

Steve Troxler Commissioner

North Carolina Department of Agriculture and Consumer Services Food and Drug Protection Division

Anita MacMullan
Director

September 21, 2018

LETTER TO INDUSTRY REGARDING FLOOD-IMPACTED CROPS AND COMMODITIES

The North Carolina Department of Agriculture & Consumer Services recognizes the significant impact to agribusiness due to flooding caused by Hurricane Florence. Many farms have crops in the field and/or commodities in storage that have been impacted by flood waters and we would like to offer the following information.

In order to properly assess how your farm may have been impacted, it is important to understand the difference between flood waters and pooled waters. Flood water can be distinguished from pooled water, as described below in guidance from US Food and Drug Administration (FDA):

"Flooding is the flowing or overflowing of a field with water outside a grower's control. Pooled water (e.g., after rainfall) that is not reasonably likely to cause contamination of the edible portions of fresh produce is not considered flooding."

FDA also offers the following guidance on crops and commodities exposed to flood waters:

"If the edible portion of a crop is exposed to flood waters, it is considered adulterated... and should not enter human food channels.

There is no practical method of reconditioning the edible portion of a crop that will provide a reasonable assurance of human food safety. Therefore, the FDA recommends that these crops be disposed of in a manner that ensures they are kept separate from crops that have not been flood damaged to avoid adulterating "clean" crops.

This applies to all food crops including:

- Surface crops such as leafy greens, tomatoes and corn;
- Underground crops such as peanuts and sweet potatoes;
- Crops with a hard-outer skin such as pumpkin, watermelon and winter squash; and
- Commodities such as grains, nuts, corn and similar products stored in bulk.

FDA has also provided the following guidance on the use of these crops and commodities in animal feed:

"The FDA reminds harvesters that crops harvested from flooded fields are often unacceptable because of contamination. Flood waters, which are different from pooled rain water, may contain sewage, pathogenic organisms, pesticides, chemical wastes, or other toxic substances. Mold growth is another serious concern for flood impacted crops intended for use in animal food. Some molds produce mycotoxins, which are toxic to certain animals and people.

Please take caution if you harvest crops from flood-impacted fields to ensure that they are kept separate from commodities that have not been exposed to flood waters to avoid adulterating the clean commodities.

In an effort to assist farmers in recovering from flood-related impacts, NCDA&CS is collaborating with N. C. State Extension in the College of Agriculture and Life Sciences (CALS) at North Carolina State University to help farmers to determine safe uses for flood-impacted crops and commodities. While these products cannot be used for human food, FDA has established a process by which a request can be submitted to divert these products to animal feed provided that they pass a testing protocol.

Before crops or commodities contacted by flood waters can be used for animal feed, the farm must develop a diversion request detailing the process to assure the safety of diverted crops or commodities. Requests should be submitted to the NCDA&CS Food and Drug Protection Division. We encourage you to not initiate any diversion actions until your request has been approved. Please contact your local Cooperative Extension Agent for further information and guidance.

To assist those submitting diversion requests requiring sample testing, NCDA&CS will provide all testing at no cost to the farm. Please know that we are committed to helping in this recovery effort and appreciate your attention to the information provided in this letter.

Sincerely,

/s

Anita MacMullan, Director NCDA&CS, Food & Drug Protection Division

References:

CPG 675.100 Diversion of Contaminated Food for Animal Use

CPG 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use

CPG 675.300 Moisture Damaged Grain

FDA: Resources for Animal Food Producers in Flooded Areas

NCSU Cooperative Extension

cc:

Joe Reardon, NCDA&CS, Assistant Commissioner Sandy Stewart, NCDA&CS, Assistant Commissioner George Ferguson, NCDA&CS, Feed Administrator Anita MacMullan, NCDA&CS, Food Administrator

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N.C. Department of Agriculture & Consumer Services



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Flooded crops cannot be used for human food

NCDA&CS, NCSU to help farms divert crops to animal feed with proper testing

RALEIGH – Farmers whose crops were flooded by Hurricane Florence face not only the prospect of lower yields and loss of quality, but also the reality that those crops cannot be used for human food.

