

CHAPTER 07 - MOLECULAR BIOLOGY AND NATURAL TOXINS

SUBJECT: MYCOTOXINS IN DOMESTIC AND IMPORTED FOODS FY 15/16	IMPLEMENTATION DATE Upon Receipt
	COMPLETION DATE 09/30/16 or until revised
DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
See Attachment A	07001 All domestic and import sample collections and analysis

FIELD Reporting Requirements

1. Reporting under PAC 07001 is required for all domestic and imported **food** samples collected and analyzed for aflatoxin, patulin, deoxynivalenol, fumonisin, or ochratoxin A contamination even if samples were collected during operations conducted under other compliance programs.
2. The analyzing district will report analytical results into FACTS using PAF = "MYC" and ensure that the correct Mycotoxin Code **for the mycotoxins analyzed for** is selected from the FACTS drop-down box.
3. When entering information into FACTS:
 - use operation code 31 to report domestic sample collection and operation code 41 to report domestic sample analysis.
 - use operation code 33 to report import sample collection and operation code 43 to report import sample analysis.
4. Refer to Part IV for sample classification instructions.

PART I - BACKGROUND**A. General**

Mycotoxins are toxic metabolites produced by certain fungi that can infect and proliferate on various agricultural commodities in the field and/or during storage. The occurrence of these toxins on grains, nuts and other commodities susceptible to mold infestation is influenced by environmental factors such as temperature, humidity, and extent of rainfall during the pre-harvesting, harvesting, and post-harvesting periods. Mycotoxins may exhibit various toxicological manifestations; some are teratogenic, mutagenic and /or carcinogenic in susceptible animal species and are associated with various diseases in domestic animals, livestock, and humans in many parts of the world.

The occurrence of mycotoxins in foods and feeds is not entirely avoidable; therefore small amounts of these toxins may be legally permitted in foods and feeds. Strategies used by the Food and Drug Administration (FDA) to minimize mycotoxins in the United States (U.S.) food supply include establishing guidelines (e.g., limits established in compliance policy guides (CPG), and monitoring the food supply by collecting and analyzing domestic and import foods. The data obtained over the years from FDA's monitoring programs are used to provide: (a) estimates of the incidence and levels of contamination by various mycotoxins in affected areas in the country, (b) dietary exposure data (estimates) for use in making risk assessments for specific mycotoxins, (c) background data for use in considering the establishment of guidelines for specific mycotoxins, (d) an estimate of the economic impact of the enforcement of regulatory guidelines on foods and feeds during a given crop year, (e) information needed to prepare answers to questions including congressional inquiries, and (f) basic information needed to support the position and recommendations of U.S. delegates participating in international meetings. The monitoring data also serve as a database describing the background distribution of various mycotoxins in domestic grains and their products in the U.S. as a function of geographic area and environmental conditions.

B. Specific Mycotoxins to be included in this program

1. **Aflatoxins**, metabolic products of the molds *Aspergillus flavus* and *A. parasiticus*, may occur in food as a result of mold growth in a number of susceptible commodities, including peanuts and corn. Tree nuts and some small grains are also susceptible but less prone to contamination with aflatoxins. Aflatoxins are known carcinogens to susceptible laboratory animals and presumably to humans; therefore, the presence of aflatoxins in foods should be restricted to the lowest practical levels attainable using modern processing techniques.

The current CPG limits for aflatoxins can be found in the appropriate section of the CPG. See Part V for CPG references. Historically, aflatoxin levels in peanuts and corn have been highest in the Southeastern states. Corn from anywhere in the U.S. may be affected, however, depending on the growth, harvesting and storage conditions involved.

2. **Patulin** is a toxic substance produced by *Penicillium*, *Aspergillus*, and *Byssochyllum* molds that may grow on apples and may be present if rotten, moldy or damaged apples are used to make apple juice.

Patulin is not destroyed by heat processing, and can occur at high levels in apple juice, including pasteurized apple juice, therefore both pasteurized and non-pasteurized single strength juice and concentrated juices are to be collected. Animal feeding studies have demonstrated that high levels of patulin in apple juice could pose a health risk if the juice is consumed over an extended period of time. In 2001, FDA established a limit for patulin in apple juice and in the apple juice component of a food that contains apple juice as an ingredient. The published action level for patulin is in CPG Section 510.150. See Part V for CPG references. This limit for patulin at or above 50 ppb is determined on (a) single strength apple juice, (b) reconstituted single strength apple juice (if the food is an apple juice concentrate), or (c) the single strength apple juice component of the food (if the food contains apple juice as an ingredient). Single strength juice is 100 percent juice that is unconcentrated (see 21 CFR 101.30(h)). Under the juice Hazard Analysis Critical Control Point (HACCP) (21 CFR part 120) some apple juice processors may need to establish control measures such as using only tree picked fruit, and culling their apples to be used for juice production to remove rotten and damaged fruit.

