent commingling or cross-contamination with prohibited material? ◯ Yes ◯ No

12. a) Are any outgoing feeds or feed ingredients transported in bulk form? ◯ Yes ◯ No
☐ No Outgoing Feeds/Ingredients

b) Are any outgoing feeds or feed ingredients transported in bagged/packaged form? ◯ Yes ◯ No
☐ No Outgoing Feeds/Ingredients

c) Does the firm utilize **its own** transportation vehicles for the delivery of any going bulk feeds or feed ingredients? ◯ Yes ◯ No
☐ No Outgoing Feeds/Ingredients

d) Does the firm utilize **other firms'** transportation vehicles for the delivery of any outgoing bulk feeds or feed ingredients? ◯ Yes ◯ No
☐ No Outgoing Feeds/Ingredients

e) If 12(d) is "**YES**," do **ALL** outbound transporters provide written assurance that they utilize dedicated transport equipment OR utilize clean-out measures that adequately prevent commingling or cross-contamination with prohibited material? ◯ Yes ◯ No

Section 4 - Complete this section ONLY if the firm is marked as: Q1a) Firm Type = "Feeder of Ruminants"

13. Are ruminant feeders doing the following?

a) Observing the caution statement on feeds containing prohibited material (**PM**) ◯ Yes ◯ No ☐ No PM-feeds on premises

b) Maintaining copies of labeling for feeds containing animal protein (**AP**) (**Not including** retail pet food for cats and dogs) ◯ Yes ◯ No ☐ No AP-feeds on premises

c) Maintaining copies of purchase invoices for feeds containing animal protein (**Not including** retail pet food for cats and dogs) ◯ Yes ◯ No ☐ No AP-feeds on premises

d) Feeding non-ruminant species (**Not including** cats and dogs) ◯ Yes ◯ No

e) Feeding non-ruminant species (**Not including** cats and dogs) feeds containing prohibited material ◯ Yes ◯ No ☐ No PM-feeds on premises

f) Feeding cats and/or dogs ◯ Yes ◯ No

Section 5 - Complete for ALL Firm Types

14. a) Check all deviations that were noted at the time of inspection.
☐ Commingling ☐ Labeling ☐ No Deviations Needed
☐ Recordkeeping ☐ Feeding Ruminants Prohibited Material

b) If any deviations were noted above, describe the deviations, and the actions and commitments made to correct each deviation,

15. Are you attaching any descriptions, exhibits, records, labeling, reports or supplemental information? ◯ Yes ◯ No

Print Form Reset Form

INSTRUCTIONS - For the Lead Investigator

District BSE Coordinator. The FDA District BSE Coordinator is responsible for communicating and receiving information related to the BSE Checklist/Report. Questions, comments and concerns should be directed to this individual. Completed BSE Reports of Inspection generated by State agencies should be mailed to the District BSE Coordinator, not to CVM. The Districts are responsible for checking the forms for completeness and accuracy, and for entering the information into FACTS.

BSE Checklist/Report Version. Please make sure you are using the most current BSE Checklist/Report version. The version date is located at the top of the form. Check with your BSE District Coordinator or the FDA/CVM website (www.fda.gov/cvm/form/forms.html) to make sure you are using the most recent version. Other versions may not be compatible with the BSE Checklist/Report Database and may invalidate the information collected.

BSE Checklist/Report Alterations. Some agencies may choose to alter the BSE Checklist/Report to better fit their own operations. While CVM does not necessarily object to such alterations, changes must be added to the end of the form. No additions, deletions or revisions should be made to the main body of the CVM-version of the BSE Checklist/Report.

Legibility. Illegible writing results in inaccurate data, which compromises the BSE Compliance Program. If you are submitting a handwritten checklist, please print your responses to the questions.

Completing Sections. Sections should be fully completed for each of the firm types indicated in the header of each Section. Sections inappropriately skipped (based on the firm type) may cause the BSE Checklist/Report to be considered incomplete. Incomplete BSE Reports of Inspection may require follow-up with the investigator and may require a follow-up inspection at the firm.