Crops and commodities exposed to floodwaters are considered adulterated by the U.S. Food and Drug Administration and cannot enter human food channels. They also cannot be used for animal feed unless they pass a testing protocol.

"Floodwater may contain sewage, harmful organisms, pesticides, chemical wastes or other substances," said Agriculture Commissioner Steve Troxler. "Also, wet foods may grow mold, which can produce toxins that can harm humans and animals."

The FDA guidance applies to all food crops, including:

- Surface crops such as leafy greens, tomatoes and corn;
- Underground crops such as peanuts and sweet potatoes;
- Crops with a hard outer skin, such as watermelon and winter squash; and
- Commodities such as grains, nuts, corn and similar products stored in bulk.

The FDA guidance applies to crops that were flooded with water from rivers, creeks or streams. Pooled water, or rainwater that has collected in the field, is different from floodwater and is not likely to contaminate field crops.

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The N.C. Department of Agriculture and Consumer Services is collaborating with N.C. State Extension in the College of Agriculture and Life Sciences at N.C. State University to help farmers determine safe uses for crops affected by Florence's flood waters.

Under an FDA process, farmers can submit a request to divert flooded crops or commodities to animal feed as long as they pass a testing protocol.

Before crops or commodities contacted by floodwaters can be used for animal feed, the farm must develop a diversion request detailing the process to assure the safety of the crop or commodity. Requests should be submitted to the NCDA&CS Food and Drug Protection Division.

To assist farmers submitting diversion requests, the department will provide testing at no cost to the farm. "This testing process can help farmers find alternative uses for their crops and commodities while maintaining confidence in the safety of our food supply," Troxler said. "The department and the university are committed to helping in this recovery effort. We encourage farmers not to initiate any diversion actions until their request has been approved."

Farmers should contact their local Cooperative Extension agents for further information and guidance. Contact information for local offices can be found at https://www.ces.ncsu.edu/

Crops Harvested from Flooded Fields Intended for Animal Food: Questions and Answers

1. Can I use crops that have been harvested from fields impacted by flooding for animal food?

Each situation must be considered on a case-by-case basis looking at a variety of factors such as the extent of flooding and the type of crop. In certain circumstances, crops harvested from fields that have been impacted by flood waters can be used for animal food, but usually these crops are unacceptable because of contamination. Flood waters from storms often contain sewage, pathogenic organisms, pesticides, chemical wastes, or other toxic substances. Mold growth is another serious concern for flood impacted crops intended for use in animal food. Some molds produce mycotoxins, which are toxic to certain animals and people. People who eat food products from animals that ate the mold may also suffer health effects.

2. How can I determine whether a crop harvested from flooded fields can be salvaged for animal food?

Before being used in animal food, crops exposed to flooding should, at a minimum, be tested for mold, bacteria, chemicals, and heavy metals contamination. Depending on the test results, the crop may be acceptable for animal food use or it may be possible to salvage the crop by reconditioning the crop. Reconditioning is a broad term that covers certain types of processing.

3. What type of testing should I do?

Specific testing should include:

- Mycotoxins, including aflatoxin, fumonisin, vomitoxin, zearalonone, and ochratoxin. Aflatoxins, fumonisins, and vomitoxins should not be present above levels found in FDA guidance. (Please see "For More Information" for the relevant guidance documents.)
- Heavy metals, specifically cadmium, mercury, and lead.
- Certain pathogenic bacteria and their toxins, especially Salmonella, E. coli 0157:H7, and Clostridium perfringens and botulinum.
- Chemicals, such as pesticides, with particular emphasis on organophosphate and chlorinated hydrocarbon pesticides.