3. **Deoxynivalenol (DON)**, commonly called vomitoxin, is a natural toxin produced by several molds of the genus *Fusarium*, especially *F. graminearum*, which is a common contaminant of several grains, including wheat, corn, barley, and rye. DON has been associated with a number of adverse health effects in humans and animals. Several adverse weather related DON contamination episodes in the U.S. caused the FDA to issue Advisory levels for food (wheat) and feed in 1982 and updated levels in 1993. A review of the scientific literature since 1993 revealed that higher levels of DON in feed for cattle would not appear to present an animal or public health hazard, therefore, a revised Advisory level was issued in 2010. (See Part VI, Additional References, #4.) FDA is continuing to study the scope and toxicological significance of the DON problem to determine if further regulatory measures are needed to control DON in food and feed products.
4. **Fumonisin** (Fumonisin FB₁, Fumonisin FB₂, and Fumonisin FB₃) are natural toxins produced by *Fusarium verticillioides* (previously known as *F. moniliforme*), and other *Fusarium* species; these molds are common natural contaminants of corn. Fumonisin have been linked to fatalities in horses and swine. Recent studies have demonstrated the presence of fumonisins in human foods, including corn meal and breakfast cereals. Epidemiological investigations demonstrating a possible association of *F. verticillioides* with esophageal cancer and recent animal studies indicating the carcinogenicity of fumonisin FB₁ have highlighted the need to ensure that foods do not contain excessive amounts of fumonisins. Dry milling of whole corn kernels generally results in the production of fractions called bran, flaking grits, grits, meal, and flour. Because fumonisins are concentrated in the germ and the hull of the whole corn kernel, dry milling results in fractions with different concentrations of fumonisins. For example, dry milled fractions (except for the bran fraction) obtained from degermed corn contain lower levels of fumonisins than dry milled fractions obtained from non-degermed or partially-degermed corn. Industry information indicates that dry milling results in fumonisin-containing fractions in descending order of highest to lowest fumonisin levels: bran, flour, meal, grits, and flaking grits.

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5. **Ochratoxin A** is a naturally occurring nephrotoxic fungal metabolite produced by certain species of the genera *Aspergillus* and *Penicillium*. It is mainly a contaminant of cereals (corn, barley, wheat and oats), and has been found in edible animal tissues as well as in human blood sera and milk. Studies indicate that this toxin is carcinogenic in mice and rats. It is not completely destroyed during the processing and cooking of food, therefore the implication of risk to human health and safety must be considered. FDA needs up-to-date information on the incidence and levels of occurrence of this toxin in the U.S. for use in considering any necessary regulatory control measures for this substance.

PART II - IMPLEMENTATION

OBJECTIVES

To collect and analyze domestic and import samples of various food products to determine the occurrence and levels of aflatoxins, patulin, fumonisins, deoxynivalenol, and ochratoxin A;

To collect monitoring and incidence data to support establishment of future limits for fumonisins, deoxynivalenol, and ochratoxin A in foods.

PROGRAM MANAGEMENT INSTRUCTIONS

Federal/State Relations

State officials are valuable sources of information on current and potential aflatoxin problems in foods. In the past, a number of states have participated in an aflatoxin data exchange program with FDA. Districts should encourage state participation via State Liaisons in this data exchange program and should coordinate aflatoxin program activities with State officials to prevent duplication of efforts in both food and feed sampling. Information on this data exchange program can be obtained from the Office of Partnerships (formerly the Division of Federal-State Relations), HFC-150, (301) 796-5390; OP-ORA@fda.hhs.gov

USDA provides FDA with copies of certificates of analysis on lots of raw peanuts with an aflatoxin content over 25 ppb. In addition, the National Advisory Council member companies will provide FDA personnel analytical results on request. I/S shipment of lots with aflatoxin levels above 25 ppb are allowed when the consignee has adequate facilities to remove contaminated peanuts.

<http://inside.fda.gov:9003/ProgramsInitiatives/FieldOperations/Federal-StateRelations/default.htm>

PART III - INSPECTIONAL

A. Inspectional

This program does not direct inspections. However, districts will conduct follow-up inspections if levels of aflatoxin that exceed CPG limits are detected in compliance (not surveillance) samples.

