

# NOTICES OF SUMMARY RULEMAKING

The Administrative Procedure Act allows an agency to use the summary rulemaking procedure instead of the regular rulemaking procedure for repeals of rules made obsolete by repeal or supersession of an agency's statutory authority or the adoption, amendment, or repeal of rules that repeat verbatim existing statutory authority granted to the agency. An agency initiating summary rulemaking shall file the proposed summary rulemaking with the Governor's Regulatory Review Council and the Secretary of State's Office for publication in the next available issue of the *Register*. The proposed summary rule takes interim effect on the date of publication in the *Register*.

## NOTICE OF ADOPTED SUMMARY RULEMAKING

### TITLE 9. HEALTH SERVICES

#### CHAPTER 17. DEPARTMENT OF HEALTH SERVICES PURE FOOD CONTROL

##### PREAMBLE

- 1. Sections Affected**

	<u>Rulemaking Action</u>
Article 3	Repeal
R9-17-311	Repeal
R9-17-312	Repeal
R9-17-313	Repeal
R9-17-314	Repeal
R9-17-315	Repeal
R9-17-316	Repeal
R9-17-317	Repeal
R9-17-318	Repeal
R9-17-319	Repeal
R9-17-320	Repeal
R9-17-321	Repeal
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statute: A.R.S. § 36-136(A)(7)  
Implementing statute: A.R.S. § 36-904.01(D)
- 3. The effective date of the summary rules:**

October 15, 1999
- 4. A list of previous notices appearing in the Register addressing the final rule:**

Notice of Proposed Summary Rulemaking: 5 A.A.R. 3861, October 15, 1999
- 5. The name and address of agency personnel with whom persons may communicate regarding the rule:**

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- 6. The concise explanatory statement, including an explanation of the rule and the agency's reasons for initiating it:**  
The summary rulemaking action will repeal obsolete rules contained in A.A.C. Title 9, Chapter 17, Article 3 relating to the ammoniation of cottonseed to reduce aflatoxin content. The summary repeal is necessary because the statutory authority under A.R.S. § 36-904.01 was repealed effective August 6, 1999. Similarly, A.R.S. § 3-145, A.R.S. § 3-2611, and A.R.S. § 3-904 were amended and A.R.S. § 3-2611.01 was added to include the provisions of A.R.S. § 36-904.01 that were repealed. The repeal of A.R.S. § 36-904.01 removed the authority of the Director of the Arizona Department of Health Services to adopt rules permitting ammoniation of cottonseed and to otherwise carry out the purposes of A.R.S. § 36-904.01. The amendments to A.R.S. § 3-145, A.R.S. § 3-2611, and A.R.S. § 3-904 and the addition of A.R.S. § 3-2611.01 give the Arizona Department of Agriculture the authority relating to the ammoniation of cottonseed.
- 7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:**  
None
- 8. A showing of good cause why the rule is necessary to promote a state wide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**  
Not applicable
- 9. The economic, small business, and consumer impact:**  
Not applicable under A.R.S. § 41-1055(D)(2)
- 10. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business and consumer impact statement:**  
Not applicable
- 11. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule:**  
No oral proceeding was conducted, and the agency received no written comments.
- 12. An explanation of why summary proceedings are justified:**  
A.R.S. § 41-1027 allows summary rulemaking when rules are made obsolete by repeal or supersession of an agency's statutory authority. The repeal of A.R.S. § 36-904.01 removed the authority of the Director of the Arizona Department of Health Services to adopt rules permitting ammoniation of cottonseed to reduce aflatoxin content and to otherwise carry out the purposes of A.R.S. § 36-904.01. The Arizona Department of Agriculture now has the authority relating to the ammoniation of cottonseed to reduce aflatoxin content.
- 13. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**  
None
- 14. Incorporations by reference and their location in the rules:**  
None
- 15. The full text of the rules follows:**

TITLE 9. HEALTH SERVICES

CHAPTER 17. DEPARTMENT OF HEALTH SERVICES  
PURE FOOD CONTROL

**ARTICLE 3. AFLATOXIN IN ANIMAL FEED REPEALED**

Section	
R9-17-311.	Definitions Repealed
R9-17-312.	Legal authority Repealed
R9-17-313.	Enforcement levels Repealed
R9-17-314.	Scope Repealed
R9-17-315.	Approved laboratories Repealed
R9-17-316.	Sampling Repealed
R9-17-317.	Method of analyzing whole cottonseed Repealed