As information becomes available regarding conditions near flooded crops, additional testing (for example, for a specific chemical, industrial or environmental contaminant) may be appropriate for producers to consider to ensure the safety of their products for use in animal food.

4. Can I salvage an adulterated crop into food that is acceptable for animal consumption?

The FDA will work with producers to consider requests to recondition an adulterated crop into animal food on a case-by-case basis. Those requests should be directed to the <u>public affairs specialist</u> (/AboutFDA/ContactFDA/ucm2005604.htm) located at the closest FDA field office.

Additionally, your state's Department of Agriculture may have state-specific requirements regarding any attempt to clean, process, test, and sell/use these crops in animal food. FDA will also continue working with USDA, state partners, and associations on broader questions that may arise about crops for animal food.

5. What information do I need to provide to the FDA District Office if I have a reconditioning request?

FDA's compliance guide (CPG 675.200

(https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074694.htm)) provides a step-by-step process for reconditioning requests.

For more information:

- <u>General Information on Evaluating the Safety of Food and Animal Food Crops Exposed to Flood Waters</u> (/Food/RecallsOutbreaksEmergencies/Emergencies/ucm112723.htm#general)
- <u>CPG Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds</u>
 (https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074703.htm)
- <u>Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds Final Guidance</u> (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm109231.htm)
- Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed

 (https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120184.htm)
- <u>CPG Sec. 575.100 Pesticide Residues in Food and Feed Enforcement Criteria</u> (<u>https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm123236.htm</u>)
- <u>CPG 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use</u>
 (https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074694.htm)

More in Resources for You
(/AnimalVeterinary/ResourcesforYou/default.htm)

For Industry (/AnimalVeterinary/ResourcesforYou/ucm508946.htm)

For Veterinarians (/AnimalVeterinary/ResourcesforYou/ucm214771.htm)

Publicaciones en Español del Centro de Medicina Veterinaria (CVM) (/AnimalVeterinary/ResourcesforYou/ucm135578.htm)

Animal Health Literacy (/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/default.htm)

CPG Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use

BACKGROUND:

In the past, FDA has authorized the salvage of human or animal food considered to be adulterated for its intended use by diverting that food to an acceptable animal feed use. Most of these instances have involved, but have not been limited to, the interpretation of section 402(a)(3) and (4) of the Federal Food, Drug, and Cosmetic Act to allow different standards for foods intended for human use vs. food intended for animal use, e.g., defect action levels for filth in a food intended for human use but not for the same food intended for animal feed use. Diversion requests, however, have also included USDA detained meat and poultry products contaminated with drug or other chemical residues, as well as food and feed under voluntary industry recall or quarantine that may be considered adulterated for their intended use(s). To assist in handling certain specific types of diversion requests, the Agency has developed Compliance Policy Guide 7126.05. [Diversion (after heat treatment) of rodent, roach, or bird contaminated food for animal use.] No single set of criteria, however, can be prepared to cover diversion requests in all possible situations. This guide provides procedures for submitting requests to the agency for authorization to divert adulterated foods for which no criteria have been established.

To facilitate handling, requests for diversion should be submitted in writing to the appropriate FDA District Office. The District will transmit the requests to Division of Compliance, *Center for* Veterinary Medicine, HFV-230. Each request should include the following information.

- a. Name and address of the requestor, and the name of the owner of the subject articles.
- b. The precise physical location of the product.
- c. A precise identification of the product (including lot numbers, amount of articles in each lot, etc.).
- d. The reason(s) the articles are considered adulterated for their originally intended food uses.
- e. The levels, on a lot-by-lot basis, of any adulterant; all analytical data regarding such levels of an adulterant, and the methodology used in determining the levels of the adulterant.
- f. The cause of adulteration if known.
- g. The name and address of the proposed consignee.
- h. The reconditioning or denaturing procedure, if any.
- i. The proposed labeling as well as written information or instruction to accompany the product.
- j. All special restriction information, e.g., the product may be under detention by the United States Department of Agriculture and therefore require an official correspondence between agencies regarding approval of the diversion.