Inspectional instructions for mycotoxin inspections are contained in Section 8 of the Guide to Inspections of Manufacturers of Miscellaneous Food Products Volume II. This guide is available online at:

<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074988.htm>

B. Sampling

General Instructions:

NOTE: PRODUCT SAMPLE SIZES

(Includes 702(b) portion each sample unit, contains product for the reserve portion, no duplicate subs are necessary)

<http://www.fda.gov/ICECI/Inspections/IOM/ucm127685.htm>.

Refer to the current ORA workplan and to Attachment A of this compliance program for all sample obligations and acceptable products. The numbers of samples to be collected and the products to sample for each mycotoxin are located in the **Sample Collection Operations Planning Effort** (SCOPE) (<http://inside.fda.gov:9003/programsinitiatives/food/fieldprograms/ucm272937.htm>) sent to all districts.

It is imperative that the products specified in Attachment A, for each analyte, be collected and analyzed as a unique sample; therefore, a sample from a single lot of a product is **not** to be collected for multiple mycotoxin analyses. Specifically, a product collected for aflatoxin, fumonisin or ochratoxin A analysis is not to be analyzed for more than one mycotoxin. In the past, with CFSAN's concurrence, samples were bundled, i.e., a single sample was collected for multiple mycotoxin analysis. This approach did not yield the requested analyte/product combinations. The collection report must explicitly state the specific mycotoxin that is being tested for so that the lab does not need to contact the investigator before beginning the analysis.

Mycotoxin contamination can occur in localized pockets at high concentrations in foods such as unprocessed grains and nuts. For sampling bulk products, representative samples should be obtained by using a trier or other device that will provide representative portions from all sections of the container sampled. Commodities such as fruit juice, other fluid items, and mixed preparations (paste, spreads, butters) are generally homogenous and do not require any special devices for sampling.

Collect subsamples randomly so as to be representative of the lot.

Sample only the foods listed in Attachment A. For subsample/sample size follow instructions in this compliance program. If none are provided, follow the instructions in the IOM Chapter 4, Sample Schedule 6, Aflatoxin Sample Sizes

<http://www.fda.gov/ICECI/Inspections/IOM/ucm127685.htm>

1. Aflatoxin

- a. Sample only the foods listed in Attachment A, Section 1.

If the District wishes to sample another product, **BEFORE** sampling consult the Domestic and Import Mycotoxin Monitor, Kaniz Shireen, at (240) 402-2775 or via email at Kaniz.Shireen@fda.hhs.gov.

If the additional product collection is pre-authorized by CFSAN, the investigator must note this in the remarks section of the Collection Report. Otherwise, the laboratory will need to consult with CFSAN prior to beginning analyses.

If not referenced below, additional sample sizes are referenced in the Investigations Operations Manual (IOM), Chapter 4, Sample Schedule 6 (<http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123507.pdf>). IOM Sample Schedule Chart 6 provides instructions on sample sizes for surveillance and follow-up sampling for aflatoxins. An initial sample (surveillance) is a sample collected in reduced amounts (to lower costs) to determine if there is an aflatoxin problem with the product. This sample is not large enough to be considered representative of the lot, and, therefore a follow-up sample must be collected for compliance purposes. See Sample Reporting section below for additional instructions.

Do not collect more than 2 samples of any specific commodity at any firm, unless there is a need to collect more samples of that commodity for compliance purposes.

- b. Corn and Corn Products

Do not sample unpopped popcorn for aflatoxin unless there is reason to believe that aflatoxin contamination may be present due to late harvest or adverse environmental conditions. The characteristics of the cultivar of corn used for popping make it unlikely to be contaminated with aflatoxins.

Aflatoxin levels, in food products made from corn (grits, meal, flour, snack foods or cereals), are likely to be higher in "full fat" than in degermed products, since the highest levels of aflatoxin in the kernel are associated with the germ.

Samples of shelled corn (designated for human use), corn meal, corn based snacks, and corn based breakfast cereals (corn flakes, grits) will be collected and analyzed for the presence of aflatoxins.

Various corn-based foods such as tacos, chips, cereals and snack foods are acceptable for sampling under this program for aflatoxin testing only. However, it is preferable to sample the corn ingredient that will be used in manufacturing these products.

c. Peanuts

The testing for aflatoxin in roasted in-shell and shelled peanuts, as well as processed peanut products for consumer use, is the responsibility of FDA.