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- R9-17-318.      Methods of ammoniation Repealed
- R9-17-319.      Labeling requirements Repealed
- R9-17-320.      Record requirements Repealed
- R9-17-321.      Enforcement action Repealed

**ARTICLE 3. AFLATOXIN IN ANIMAL FEED REPEALED**

**R9-17-311.      Definitions Repealed**

In this Article, unless the context otherwise requires:

1. "Aflatoxin" means the sum of concentrations of all specific aflatoxins identified in the testing conducted pursuant to this Article.
2. "Approved laboratory" means an analytical facility which examines ammoniated cottonseed for aflatoxin and has been issued a certificate under this Article.
3. "Cottonseed distributor" means any person holding a commercial feed license issued by the State Chemist pursuant to A.R.S. § 24-911 who distributes cottonseed or any person who distributes cottonseed for feed purposes.
4. "Dairy animals" means all animals whose milk is intended for human consumption.
5. "Department" means Arizona Department of Health Services.
6. "Director" means the Director of the Department of Health Services.
7. "Lot" means any distinct, describable and measurable configuration of cottonseed which contains no more than one hundred tons. For purposes of calculating lot size, one cubic foot of whole cottonseed equals twenty-six pounds.
8. "Non-dairy animals" means all animals, other than dairy animals as defined in paragraph (4), above, including without limitation, those animals whose milk is not intended for human consumption.

**R9-17-312.      Legal authority Repealed**

The regulations in this Article, are adopted pursuant to the authority granted by A.R.S. §§ 36-132, 36-136, 36-473, 36-904.01, 36-905 and 36-911.

**R9-17-313.      Enforcement levels Repealed**

- A.** Cottonseed containing aflatoxin in excess of 20 parts per billion is not permitted for use in rations of dairy animals.
- B.** Cottonseed containing aflatoxin in excess of 100 parts per billion is not permitted for use in the rations of non-dairy animals.
- C.** The sampling and testing methods specified in R9-17-316 and R9-17-317 shall be followed for purposes of compliance with the testing, sampling and analysis requirements of A.R.S. § 36-904.01 and R9-17-314 through R9-17-317.

**R9-17-314.      Scope Repealed**

- A.** An analysis shall be performed on samples of cottonseed drawn according to the sampling and testing methods referenced in this Article. The analysis will remain valid for the lot or an identifiable portion of the lot. However if the lot, or a portion thereof, is mixed with another ingredient or comingled with a material of similar composition, except for purpose of making up daily mixed feed rations, a new analysis shall be required. All cottonseed which has not previously been tested shall be evaluated for aflatoxin content prior to its final use as a feed or feed ingredient.
- B.** No sale, transfer, distribution, mixing, processing or feeding of any lot of ammoniated whole cottonseed or ammoniated cottonseed product shall be conducted prior to completion of a written report by a laboratory certified pursuant to R9-17-315 showing the aflatoxin content of such lot of cottonseed, based on analysis performed pursuant to R9-17-317.
- C.** No lot of ammoniated whole cottonseed or ammoniated cottonseed product shall be used as animal feed unless the written results of an analysis performed pursuant to R9-17-315 through R9-17-317 indicate that the aflatoxin content of such lot has been reduced to acceptable levels for those animals to which it is intended to be fed and the labeling so states.

**R9-17-315.      Approved laboratories Repealed**

- A.** Application for certification. A laboratory which desires to perform testing required by A.R.S. § 36-904.01 and has not been certified by A.R.S. § 145 shall first apply to be certified by the Director as a laboratory which meets the standards to perform aflatoxin testing of ammoniated cottonseed stated in this Article. Any laboratory found by the Director to comply with the standards required by this Article will be certified as an approved laboratory. To obtain this certification, the laboratory must apply to the Department for a certificate on a form provided by the Department. The application shall be prepared and signed by both the owner of the laboratory and the laboratory director.
- B.** Revocation of certification. The Director may revoke the certificate of an approved laboratory if it fails to comply with the provisions of this Article as determined by an on-site evaluation by a representative of the Department.
- C.** Quality assurance program.
  1. Each laboratory shall provide a complete written manual, readily available to all personnel, for procedures, required to be performed in the laboratory by this Article. This shall be reviewed periodically by the laboratory director who also approves any changes, additions, deletions, etc. The manual shall include, but not be limited to, the following:
    - a. Specific instructions for the proper collection and handling of samples, if pertinent, shall be available to both laboratory personnel and people outside the laboratory who may be responsible for collecting samples. These instructions shall follow established protocols and include the number of units to be sampled, the locations from