- k. The intended use of the diverted food. This will include complete description of the class of animals involved, whether they are food or non-food producing, the part of the country in which the food will be used, and all assurances that have been secured that indeed the food will be used as agreed.
- I. All available information from the firm proposing the diversion on the safety of the adulterant for the intended animal use and, where appropriate, for the consumption of the edible products of the animals.
- m. Information from the firm proposing the diversion, sufficient for a determination whether disposition of such article, including packaging material, will result in the release of a toxic substance into the environment [See 21 CFR 25.1(f)(9) and (g) and proposed 21 CFR 25.24 (d)(4). An Environmental Impact Analysis Report under 21 CFR 25.1(j) or an Environmental Assessment under proposed 21 CFR 25.31 (44 FR 71747) is required if the proposed disposition fails to meet the above criterion for exclusion].

POLICY:

Diversion requests will be handled on an ad hoc basis. The *Center* will consider the requests for diversion of food considered adulterated for human use in all situations where the diverted food will be acceptable for its intended animal food use. Such situations may include:

- a. Pesticide contamination in excess of the permitted tolerance or action level.
- b. Pesticide contamination where the pesticide involved is unapproved for use on a food or feed commodity.
- c. Contamination by industrial chemicals.
- d. Contamination by natural toxicants.
- e. Contamination by filth.
- f. Microbiological contamination.
- g. Over tolerance or unpermitted drug residues.

Some general policy issues to be considered while evaluating proposals for diversion of food considered to be adulterated to animal feed use are:

- a. A seizure action and a voluntary request for diversion are two separate processes. A seizure action and a request for diversion cannot legally be processed simultaneously. No diversion request submitted under this guideline will be considered once a seizure recommendation has been forwarded to headquarters. If a seizure recommendation is withdrawn and if the requirements of this policy are met, a diversion request may be entertained. Naturally, a diversion-based means of reconditioning seized articles may be an appropriate means of meeting the requirements of a court-ordered consent decree arising from a seizure.
- b. Diversion may only be allowed where there is a legally enforceable assurance that the subject foods will not be placed into interstate commerce before the request is approved and the products appropriately diverted (i.e., meats not under USDA detention but nevertheless containing illegal residues would be appropriate for seizure or state embargo but not for diversion if the meats were already shipped in interstate commerce). Accordingly, this policy will primarily apply to embargoed goods or bonded goods to assure adequate control of the adulterated goods.

- c. Where diversion is legally appropriate, data are required to demonstrate that the diverted use poses no safety hazards to the animals consuming the diverted food and to the public who may be exposed to edible tissues of such animals.
- d. The diversion policy does not sanction or authorize the blending of the adulterated foods, i.e., the policy does not authorize the diluting of an adulterated product to below a tolerance or action level.

Material between asterisks is new or revised

Issued: 11/1/81 Revised: 3/95

More in Compliance Policy Guides

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

Foreword: Compliance Policy Guides (CPGs)

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm)

Chapter 1 - General (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116280.htm)

Chapter 2 - Biologics

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116336.htm)

Chapter 3 - Devices (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116801.htm)

Chapter 4 - Human Drugs

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119572.htm)

Chapter 5 - Food, Colors, and Cosmetics

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm)

Chapter 6 - Veterinary Medicine

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm117042.htm)



Steven W. Troxler Commissioner

North Carolina Department of Agriculture and Consumer Services

Anita MacMullan Director

Food and Drug Protection Division

The NCDA&CS Animal Feed Program is providing an updated list of salvage grain buyers. This list is not a recommendation or endorsement of these specific buyers and is not all inclusive, but rather should act as a guide in finding a market for damaged/salvage grain. Producers should contact the buyer before delivering.