In general, the varieties, grade, and geographical growing area for peanuts used for roasting have resulted in low aflatoxin levels in roasted-in-shell peanuts. However, when there are shortages of the usual peanut varieties used for roasting, a variety of "Runner" peanut varieties grown in northern Florida may be substituted. Peanuts of this variety and from this area have consistently had a relatively high incidence and level of aflatoxin contamination.

Do not sample in-shell peanuts (except the "Runner" variety of peanut when roasted in-shell) or nut meats destined for processing that is intended to remove aflatoxin contaminated nuts.

Do not sample raw peanuts (shelled or in-shell) for aflatoxins. USDA will collect and analyze samples of domestic and imported raw peanuts (shelled or in-shell) to determine if aflatoxin is less than 20 ppb. USDA will conduct all testing of raw peanuts, domestic and imports, for aflatoxins in accordance with FDA Memorandum of Understanding (MOU) with the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS) - MOU with USDA/AMS Concerning Aflatoxins in Peanuts and Peanut products, Brazil Nuts and Pistachio Nuts (MOU-225-11-0008), See Aflatoxins in Peanuts and Peanut Products CPG 570.375), <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074598.htm>

- d. Almonds, Brazil nuts macadamia, pecans, pistachios, walnuts, and hazelnuts are susceptible to aflatoxin contamination, but samples of these nuts have been largely in compliance (less than 1% adverse) for several years. FDA surveillance of these crops, however, is necessary to assure that industry-implemented quality control procedures continue to effectively prevent the marketing of aflatoxin contaminated nuts.

e. Domestic Milk Products Only

When dairy animals consume feed containing high levels of aflatoxins, one of the metabolized aflatoxins (aflatoxin B₁) may be secreted into the animals' milk as aflatoxin M₁. Cattle consuming feed that contains less than 20 ppb of total aflatoxins, however, should produce milk that complies with FDA's limit that is listed in the CPG for aflatoxin M₁ in milk.

Sample milk for aflatoxin M₁ if state coverage is inadequate in areas where the potential for aflatoxin in dairy rations exists. Use the results of the District's sampling of feed under Center for Vet. Medicine directives and the results of State feed analyses as indications of suspect dairy rations.

Do not sample dairy products such as cheese or yogurt, unless there is reason to suspect they were made from milk containing levels of aflatoxin M₁ that exceed CPG limits.

f. Import Products Only

Increased Surveillance of Imported Peanut Butter as a result of previous problems (e.g. recall of peanut butter from Argentina) and recent market information indicating an increase in the importation of peanut butter or imported peanuts shipped to another country (e.g., Canada), (where they are further processed into peanut butter and subsequently exported to the U.S.). Refer to the current Workplan for the numbers of samples to be collected.

In addition, nut pastes and similar ethnic foods containing nuts susceptible to contamination may be sampled.

The USDA only tests unprocessed agricultural commodities. For Brazil nuts, only in-shell un-roasted nuts are USDA Tested (See MOU 225-11-0008). For pistachios, only unroasted pistachios are USDA tested (See MOU 225-11-0008). Roasted pistachios and shelled or roasted Brazil nuts are not covered by the MOU's because they are processed. They are suitable for collection for aflatoxin analyses.

Special Surveillance Products to be Collected

See Attachment A, Section 1a for a list of these products.

Refer to the IOM, Chapter 4, Sample Schedule Chart 6 for a list of sample sizes. Collect samples randomly so as to be representative of the lot.

<http://www.fda.gov/ICECI/Inspections/IOM/ucm127685.htm>

2. Patulin

- a. See Attachment A, Section 2. Collect **only** apple juice and concentrated apple juice. Since patulin is not destroyed by heat processing, collect both pasteurized and non-pasteurized single strength juice and concentrated juices. (21 CFR 101.30(h)).
(<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074427.htm>)
- b. Sample size is dependent on product form:
- | | |
|-----------------------------------|--|
| Frozen | Collect six subsamples with a minimum |
| Concentrate: | volume of 400 mL (approximately 12 fluid ounces) per subsample; |
| Single Strength (ready to drink): | Collect six subsamples with a minimum volume of 500 mL (approximately 16 fluid ounces) per subsample |

If necessary, collect additional units to make up minimum volume requirements.

c. Domestic Products Only

If samples are collected in conjunction with the inspection of an apple juice processor under the Juice HACCP Inspection Program (7303.847) consider collecting samples if the processor does not cull apples to be used to produce juice (including stored apples) to remove rotten apples and visibly damaged apples, i.e., bruising, breaks in the skin, apples with holes, visible mold, hail damage, bird pecks. Consider collecting samples also if it is established that the processor uses drops, i.e., apples that have fallen off the tree and are harvested from the ground (also known as grounders or ground fruit) to produce juice. The Juice HACCP Inspection Program can be found at <http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm014684.htm>