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which obtained and the quantity of material to be submitted, Criteria shall be established for accepting samples and instructions delineated for storage in the laboratory.

- b. Safety precautions unique to specific procedures shall be outlined. These must meet standards required by Chapter 14, Article 1 of this Title.
  - e. Specific written methodology protocols shall include, but not be limited to, the following:
    - i. Instrumentation, glassware and equipment.
    - ii. Detailed instructions for performing the test.
    - iii. Equipment calibrations and testing conditions.
    - iv. Criteria for recording standards, controls and test results.
    - v. Criteria for repeating the test.
    - vi. Maximum allowable contaminant levels.
    - vii. Instructions for performing calculations.
    - viii. References.
  - d. There shall also be available a complete description of the facility's quality assurance program defining policies, including, but not limited to, the following:
    - i. Recovery data for control cottonseed.
    - ii. Confirmation of results by official method.
    - iii. Storage and handling of standards.
  - e. If test results may be used in evidence before a court or government agency, a written chain of evidence protocol shall be established.
2. A maintenance schedule shall be established for those equipment functions which must be performed periodically. Records shall be kept of these checks and also of any repair and non-scheduled service. The maintenance and calibration schedules shall include the following:
- a. Standard procedures for the set-up and normal operation of each instrument and, if pertinent, the specific instructions for checking periodically the reproducibility of the system.
  - b. Instructions for regular checking and recording of the critical operating characteristics of all instruments.
  - c. Functional check documentation in a convenient record including acceptable tolerance limits.
  - d. Records of monitoring of temperature controlled spaces.
  - e. Certification that thermometers and analytical balance weights meet National Bureau of Standards criteria.
  - f. Systems for evaluation of glassware and volumetric equipment.

**D. Laboratory test results:**

- 1. Laboratory records shall include the following information for each specimen:
  - a. Identification of sample.
  - b. Tests requested.
  - c. Description of sample and collection process.
  - d. Sample preparation.
  - e. Method of analysis.
  - f. Analytical data recorded as obtained.
  - g. Calculations.
  - h. Dates of collection, receipt and report.
- 2. Records of observations bearing on the final results and test results shall be recorded concurrently with the performance of each step in the examination of the sample and recorded concurrently with the performance of each calibration and control procedure.
- 3. Standardization, calibration and control records shall be maintained in such a manner so as to provide correlation of this data with sample results. Standardization, calibration and control limits shall be established, recorded, and notation of "out of control" results made with the appropriate remedial action and corrected results.

**E. Sanitation and safety. All laboratories shall be maintained and operated to prevent undue physical, chemical, and biological hazards to its employees or other members of the community. To ensure this, the following shall be met:**

- 1. Physical facilities and utilities shall be capable of supporting all types of procedures done and for the specific workload of the laboratory section.
- 2. Flammable liquids shall be stored in compliance with National Fire Protection Association Codes. Storage areas and rooms where volatile solvents are stored shall be adequately ventilated and safety cans shall only be used for appropriate volumes of volatile liquids. One quart or less of flammables in current use may be stored in open shelves.
- 3. Complete instructions for disposal of contaminated material shall be available. Laboratories are responsible for establishing and observing policies for all real or potential hazards of laboratory wastes.
- 4. Policy manuals shall define specific fire and safety procedures for the laboratory including the proper handling of suspected hazardous sample materials. These regulations shall be written and posted or readily available to personnel.
- 5. An annual fire inspection shall be required.
- 6. Fire extinguishers shall be present in laboratory sections performing tests required by this Article.
- 7. There shall be an inventory of all materials which are labeled as hazardous or carcinogenic.