Completing Questions. The BSE Checklist/Report instructions and flow of questions must be followed. Blank or unanswered required questions may cause the BSE Checklist/Report to be considered incomplete. Incomplete BSE Reports of Inspection will require a follow-up with the investigator and may require a follow-up inspection of the firm.

Descriptive Fields. For those questions that ask for an explanation or description, please be brief and capture the essential elements with as few words as possible. If you feel certain answers require a more lengthy description, consider recording the information on a separate page, which should be attached to the BSE Checklist/Report and so noted in the question at the top of the checklist which asks if additional documents are attached.

Additional Narrative. For those state BSE/Ruminant Feed inspections not being done under federal contract or those state contract BSE/Ruminant Feed inspections that do not include an FDA-481, it is recommended that a brief narrative report accompany the BSE Checklist/Report summarizing the inspection. A brief summary should cover the entire inspection and should include other details not captured in the Checklist/Report.

CHECKLIST QUESTIONS

Firm information - Complete for ALL firms, regardless of the firm type.

FEI Number. The FEI number is absolutely required. It is the District's responsibility to provide this information, and you may need to contact your District BSE Coordinator for this information. The District may need to assign an FEI number after the inspection is completed. For example, if the firm has not been inspected before, the District will assign an FEI number when it receives the report.

Firm Name. Use the firm's accurate legal name. Do not use "Doing Business As" (DBA) firm names if at all possible.

Firm Address. The address should reflect the physical location of the firm's activities. Post Office Box numbers are unacceptable. If the firm's mailing address is different than their physical address, please make a note of this information.

Date Current Inspection Ended. If the inspection went more than one day, enter the date of the last day of the inspection.

Lead Investigator. Enter the name of the lead investigator.

Lead Affiliation. If the inspection was done by FDA, check this box. If the inspection was done by a State, check the box and write in the name of the State.

FDA District Office. Enter the name of the FDA District in which the inspected firm is located.

GPS Coordinates. This information is not required by FDA at this time.

Name and title of the person(s) interviewed. Record the name and title of the person(s) interviewed during the inspection.

Name and title of most responsible person at the site. Record the name and title of the most responsible person at the facility, for example the firm's President or Manager. This may or may not be the person interviewed during the inspection.

Operational Status. Mark the firm's operational status. Inspection reports should be completed for **Seasonal** and **Inactive** firms since they might begin production at any time. **Out of Business** firms require no more information gathering.

Changes to firm name and address. If the facility/site has a new name and/or address, please check the box indicating this and make sure the address recorded on the inspection report is correct. Please record the firm's former name and/or address somewhere in your inspection report.

Section 1 -- Complete for **ALL** firms, regardless of the firm type (with the exception of firms which are Out of Business).

Question 1a) Firm Type. Please understand the firm type categories provided and use these categories whenever applicable. More detail is provided in Compliance Program 7371.009.

Considerations:

- A single firm can be categorized as one or more firm types, so mark all firm types that are appropriate.
- The BSE Checklist/Report may not fully describe the activities of certain multiple firm type combinations. Please contact your BSE District Coordinator if additional guidance is needed.
- **Warehouse operations** should be marked as Distributor/Retailer.
- **Feed mills** should be described on the basis of FDA licensure and NOT on whether the firm produces medicated feeds. A single firm cannot be marked as both a licensed feed mill and an unlicensed feed mill.
- **Ingredient manufacturers** are considered unlicensed feed mills.
- **Ruminant feeders** (e.g. dairy farms, feedlots) might also be On-farm Mixers, but On-farm Mixers might not be ruminant feeders (e.g. swine farms). The "Feeder of Ruminants and Other Species" category has been deleted in this version of the inspection report form. If doing an inspection at a farm that does NOT feed ruminants, but does feed other species of livestock, check the "Other" box and write-in "non-ruminant feeder".
- **On-farm Mixing** applies to mixing that is not performed for the purpose of commercial distribution. Generally the use of on-farm mixed feeds occurs on the same farm premises where the feed is made. However, in some cases feeds mixed on-farm are utilized off-premises and/or outside the direct supervision of the farm manager (e.g., a farm where mixed feeds are delivered for feeding at physically different farm locations, perhaps under a contract arrangement).
- On-farm Mixers are subject to the requirements of the BSE/Ruminant Feed regulation (21 CFR 589.2000) just like commercial feed mills.
- The **"Human Food Processor"** category has been added to this version of the inspection report form. If the firm manufactures human food, mark this box.
- The **"Other"** category should be used only for firm operations that are not described by the other categories listed. Improper use of the "Other" category may cause inaccurate and/or inadequate information to be collected in the remaining Sections.
- **Feed or Feed Ingredients.** These are products intended to be fed to animals or used to manufacture animal feeds. Substances intended solely for other purposes (e.g. fertilizers) are not included in this category.

