Precision Agricultural Services, Inc. – Revised 11-2-17

Hazard Analysis for Corn Cobs, Corn Kernels, and Corn Husks as a byproduct of Corn Seed Processing

The following is the hazard analysis for Corn byproducts from corn seed processing used for feed—specifically Corn Cobs, Corn Kernels, and Corn Husks. This was prepared and reviewed by two Preventive Controls Qualified Individuals (PCQIs). These hazards are generalized for a basic corn seed processing facility. Regarding probability, these justifications assume the implementation of our recommended cGMP processes. This information needs to be tailored for each facility based on its own experience, particularly for the probability rationale.

The following rubric was used to assess risk for each known or reasonably foreseeable hazard. Each company should adjust this rubric to align with individual risk management profiles. Each company may choose to assess risk in other preferred methods. The rubric method below was selected based on the PCQI Training. The selections of Critical, Moderate and Negligible are based on the risk tolerance assumed by Precision Agricultural Services, Inc. (PAS). Other risk tolerances may vary.

Under 21 CFR § 507.33, facilities must conduct a hazard analysis to identify known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility and determine whether any of the hazards requires a preventive control. The hazard analysis must be written, regardless of its outcome, and must consider biological, chemical including radiological, and physical hazards. The determination of whether or not a hazard requires a preventive control must consider the severity of the illness or injury if the hazard were to occur, as well as the probability that the hazard will occur in the absence of controls. The hazard analysis should be based on experience, illness data, scientific reports, and any other relevant information.

Critical		Moderate		Negligible	
	Severity	**High (I)**	**Medium (II)**	**Low (III)**	**Very Low (VI)**
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**	**VI-A**
Medium (B)	Probably will occur in time if not corrected.	**I-B**	**II-B**	**III-B**	**VI-B**
Low (C)	Possible to occur in time if not corrected.	**I-C**	**II-C**	**III-C**	**VI-C**
Very Low (D)	Unlikely to occur; may assume hazard will not occur.	**I-D**	**II-D**	**III-D**	**VI-D**

Based on the above, anything determined to be in the "Critical" area should be addressed by a Preventive Control. Anything in the "Moderate" section should be examined more closely to assess whether it is a "hazard requiring a preventive control." Anything falling in the "Negligible" category can be fully managed with cGMPs.

PAS performed a review for consideration of a wide range of hazards during the process of analysis. The following hazard analysis focuses on the hazards that have been determined to be the most known or reasonably foreseeable hazards associated with a corn production facility.

Justification 1: Mycotoxins: Determined (I-D) Negligible, hazard does not require a preventive control.

- Severity - High – Due to its impact on animals the FDA has issued Action Levels for Aflatoxin and Advisory Levels for deoxynivalenol, vomitoxin and fumonisin. FDA Mycotoxin Regulatory Guidance: A Guide for Grain Elevators, Feed Manufacturers, Grain Processors and Exporters ; Prepared by National Grain and Feed Association 1250 Eye St., N.W., Suite 1003, Washington, D.C., 20005-3922 Phone: (202) 289-0873 Fax: (202) 289-5388 Web Site: www.ngfa.org August 2011 - https://www.ngfa.org/wp-content/uploads/NGFAComplianceGuide-FDARegulatoryGuidanceforMycotoxins8-2011.pdf

- Probability - Very Low –Below is a study regarding a field heavily infested with Aspergillus Flavus, with a sample of 50 corn plants to inspect the kernels, cobs, husks, leaves and stalks, the following was determined showing the impact of mold on cobs and husks. At the time of the study approximately 95% of the ears has visible Aspergillus Flavus mold and the combine-harvested corn kernels from the field was 1,170 ug/kg. Plants were dried directly after harvest and analyzed. This study represents a field with severe conditions. Fields harvested for seed corn would not come close to this type of mold contamination. However, to understand the significantly small amount of mycotoxin development on the cob and ear, mean aflatoxin level of the cobs for Aflatoxin B1 was 13ppb and for husks was 11ppb while the mean B1 level for kernels as 1,934 PPB. Both the mean aflatoxin level for cobs and husks fell below the FDA action level of 20ppb for all foods including animal feeds.