3. **Deoxynivalenol (DON)**

a. See Attachment A, Section 3 for products to be collected.

b. Dry milled wheat products (whole wheat flour, white flour and bran) will be collected.

c. Samples will consist of four (4) 450 gram (approximately 1 pound) subsamples to be collected from a single lot of product.

d. Domestic Products Only

Some samples of bran that may be used as a component of bran cereal, but not the cereal itself, may be collected at cereal manufacturers.

e. **Do not collect samples of unfinished wheat commodities (i.e. products that will be further processed) for either domestic or imported products.**

4. **Fumonisin FB₁, FB₂, and FB₃**

a. See Attachment A, Section 4 for products to be collected.

Samples of whole, partially degermed, and degermed dry-milled corn products (flour, meal, grits, flaking grits, bran) and cleaned corn intended for masa production and for popcorn (unpopped) will be collected and analyzed for the presence of fumonisins.

b. Collect ten 454-gram (one pound) subsamples per sample.

c. Domestic Products Only

For program needs, the Center requests approximately half of the samples to be degermed, i.e., low fat. Therefore, each district should try to collect half of their samples as whole or partially degermed dry-milled corn products (fat content greater than or equal to 2.25%, dry weight basis)

AND for the other half, degermed dry-milled corn products (fat content less than 2.25%, dry weight basis) of corn flour, corn meal, corn grits and corn flaking grits. Because of this requirement, these products should be collected at a mill if possible; however, major processors using these products will have fat content as one of the specifications and if the investigator can determine the approximate fat content, samples can be collected from processors. State on the collection report, in the remarks section, that the product is either whole, partially degermed or degermed and state the approximate fat content obtained from either the miller or processor.

5. **Ochratoxin A**

- a. See Attachment A, Section 5 for products to be collected.
- b. Rye flour, wheat flour, barley (cereals), oats, both whole and cereals, dried beans, cornmeal, raisins, coffee, soya flour and soya based baby foods will be collected and analyzed for ochratoxin A.

The cornmeal and corn based cereal products listed in 4a (above) will also be collected and analyzed for ochratoxin A.

- c. For cereals and soya based baby food products, collect 4 (four) 200 gram (Approximately 8 ounces) subsamples per sample, for all other products collect 4 (four) 450 gram (approximately one pound) subsamples per sample.

C. Sample Reporting

When collecting an additional sample as follow up to a positive surveillance sample for aflatoxin, record the sample number and ppb findings for the surveillance sample in the "Remarks" section of the new collection report.

D. Sample Handling

DO NOT pack samples (other than milk or fluid items) in plastic bags or other moisture-proof containers as this may cause sweating and result in an unstable sample.

E. Sample Submission

Per IOM chap 4: Collecting Districts are instructed to submit samples utilizing the Servicing Laboratory Table (SLT) located in the ORA Workplan.

PART IV - ANALYTICAL**I. General Information****1. Sample analysis**

Do not use a screening test as it is only a yes or no qualitative method. CFSAN must have data for risk assessment so a quantitative method must be used. Specific methods for each mycotoxin analysis are listed in the following sections. Performance of the method must be supported by recoveries of added mycotoxin from the matrix with average recoveries dependent on the concentrations of the mycotoxins fortified into the matrix. Details can be found in Ref: FDA Foods Program Guidelines for Chemical Methods <http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM298730.pdf> Confirmation of Identity of toxins in violative samples must be performed by mass spectrometric analysis.

2. Confirmation of Identity

For compliance samples, confirmation is to be performed by mass spectrometry (MS) using a method that has been shown to be fit for this purpose parameters and prepare a worksheet of the analyses including the following information.

- a. Sample preparation - see method of analysis for specific toxins
- b. Specify LC or GC parameters used in the analysis
- c. Specify MS acquisition parameters used in the analysis

Conclusion should be a concise statement indicating confirmation based on retention time and spectral comparison against a reference standard.

3. Confirmation of identity criteria

Chromatographic retention time that matches the reference standard plus full scan mass spectra that matches the reference standard or at least two structurally significant ions are utilized for confirmation. The confirmation criteria should be consistent with the FDA ORA-LAB.010 document.

II. Mycotoxins addressed by Compliance Policy Guides**A. Aflatoxin Analyses**

Prior to beginning analyses review the collection report (C/R) to verify that collection of a product not listed on Attachment A, Section 1 has been pre-authorized by CFSAN. If not, contact the general assignment contact for instructions.