2018 Damaged/Salvage Grain Buyers

Company	Telephone	Email/Web Address	Address/State	Comment	
Callan Salvage &			Eads (Memphis),	International	
Appraisal	(800) 238-2632	www.callansalvage.com	TN	Company	
				POC Jim or Penny;	
Jim Newsom			PO Box 450 Glen	Daily Service to NC &	
Trucking, Inc.	(662) 839-4613	intdumps@msdeltawireless.com	Allan, MS 38744	SC	
			8545 Main St.		
Lackawanna			Clarence, NY	POC Scott	
Products	(716) 633-1940	swesolowski@lpctrade.com	14031	Wesolowski	
			12732 S. Pflumm	POC Greg Marsh,	
			Rd. Olathe, KS	Southeast Region	
MGM Marketing	(800) 214-7788	gmarsh@teammgm.com	66062	Purchasing Manager	
Pruess Elevator,			717 Union Ave		
Inc.	(800)828-6642	info@pruesselevator.com	Lowden, IA 52255	POC Todd	

REQUEST FOR DIVERSION OF ADULTERATED FOOD TO ACCEPTABLE ANIMAL FEED USE

STEP 1 OF 6: Submit Initial Diversion Request and Sampling Plan

THE FOLLOWING INFORMATION MUST BE SUBMITTED TO THE NCDA&CS, ANIMAL FEED PROGRAM FOR REVIEW AND ACCEPTANCE PRIOR TO SUBMISSION OF SAMPLES FOR TESTING.

1.	Name of the requestor: Address of the requestor: County: Phone: Alt Phone: Email: Name of the owner of the subject articles (If requestor, then "same"): Name of Extension Agent or other advisor helping to complete the form: Agent/Advisor email:
	Agent/Advisor phone:
	Agent/Advisor cell:
2.	The precise physical location of the product:
3.	A precise identification of the product (including lot numbers, amount of articles in each lot, value, etc.):
4.	The reason(s) the articles are considered adulterated for their originally intended food uses:
5.	The cause of adulteration if known:
6.	Potential/proposed future use and/or consignee:
7.	Please provide a detailed plan for sample collection to include diagrams, procedures, sample amount sample number collected, and sample location. For additional assistance with developing a sampling plan, please contact the Animal Feed Program at (919) 733-7366.

PLEASE SUBMIT REQUESTS VIA EMAIL TO:

George Ferguson, Feed Administrator NCDA&CS, Animal Feed Program George.ferguson@ncagr.gov

Phone: (919) 733-7366; FAX: (919) 733-6801

STEP 2 OF 6: NCDA Review for Acceptance & Notification

THE INITIAL DIVERSION REQUEST AND SAMPLING PLAN WILL BE REVIEWED BY THE NCDA&CS ANIMAL FEED PROGRAM. UPON COMPLETION OF THE REVIEW, THE REQUESTOR AND ANY IDENTIFIED AGENT/ADVISOR WILL BE NOTIFIED OF THE SUBMISSIONS ACCEPTANCE OR REJECTION. THE DIVERSION REQUEST AND SAMPLING PLAN MUST BE ACCEPTED BEFORE CONTINUING TO THE NEXT STEP.

STEP 3 OF 6: Submission of Product Samples for Analysis

UPON RECEVING NOTIFICATION OF THE SUBMISSIONS ACCEPTANCE, THE REQUESTOR SHALL COLLECT ALL SAMPLES IN ACCORDANCE WITH THE ACCEPTED SAMPLING PLAN AND SUBMIT THEM TO THE NCDA&CS CONSTABLE LABORATORY FOR ANALYSIS. SAMPLE ANALYSIS WILL BE CONDUCTED AND RESULTS REPORTED TO THE REQUESTOR AT NO CHARGE.