  Aflatoxin: Distribution in Contaminated Corn Plants O. L. SHOTWELL, M. L. GOULDEN, C. W. HESSELTINE,2 J. W. DICKENS,3 and W. F. KWOLEK4
  https://www.aaccnet.org/publications/cc/backissues/1980/Documents/chem57_206.pdf

  Facility History: The facility has received _____ reports of animal illnesses from customers regarding animal consumption of corn cobs, corn husks or whole kernel corn from this facility over the past _____ years. The combination of monitoring weather conditions favorable to aflatoxin development, and the stringent harvesting, sorting and drying processes will reduce the probability of contamination to a negligible level. If a high stress year brings about a portion of

seed or culls that may be contaminated, this seed can be isolated, tested, and directed accordingly.

Because the severity is high and the probability is very low, based on the rubric the conclusion is that this is not a hazard that requires a preventive control.

Justification 2: Salmonella: Determined (II-D) Negligible, hazard does not require a preventive control.

- Severity – Medium – If the hazard were to occur, Salmonella may cause illness to animals but only if it were the serotype pathogenic to the type of animal food being manufactured. Per the FDA Salmonella Compliance Policy Guide 690.800, the serotypes of Salmonella we must be concerned with include Cattle: Newport or Dublin, Goats: none, sheep: Abortusovis and swine: Chloraesus. There is limited physical contact between this type of animal food and humans as this food is not going to be used in the home.

- Probability – Very Low - Scientific Research shows the frequency with which different Salmonella serotypes were found in animal food and ingredients. Of those serotypes relevant to the facility, none are within the top 25 most prevalent serotypes reported with the 25th at only 0.4% of total cases in animal food. (Surveillance of Salmonella Prevalence in Animal Feeds and Characterization of the Salmonella Isolates by Serotyping and Antimicrobial Susceptibility X. Li,1 L.A. Bethune,2 Y. Jia,3 R.A. Lovell,1 T.A. Proescholdt,1 S.A. Benz,1 T.C. Schell,1 G. Kaplan,1 and D.G. McChesney1) https://www.ncbi.nlm.nih.gov/pubmed/22735034

Because the severity is medium and the probability is very low, based on the rubric the conclusion is that this is not a hazard that requires a preventive control.

Justification 3: Escherichia Coli: Determined (VI-A) Negligible, hazard does not require a preventive control.

- Severity - Very low – According to the Beef Cattle Research Council, E. coli O157:H7 has been found in feed, no association between presence in feed and the pathogen's prevalence in live animals has been found. There is limited physical contact between this type of animal food and humans as his food is not going to be used in the home.

- Probability - High – Currently there is no sound scientific data available for the likelihood of E.coli O157 being present in corn shucks and corn cobs. However, in research from 2003 on a sample of feed lots of primarily corn based feed, a study indicated that the prevalence of E. coli O157 (14.9%) in cattle feed may be significantly higher than previously reported. (Prevalence of Escherichia coli O157 in Cattle Feeds in Midwestern Feedlots Charles C. Dodd,1 Michael W. Sanderson,1 * Jan M. Sargeant,2 T. G. Nagaraja,3 Richard D. Oberst,2 Robert A. Smith,4 and D. Dee Griffin5) https://www.vetmed.auburn.edu/wp-content/uploads/2015/05/Dodd_AEM_69_5243_2003.pdf

Because the severity is very low and the probability is high, based on the rubric the conclusion is that this is not a hazard that requires a preventive control.

Justification 4: Listeria Monocytogenes: Determined (VI-B) Negligible, hazard does not require a preventive control.

- Severity - Medium - In ruminants, listeriosis can cause encephalitis, abortion or blood poisoning. Disease is more common in younger animals (1 to 3 years old). Infection can also cause mastitis in cows.