See ORA Workplan - Part I, Appendix III for the current listings of Servicing Laboratories.

SAFETY: Be aware of the potential hazards in the preparation of aflatoxin samples. See Official Method 977.16, 18th Edition of the *Official Methods of Analysis of AOAC INTERNATIONAL*.

1. Follow the procedures and methods in the 18th Edition (or, as updated) of the *Official Methods of Analysis of the AOAC INTERNATIONAL*:
 - a. Official Method 977.16 - Sampling and preparation of sample and safety precautions.
 - b. Official Method 971.22 - Standards for aflatoxins
 - c. Official Method 998.03 - (Alternative BF Method) - Aflatoxins in peanuts and peanut butter
 - d. Official Method 990.33 - Corn and peanut butter
 - e. Official Method 991.31 - Corn, raw peanuts and peanut butter.
 - f. Section 49.2.19A (AOAC Method 994.08) - Corn, almonds, Brazil nuts, peanuts, and pistachio nuts.
 - g. Official Method 999.07 - Aflatoxins in peanut butter, pistachio paste, fig paste, and paprika - immunoaffinity column/LC with post column derivatization.
 - h. Official Method 2000.16- Aflatoxin in baby food
 - i. Official Method 2005.08 - Aflatoxins in corn, raw peanuts, and peanut butter - liquid chromatography with post-column photochemical derivatization
 - j. Official Method 2008.02 - Aflatoxins and ochratoxin A in ginger and ginseng
 - k. Official Method 986.16 - Aflatoxin M₁ and M₂ in fluid milk
 1. Official AOAC 2000.08- Aflatoxin M₁ in liquid milk
2. The chart below may be used to facilitate calculations for nut samples.

Nuts	Meat, % by Wt.
Almonds	40
Peanuts	70
Pecans	50
Pistachios	50
Macadamia	29
Pumpkin seeds	74
Walnuts	50
Brazil nuts	50

3. Confirmation:

Refer to Compliance Policy Guides (See Part V) for required confirmation of identity procedures for compliance samples.

For compliance samples, confirmation is to be performed by mass spectrometry using the most convenient techniques that meet criteria stated in section I (2 and 3). Examples of acceptable procedures are:

Diana Di Mavungu, J., Monbaliu, S., Scippo, M.-L., Maghuin-Rogister, G., Schneider, Y.-J., Larondelle, Y., Callebaut, A., Robbens, J., Van Peteghem, C. & De Saeger, S. "LC-MS/MS multi-analyte method for mycotoxin determination in food supplements", *Food Add. Contam. Part A*, **26** (6), 885 – 895 (2009)

Frenich, A.G., Martínez Vidal, J.L., Romero-González, R. & Aguilera-Luiz, M. "Simple and high-throughput method for the multimycotoxin analysis in cereals and related foods by ultra-high performance liquid chromatography/tandem mass spectrometry" *Food Chem.* **117** (4)705-712 (2009)

4. Reporting:

The analyzing district will report analytical results into FACTS using PAF = "MYC" and the correct Mycotoxin Code **for the mycotoxins analyzed for** selected from the FACTS drop-down box.

For follow-up compliance samples, report the sample number and ppb findings for the surveillance samples in the narrative field of the FDA Form 2196(b).

Do not conduct a check analysis on surveillance samples. If any level of aflatoxin is found in a surveillance sample, immediately arrange for collection of an official sample which is representative of the lot.

B. Patulin Analyses

1. General: Samples of frozen concentrate should be diluted either as per recommendation for dilution or to a Brix value of 11.5 (single strength) before analysis (Federal Register 56 No. 127, pp30452-30466, 1991).

2. Methods:

Follow the procedures and methods in the 18th Edition (or, as updated) of the *Official Methods of Analysis of the AOAC INTERNATIONAL*:

Official Method 995.10 - Patulin in apple juice, liquid chromatographic method, AOAC-IUPAC-IFJU Method.