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8. Compressed gases shall be properly secured by means of chains, base stands sufficiently strong to support weight of cylinder, or brackets. Acetylene or other extremely hazardous gases shall be stored outside the facility and piped in, or stored in accordance with National Fire Protection Association, Code 56-e.
9. There shall be an emergency water supply such as showers, hoses, eyewashes, or flushing devices convenient to areas where caustic materials are used, reagents prepared, acid cleaning of glassware, or other high risk areas.

**F. Proficiency testing.**

1. Each laboratory shall participate in an approved Aflatoxin Check Sample program and shall be required to submit to the Department a copy of its test results.
2. If deficiency is noted during on-site evaluation or in the examination of split samples, the laboratory shall submit to the Department a plan of corrective action designed to eliminate the deficiency.

**R9-17-316. Sampling Repealed**

**A. Sample size and identification.**

1. Not less than one separate gross sample of not less than thirty pounds shall be taken from each lot. Each gross sample shall consist of not less than ten probes (3 lbs. of sample each) or ten stream sample passes (3 lbs. each) taken following the procedure outlined in subsection (D) of this Section.
2. Although only one sample per lot is required, two additional samples for research purposes may be collected and sent to the University of Arizona Cotton Research Center, 4201 East Broadway, Phoenix, Arizona 85040.

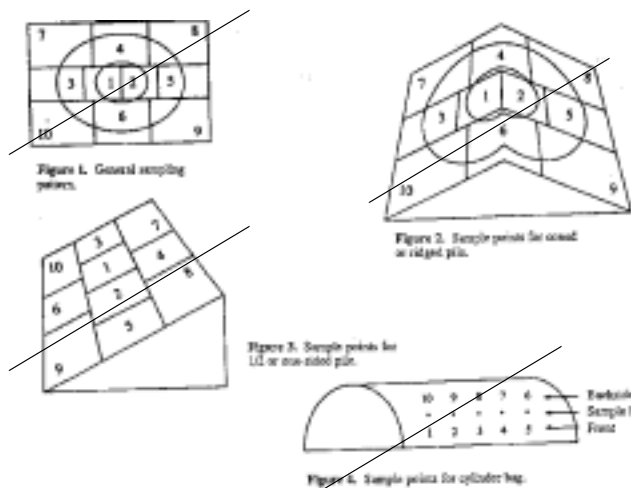
**B. Sample container.** A sample container for non-ammoniated whole cottonseed shall consist of a cloth, burlap or paper bags. The sample container for ammoniated whole cottonseed may be plastic bags if the sample is kept below 60° F. If this temperature cannot be maintained, the container shall be burlap or cloth bags, and stored in a dry, well aeriated location. The sample shall be delivered to the laboratory within twenty-four hours. Samples collected for research shall be delivered to the research center within twenty-four hours. All bags shall be clean and new and shall not be reused.

**C. Sampling equipment.** The following sampling equipment shall be utilized:

1. Scale, graduated in 1/2 lb. increments to at least 31 lbs.
2. Trier or corkscrew, made of strip steel 1/2 inch wide by 5/32 inch thick, bent to form an open cylinder 3 inches in diameter, the pitch of the twist being approximately 2 inches and the screw portion being approximately 56 inches or greater in length.
3. Pneumatic probe sampler. A pneumatic probe sampler which, by way of example includes, but is not limited to, the Probe-A-Vac Pneumatic Grain Sampler.
4. Stream sampler—a container approximately 8 x 5 x 5 1/2 inches attached to a pole long enough to enable the sampler to pass the bucket through falling stream of cottonseed.

**D. Sampling procedure.**

1. All probe samples shall be taken according to the following patterns:



Eight of the 10 probe samples shall penetrate to a minimum depth of 56 inches, or 1/2 the diameter of the pile or the bottom of the load. Not less than 2 of 10 probe samples must reach the center (1/2 the diameter) of a pile or the bottom of the lot being sampled. These two probes shall be taken from:

- a. For Figures 1 and 2 above, from points 4 and 6 or 3 and 5.
  - b. For Figure 3 above, from points 1 and 5 or 2 and 3.
  - c. For Figure 4 above, from points 2 and 7 or 4 and 9. The probe shall be inserted at an angle perpendicular to the face of the lot. A pneumatic probe shall be inserted with an easy up and down motion to prevent clogging.
2. Stream samples may be taken while the material is being discharged, if there is a uniform discharge flow over a set period of time. Sampler shall take not less than ten evenly timed and spaced passes through discharge flow, resulting

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in the proper sample size.