- Probability - Very low – Listeria is typically passed to animals in feed sources such as contaminated or poor quality silage which is not the corn by-product produced at this facility.

Because the severity is medium and the probability is very low, based on the rubric the conclusion is that this is not a hazard that requires a preventive control.

Justification 5: Foreign Materials (metal, glass, stones): Determined (VI-D) Negligible, hazard does not require a preventive control.

- Severity – Very Low: - Foreign materials are generally accepted as a low severity to the types of animals anticipated to be consuming these corn byproducts.

- Probability – Very Low - Inbound corn may contain other plant material and rocks from the field. Metal is possible from machinery, or trucks.

Because the severity is very low and the probability is very low, based on the rubric the conclusion is that this is not a hazard that requires a preventive control.

Justification 6: Pesticides –Determined (I-D) – Negligible, hazard does not require a preventive control.

- Severity – High -The EPA is responsible for the approval process of commercial pesticide use in the United States and has eliminated the use of harmful pesticides. However, pesticide exposure to livestock can cause severe illness or death.

- Probability - Very Low – The US FDA in the FY2014 Pesticide Residue Monitoring Program Pesticide Report provides results that in grains 71.9% of the samples had no pesticide residues, 28.1% showed non-volatile residues and 0% volatile residues. https://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Pesticides/UCM546325.pdf

  Additionally, each pesticide has legally established and labeled pre-harvest interval that will be part of the production plan.

Because the severity is high and the probability is very low, based on the rubric the conclusion is that this is not a hazard that requires a preventive control.

Justification 7: Bovine Spongiform Encephalopathy (BSE): Determined (I-D) Negligible , hazard Does not require a Preventive Control

- Severity - High – Bovine Spongiform Encephalopathy (BSE) is fatal to cattle.
- Probability – Very Low -The facility does not process meat products. There is slight potential that a truck utilized to deliver corn kernels, corn cobs or corn husks may have previously hauled material that may contained unauthorized material in accordance with CFR title 21 §589.2001 Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy, and CFR title 21§589.2000 Animal Proteins Prohibited in Ruminant Feed. For facilities with their own trucks, limit the hauling use to agricultural grain products. If contracting with a third party, ensure the transportation agreement will address the sanitary requirements.

Because the severity is high and the probability is very low, based on the rubric the conclusion is that this is not a hazard that requires a preventive control.

Justification 8: Seed Treatment: Determined (I-D) Negligible, hazard does not require a preventive control.

- Severity - High – Treated seed contains harmful chemicals to animals if fed. Treated seed is prohibited in grain and is not permitted to be fed.
- Probability – Very low – The treated seed process is a deliberate step to change the conditioned corn kernels after screening/sizing into treated seed just prior to packaging either in bag or bulk containers which are then sealed. Screenings and seed designated to remain untreated will not go through this process. Packaged products are intended for seed sales for planting. If treated seed is returned, it will typically only be permitted in its original packaging and placed back into storage. If the material fails standard testing to meet company standards for germination and/or purity, the seed lot will be discarded by acceptable methods per the treatment label or delivered to EPA permitted disposal facilities. Since floor sweepings in treating, packaging, and storage areas may include treated seed, this trash is treated in the same manner.

Justification 9: Weeds Seeds: Determined (I-D) Negligible, hazard does not require a preventive control.

- Severity – High – Some weed seeds have toxicity that is fatal to livestock.
- Probability – Very Low – Weeds are managed during the growing season with weed management strategies to reduce the potential of weed seed development for improved quality and yield of the production field.

Because the severity is high and the probability is very low, based on the rubric the conclusion is that this is not a hazard that requires a preventive control.

The following hazards were considered and determined not to be known or reasonably foreseeable:

Allergens – Not a concern for animal feed.

Flooded Grain – Fields will not be subject to harvest for seed production.

Bones – Not foreseeable

Radiation – Not foreseeable

Environmental Contaminants: Dioxins and polychlorinated biphenyls (PCBs) - Not foreseeable