Official Method 2000.02- Patulin in clear and cloudy apple juices and apple puree

3. Confirmation of Identity of Patulin:

For compliance samples, confirmation is to be performed by mass spectrometry using a method that has been shown to be fit for this purpose. Confirmation criteria stated in Part IV, Section I (2 and 3). Examples of three acceptable procedures are listed below:

Marks, H.S. "Rapid gas chromatography/mass spectrometry determination and confirmation of patulin in apple juice", *J. AOAC Int.* **90**(3):879-83 (2007)

Rupp, H.S., Turnipseed, S.B. "Confirmation of patulin and 5-hydroxymethylfurfural in apple juice by gas chromatography/mass spectrometry", *J. AOAC Int.* **83**: 612-626, 2000)

Roach, J.A.G., White, K.D., Trucksess, M.W., and Thomas, F.S., "Capillary gas chromatography/mass spectrometry with chemical ionization and negative ion detection for confirmation of identity of patulin in apple juice", *J. AOAC Int.* **83**: 104-112, 2000)

4. Reporting

The analyzing district will report analytical results into FACTS using PAF = "MYC" and the correct Mycotoxin Code for the mycotoxins analyzed for selected from the FACTS drop-down box.

III. Mycotoxins Not Addressed By Compliance Policy Guides

A. Deoxynivalenol Analyses (DON)

1. Method of analysis:

Follow the procedures below or future methods in current Official Methods of Analysis of the AOAC INTERNATIONAL:

Trucksess MW, Page SW, Wood GE, Cho TH. "Determination of deoxynivalenol in white flour, whole wheat flour, and bran by solid-phase extraction/liquid chromatography: interlaboratory study", *J. AOAC Int.* **81**(4): 880-886 (1998)

Trucksess, M.W., Bao, L., Weaver, C.M & White, K.D. "Determination of deoxynivalenol in processed foods", *J. AOAC Int.* **93** 1236-1242 (2010)

Neumann, G. Lombaert, G.A., Kotello, S. & Fedorowich, N. "Determination of deoxynivalenol in soft wheat by immunoaffinity column cleanup and LC-UV detection: interlaboratory study", *J. AOAC Int.* **92**: 2009 181-189

2. Confirmation of identity of deoxynivalenol:

For compliance samples, confirmation is to be performed by mass spectrometry using the most convenient techniques that meet criteria stated in section I (2 and 3). Examples of acceptable procedures are:

Diana Di Mavungu, J., Monbaliu, S., Scippo, M.-L., Maghuin-Rogister, G., Schneider, Y.-J., Larondelle, Y., Callebaut, A., Robbens, J., VanPeteghem, C. & De Saeger, S. "LC-MS/MS multi-analyte method for mycotoxin determination in food supplements", *Food Add. Contam. Part A*,

26 (6), 885 – 895 (2009)

Frenich, A.G., Martínez Vidal, J.L., Romero-González, R. & Aguilera-Luiz, M. "Simple and high-throughput method for the multimycotoxin analysis in cereals and related foods by ultra-high performance liquid chromatography/tandem mass spectrometry" *Food Chem.* **117** (4)705-712 (2009)

3. Reporting:

The analyzing district will report analytical results into FACTS using PAF = "MYC" and the correct Mycotoxin Code for the mycotoxins analyzed for selected from the FACTS drop-down box.

When reporting results for deoxynivalenol, lab findings in the original analysis above the level of 1 ppm require that the laboratory perform a check analysis and confirmation. If the findings are confirmed, the complete analytical packet should then be forwarded to the district compliance branch in order for the home district compliance branch to prepare a regulatory recommendation.

Lab findings above the level of 1 ppm for DON should be referred to the mycotoxin compliance program monitor and the supervisor of the Plant Product Branch via email for evaluation. Complete details on the product type, form and intended use must be provided in order for CFSAN to adequately evaluate the significance of these findings. Lab findings at or below 1 ppm require no further action.

B. Fumonisin Analyses

Follow the procedures and methods in the 18th Edition (or, as updated) of the *Official Methods of Analysis of the AOAC INTERNATIONAL*:

1. Method of analysis:

Official Method 2001.04- Fumonisin FB₁ and FB₂ in corn and corn flakes.

Official Method 995.15 - Fumonisin FB₁, FB₂, and FB₃ in corn, liquid chromatographic method. The method was developed specifically for corn, therefore for products other than corn, it is recommended that recovery studies be done on such products before the final analysis.

2. Confirmation of identity of fumonisin:

For compliance samples, confirmation is to be performed by mass spectrometry using the most convenient techniques that meet criteria stated in section I (2 and 3). Examples of acceptable procedures are:

Khayoon WS, Saad B, Salleh B, Ismail NA, Abdul Manaf NH, Abdul Latiff A. "A reversed phase high performance liquid chromatography method for the determination of fumonisins B1 and B2 in food and feed using monolithic column and positive confirmation by liquid chromatography/tandem mass spectrometry" *Anal Chim Acta.* **679**(1-2), 91-97. (2010)

Musser, S.M., Eppley, R.M., Trucksess, M.W. (2002) "Electrospray Mass Spectrometry for Fumonisin Detection and Method Validation" in *Mycotoxins and Food Safety (Advances in Experimental Medicine and*

Biology, volume 504), Devries, J.W., Trucksess, M.W., Jackson, L.S. (eds), Kluwer Academic/Plenum Publishers, New York, pg. 95-105.