NCDA&CS Food & Drug Protection Division
Attention: Animal Feed Program, Diversion Request Samples
US Postal Service: 1070 Mail Service Center, Raleigh NC 27699-1070
UPS/FedEx: 4000 Reedy Creek Road, Raleigh NC 27607-6465

STEP 4 OF 6: Analysis of Samples

SAMPLE ANALYSIS WILL BE CONDUCTED AND/OR DIRECTED BY THE NCDA&CS CONSTABLE LABORATORY.

Sample analysis to be conducted by the laboratory:

- 1. The levels, on a lot-by-lot basis, of any adulterant; all analytical data regarding such levels of an adulterant, and the methodology used in determining the levels of the adulterant. As a minimum, the material would need to be tested for the following:
 - a. Mycotoxins to include at least aflatoxin, fumonisin, vomitoxin, zearalonone, and ochratoxin. [Mycotoxins should not be present above guidance levels found on FDA's website.]
 - b. Heavy metals, with emphasis on cadmium, mercury, and lead. [Maximum acceptable levels for these metals in complete animal feeds are available in the NAS/NRC "Mineral Tolerance of Domestic Animals".]
 - c. Presence of certain pathogenic bacteria and their toxins, especially Salmonella, E. coli 0157:H7, and Clostridium perfringens and botulinum. Heat treatment should have been sufficient to destroy pathogenic organisms.
 - d. Pesticide screen, with particular emphasis on organophosphate and chlorinated hydrocarbon pesticides. [Information on multi-residue pesticide test screens and permitted pesticide levels on food and feed is available on FDA's website.]
 - e. Presence of PCBs [polychlorinated biphenyls] consistent with the levels found in Title 21, Code of Federal Regulations, Part 500.45.

Additional testing of specific industrial or environmental contaminants may be required as information on the industries and facilities located near crops in affected areas becomes available.

FINAL SAMPLE ANALYSIS RESULTS WILL BE SENT TO THE REQUESTOR IN ORDER TO COMPLETE STEP 5, AS APPLICABLE.

Step 5 of 6: Submission of Proposal

UPON RECEIPT OF FINAL SAMPLE ANALYSIS, THE REQUESTOR SHALL COMPLETE AND SUBMIT THE FOLLOWING INFORMATION TO THE NCDA&CS ANIMAL FEED PROGRAM FOR FINAL DIVERSION REQUEST REVIEW.

To be completed by the requestor:

1.	The name of the proposed	consi	ignee ((buyer)
	Address of the proposed c	onsigi	nee:	

County:

State:

Phone Number:

Email:

- 2. The reconditioning or denaturing procedure, if any:
- 3. The proposed labeling as well as the written information or instruction to accompany the product:
- 4. All special restriction information, e.g., the product may be under detention by the United States Department of Agriculture and therefore require an official correspondence between agencies regarding approval of the diversion:
- 5. The intended use of the diverted food/feed. This will include complete description of the class of animals involved, whether they are food or non-food producing, the part of the country in which the food will be used, and all assurances that have been secured that indeed the food will be used as agreed:
- 6. All available information from the firm proposing the diversion on the safety of the adulterant for the intended animal use and, where appropriate, for the consumption of the edible products of the animals:

PLEASE EMAIL SUBMISSION OF PROPOSAL TO:

George Ferguson, Feed Administrator NCDA&CS, Animal Feed Program George.ferguson@ncagr.gov

Phone: (919) 733-7366; FAX: (919) 733-6801

Step 6 of 6: Approval and Notice of Release.

UPON COMPLETION OF THE FINAL REVIEW, THE REQUESOTR WILL BE NOTIFIED OF THEIR APPROVAL OR DENIAL. IF APPROVED, THE REQUESTOR WILL RECEIVE A NOTICE OF "DEEMED SAFE FOR USE IN ANIMAL FEED" THAT CONTAINS ANY AGREED UPON USE RESTRICTIONS AND/OR LIMITS, IN ORDER TO ASSIST THE REQUESTOR IN FINAL DISTRIBUTION AND/OR USE OF THE PRODUCT.