3. After the full gross sample is drawn, the entire sample shall be weighed to the nearest one-half pound. In no case shall the gross sample be reduced in size. If any gross sample does not meet the minimum thirty pound weight, that gross sample shall be discarded and the procedure repeated from the beginning.
4. Truck load lots of cottonseed shall be sampled by taking at least ten probes at uniformly separated locations throughout the load as shown in Figure 1 of this Section.

**R9-17-317. Method of analyzing whole cottonseed Repealed**

**A. Sample preparation:**

1. High moisture ammoniated or other wet samples shall be dried within twenty-four hours of receipt by the laboratory at a temperature not less than 30° C. and not more than 130° C. until they have dried sufficiently to be dehulled. If the sample cannot be dried within twenty-four hours, it shall be maintained at 16° C. or less until it can be dried.
2. The entire sample shall be weighed after drying. This weight and the weight from R9-17-316.D. will be used in Method of reporting (see subsection (C), paragraph (2) of this Section).
3. The entire sample shall be dehulled by passing it through a mill or decorticator to crack at least 99% of hulls.
4. Meats shall be separated from hulls by sieve, shaker, scalper or beater.
5. After separation of hulls and meats, each fraction shall be weighed for use in determining weights in Method of reporting (see subsection (C), paragraph (1) of this Section).
6. The entire sample of meats shall be ground to pass a 20 mesh screen.
7. The ground meats shall be blended in a double cone or twin shell blender or small cement type mixer for a minimum of fifteen minutes.
8. The laboratory sample of approximately 1100 grams shall be drawn by passing ground meats through a divider system such as a Boerner or riffle.
9. An analytical sample of approximately 250 grams shall be drawn by dividing the laboratory sample with a riffle.
10. The retained portion (approximately 850 grams) of the sample shall be refrigerated at a temperature of 16° C. or less.
11. High moisture is defined as 10% moisture by weight.

**B. Sample analysis:**

1. Thin layer chromatography:
  - a. Determination of aflatoxin in cottonseed shall be performed according to Official Methods of Analysis of the Association of Official Analytical Chemists, Section 26.052-26.060 (13th Edition, 1980).
  - b. Confirmation procedures shall be done according to Official Methods of Analysis of the Association of Official Analytical Chemists, Sections 26.076, 26.082 or 26.083 (13th Edition, 1980).
  - c. The following modifications shall be permitted to the above method:
    - i. Precipitation of the extract using 2.5 ml of a solution of 20% aluminum chloride and 15 ml of a 20% solution of zinc acetate.
    - ii. Liquid partitioning of the aflatoxin into chloroform.
    - iii. The use of a tank solvent of formic acid, ethyl acetate and toluene (1 + 3 + 6).
2. Liquid chromatography:
  - a. High performance liquid chromatography may be used as an alternate to thin layer chromatography (see Official Methods of Analysis of the Association of Official Analytical Chemists, Section 26 A09, 13th Edition, 1st Supplement, 1980).
  - b. The use of a fluorometric detector with a silica gel-packed flowcell may be used if it complies with the description in the Journal of the Association of Official Analytical Chemists, Vol. 60 No. 3, 1977 by Thavil, Panalaks and Scott, entitled "Sensitive Silica Gel-Pack Flowcell for Fluorometric Detection of Aflatoxins by High Pressure Liquid Chromatography". A copy of the Journal of the Association of Official Analytical Chemists procedure is on file with the Secretary of State.
  - c. The following modifications are permitted to the above method:
    - i. Precipitation of the extract using 2.5 ml of a solution of 20% aluminum chloride and 15 ml of a 20% solution of zinc acetate.
    - ii. Liquid partitioning of the aflatoxin into chloroform.