Question 1 -- b) Further defines "handling" for better clarification. **c)** Is new and asks whether the firm makes feed for non-ruminant animals. **d)** Is new and asks whether the firm is aware of the BSE rule or not.

Question 2 - Has been changed slightly. If you answer "NO" or "YES, but PM is only in Retail Pet/Lab feed" then go through the list of boxes in **2a)** to describe the safeguards the firm is taking to make sure they do not receive prohibited material for use in their manufacturing operation. If the answer to Q2) is "no", or if the firm is only a "feeder of ruminants", then do not complete question #2b) and skip to Section 3, Question 11, of the inspection report form. **2b)** If imported prohibited material is used, please record the country of origin of that product.

Question 3 - Is the received product that contains prohibited material being held only for further distribution? Mark "Yes" or "No".

Question 4 - Is the firm manufacturing, or otherwise processing, products that contain prohibited material? Mark "Yes" or "No". Note - The answers to questions Q3) and Q4) can both be "No", but they cannot both be "Yes".

Question 5 - Are feeds containing prohibited material properly labeled with the caution statement? Raw animal products destined for a renderer are not required to be labeled. If you are inspecting someone supplying/transporting raw animal products to a renderer, mark "PM is only for rendering". Retail pet foods are exempted from the requirement to have the caution statement on the label, unless the product is salvaged or distressed.

Section 2 - If the firm "handles" (manufacture, process, blend, distribute, transport or use) prohibited materials or feeds which may contain prohibited material, complete section 2.

Question 6 - Asks if outgoing feeds that contain (or may contain) prohibited material are properly labeled with the caution statement. The first option, "No Outgoing Feeds/Ingredients containing PM", for example, may be used when inspecting a farm that mixes its own feed. The second box, "PM is ONLY in Retail Pet/Lab Feeds" is to be used in those cases where the only prohibited material on the premises is found in pet or lab animal feed.

Question 7 -The purpose of the question is for the Investigator/Inspector to simply note the types of recordkeeping being utilized and not to indicate their adequacy with respect to the BSE/Ruminant Feed Regulation (21 CFR 589.2000). Recordkeeping inadequacies should be indicated and described in **Section 5**. Retail sales are sales made to the ultimate consumer - people purchasing feed for their animals. **g)** Mark "yes" if the firm sells feed (any kind of feed, including pet food) but does not manufacture feed at the site. **h)** If you marked "yes" on g) and the only type of feed sold at the firm is pet food, mark "yes" on h) as well.

Question 8 - Commingling and cross-contamination can occur when products are processed or handled, such as with manufacturing, blending, repackaging or transporting a product. **a)** Asks if the firm makes a feed product containing prohibited material AND a feed product which does not contain any prohibited material. **b)** Asks if the firm makes a feed product containing prohibited material AND a feed product for ruminants.

Question 9 - If the answer to 8a) is "NO", skip to Question 10. If 8a) is "YES", then answer 9a) by indicating whether or not the firm has a system in place to avoid commingling and cross-contamination. Mark the boxes in 9b) that best describe the measures the firm has adopted to avoid commingling and cross-contamination. Use the narrative fields if necessary. One additional option has been added to the list that was in the last version of the checklist - "Product containing prohibited material is always in packaged form when in the firm's possession".

Question 10 - Briefly describe in writing any additional safeguards the firm may have in place to prevent outgoing feed products that contain prohibited material from being shipped to ruminant feeders.

Section 3 - This section is new, and deals with the transportation of feeds and feed ingredients in and out of manufacturing facilities and feeding operations, including feed mills, ingredient manufacturers, and ruminant feeders. This section of the checklist is not intended to be used during the inspection of firms engaged only in transportation. Transportation equipment is treated like mixing equipment, for example, and when inspecting a transportation firm you would ask the same questions about recordkeeping and cleanout asked of feed mills, renderers and other facilities that may handle prohibited material.

Question 11 - Deals with the transport of feeds and ingredients into the firm. On **11 e)** only answer "yes" if EVERY inbound transporter provides written assurance that they use dedicated equipment or have adequate cleanout procedures, otherwise the answer is "no".

Question 12 - Deals with the transport of feeds and ingredients from the firm. On **12 e)** only answer "yes" if EVERY outbound transporter provides written assurance that they use dedicated equipment OR have adequate cleanout procedures, otherwise the answer is "no".

Section 4. This section is to be used only when the firm feeds ruminant animals.

Question 13 - Contains six questions to be answered when inspecting a ruminant feeder. **a)** Mark "No PM-feeds on premises" only if you found NO feed on the premises containing prohibited material, not including retail pet food intended for cats and dogs. **b)** Mark "No AP-feeds on premises" only if you found NO feed on the premises containing animal protein, not including retail pet food intended for cats and dogs. **c)** Mark "No AP-feeds on premises" only if you found NO feed on the premises containing animal protein, not including retail pet food intended for cats and dogs. **d)** Are they feeding animals other than ruminants and dogs/cats? "Yes" or "No". **e)** Mark "No PM-feeds on premises" if the feed for the non-ruminant species does not contain prohibited material, not including retail pet food intended for cats and dogs. **f)** Does the firm have pet cats and/or dogs? Please answer.

Section 5. This section should be completed for all firms, unless the firm was found to be Out of Business (OOB).

Question 14 - **a)** Mark the boxes for any deviations of 21 CFR 589.2000 identified during the inspection. **b)** Is to be used to further describe any deviations identified, and to record action taken, or commitments made, by the firm in response. Issues related to 21 CFR 589.2000 may be noted for firms that are not handling prohibited material. An example would be the use of the caution statement when the firm is not handling prohibited material.

Question 15 - Are you attaching any descriptions, exhibits, records, labels or supplemental information? If so, check the box and do not forget to attach the other documents.

INSTRUCTIONS - For the District BSE Coordinator

The District BSE Coordinator has a key role and overall responsibility for ensuring that BSE Reports of Inspection are completed fully and accurately, which is vital to the success of BSE compliance efforts. The District BSE Coordinator should pay particular attention to ensuring the following:

- Familiarity with the Instructions for the Lead Investigator.
- The most recent version of the BSE Checklist/Report and accompanying instructions are distributed and utilized.
- The BSE Checklist/Report has not been unacceptably altered.
- All required sections are completed. All questions within a required section are completed.
- Handwritten forms are legible.
- The FEI number is provided
- The FDA District Office identity is provided.
- Response inconsistencies are resolved.

All completed BSE Reports of Inspection generated by State agencies should be sent to the District BSE Coordinator, not to CVM. The Districts are responsible for checking the forms for completeness and accuracy, and for entering the information into FACTS.

Any questions, concerns or comments regarding the BSE Checklist/Report or the BSE/Ruminant Feed Inspection Compliance Program should be directed to the BSE Coordinator in the appropriate District. The following individuals are additional BSE/Ruminant Feed Inspection Compliance Program contacts:

CVM: Shannon Jordre
shannon.jordre@fda.hhs.gov
240-276-9229

ORA: Jim Dunnie
james.dunnie@fda.hhs.gov
301-827-5652