**C. Method of reporting:**

1. The following formula shall be used to calculate the amount of aflatoxin in the dried whole seed: Weight of meats divided by the sum of the weight of hulls plus weight of meats times the ppb of aflatoxins b1 and b2 found which is equal to the ppb of aflatoxin in dried whole seed.
2. The results of the aflatoxin tests shall be reported on an "as taken" basis and the following formula shall be used: Weight of the dried seed (as described in subsection (A), paragraph (1) of this Section) divided by the weight of seed when taken (as described in R9-17-316(D)(3)) times the ppb aflatoxin in dried whole seed (calculated in subsection (C), paragraph (1) of this Section) which is equal to the ppb aflatoxin "as taken".
3. Determination of pass-fail samples:
  - a. An initial single sample shall be run and if the results are 20 ppb or less for dairy animals, or 100 ppb or less for non-dairy animals it shall be considered as a passed sample.

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- b. If the results of a single sample are greater than 20 ppb or 100 ppb, on a 20 ppb or 100 ppb level respectively, the sample shall be rerun in duplicate.
- e. If the average of all three tests of a sample run for a 20 ppb level, is over 20 ppb, it shall be described as a failed sample. If the average of all three tests of a sample run for a 100 ppb level, is over 100 ppb, it shall be described as a failed sample.

**R9-17-318. Methods of ammoniation Repealed**

The Otis Lough Process for Aflatoxin Reduction (OLPAR) method is authorized by the Director for treatment of cottonseed. Any other method must be approved by the Director to be safe and effective prior to its use. Any person may apply to the Director for approval of an alternate method of ammoniation. The Director shall establish an advisory committee to make recommendations about the safety and effectiveness of ammoniation processes other than the Otis Lough Process for Aflatoxin Reduction method. The committee shall be comprised of a public health official designated by the Director, the Dairy Commissioner or his designee, the State Chemist or his designee, a member of the College of Agriculture of the University of Arizona, one person nominated by the Commission of Agriculture and Horticulture, and one representative each from the feed, cattle, cotton, and dairy industries. The Director will approve or disapprove any proposed alternate method based on his determination of its safety and effectiveness. A copy of the Otis Lough Process for Aflatoxin Reduction is on file with the Secretary of State.

**R9-17-319. Labeling requirements Repealed**

Prior to its final use as a feed or feed ingredient, all whole cottonseed, except cottonseed that has been ammoniated on the premises of a dairy or feed lot and is not intended for further distribution, shall be accompanied by an invoice which clearly states, as applicable:

- 1. This cottonseed contains not more than 20 parts per billion (ppb) or aflatoxin and may be fed to any animal; or
- 2. For distribution and use only in Arizona—non dairy animal feed. This cottonseed contains not more than 100 parts per billion (ppb) of aflatoxin and may be fed to any animals except those whose milk is intended for human consumption; or
- 3. This cottonseed contains more than 100 parts per billion (ppb) aflatoxin and may not be fed to any animals.

**R9-17-320. Record requirements Repealed**

~~A. Any cottonseed distributor who is required to test for aflatoxin under these regulations shall keep records to be made available to the Department and the State Chemist for a period of three years which shall contain the following information:~~

- 1. Name or description of product.
- 2. Identity of lot sampled and analytical results reported for aflatoxin content.
- 3. Weight of product.
- 4. Name, mailing address, and location of person to whom the product was distributed.
- 5. Name and address of person invoiced.
- 6. Date of distribution.

~~B. Any person ammoniating cottonseed shall file with the Department a copy of the written results of the aflatoxin content as determined by an approved or certified laboratory prior to any sale, transfer, distribution, mixing, processing, or feeding of the ammoniated cottonseed.~~

**R9-17-321. Enforcement action Repealed**

~~A. Any cottonseed or cottonseed product which is not intended for ammoniation or has been ammoniated and exceeds the enforcement levels established in R9-17-313 of this Article shall be deemed adulterated and may be removed from distribution by embargo.~~

~~B. Any cottonseed or cottonseed product deemed to be adulterated with aflatoxin by the Department or the State Chemist shall not be blended with any other feed or feed ingredient. Any cottonseed or cottonseed product containing aflatoxin above 20 parts per billion shall not be blended with any other feed or feed ingredient to provide feed for dairy animals. Any cottonseed or cottonseed product containing aflatoxin above 100 parts per billion shall not be blended with any other feed or feed ingredient to provide feed for any animal.~~