3. Reporting:

The analyzing district will report analytical results into FACTS using PAF = "MYC" and the correct Mycotoxin Code for the mycotoxins analyzed for selected from the FACTS drop-down box.

When reporting results for fumonisin, lab findings in the original analysis above the levels noted below for fumonisin require that the laboratory perform a check analysis and confirmation. If the findings are confirmed, the complete analytical packet should then be forwarded to the district compliance branch in order for the home district compliance branch to prepare a regulatory recommendation.

Lab findings above the guidance levels listed in the table below for fumonisin should be referred to the mycotoxin compliance program monitor and the supervisor of the Plant Product Branch via email for evaluation. Complete details on the product type, form and intended use must be provided in order for CFSAN to adequately evaluate the significance of these findings. Lab findings at or below guidance levels listed in the table below require no further action.

The following guidance levels for fumonisins (FB₁+FB₂+FB₃) in foods have been established.

Levels for Fumonisin in Foods	Total Fumonisin (FB ₁ +FB ₂ +FB ₃)
Degermed dry milled corn product	2 ppm
Whole/partly degermed dry milled corn product	4 ppm
Dry milled corn bran	4 ppm
Cleaned corn intended for popcorn	3 ppm
Cleaned corn for masa production	4 ppm

Note: These levels are more commonly referred to as micrograms per gram but because limitations in electronic transmission cause the symbol for microgram to be distorted or omitted, the ppm unit of measurement is being used.

C. Ochratoxin A Analyses

Follow the procedures and methods in the 18th Edition (or, as updated) of the *Official Methods of Analysis of the AOAC INTERNATIONAL*:

1. Method of analysis:

Official Method 991.44- Ochratoxin A in Corn and Barley. The method was published in JAOAC 79:1102 1996. This method was modified and a copy of the modified method was supplied to the PRL-NW and to the KAN-DO lab.

Official Method 2000.03- Ochratoxin A in barley, immunoaffinity column/LC method.

Official Method 2000.09 Ochratoxin A in roasted coffee, immunoaffinity column HPLC method.

Official Method 2004.10) Ochratoxin A in green coffee, immunoaffinity column HPLC method.

Official Method 2008.02 - Aflatoxins and ochratoxin A in ginger and ginseng, immunoaffinity column HPLC method.

2. Confirmation of identity of ochratoxin A:

For compliance samples, confirmation is to be performed by mass spectrometry using the most convenient techniques that meet criteria stated in section I (2 and 3). Examples of acceptable approaches are:

Diana Di Mavungu, J., Monbaliu, S., Scippo, M.-L., Maghuin-Rogister, G., Schneider, Y.-J., Larondelle, Y., Callebaut, A., Robbens, J., Van Peteghem, C. & De Saeger, S. "LC-MS/MS multi-analyte method for mycotoxin determination in food supplements", *Food Add. Contam. Part A*, **26** (6), 885 – 895 (2009)

Frenich, A.G., Martínez Vidal, J.L., Romero-González, R. & Aguilera-Luiz, M. "Simple and high-throughput method for the multimycotoxin analysis in cereals and related foods by ultra-high performance liquid chromatography/tandem mass spectrometry" *Food Chem.* **117** (4)705-712 (2009)

Lombaert, G.A., Pellaers, P., Chettiar, M., Lavalee, D., Scott, P.M. & Lau, B.P.-Y (2002) "Survey of Canadian retail coffees for ochratoxin A", *Food Addit. Contamin.* **19**, 869-877.

3. Reporting:

The analyzing district will report analytical results into FACTS using PAF = "MYC" and the correct Mycotoxin Code **for the mycotoxins analyzed for** selected from the FACTS drop-down box.

Lab findings at or below 20 ppb require no further action. Lab findings above 20 ppb for ochratoxin A should be sent to the mycotoxin compliance program monitor and the supervisor of the Plant Product Branch via email for evaluation. Complete details on the product type, form and intended use must be provided in order for CFSAN to adequately evaluate the significance of these findings.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

In general, refer to the Compliance Policy Guides (CPG's), <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm> and Import Alerts (<http://inside.fda.gov:9003/ORA/OfficeofRegionalOperations/DivisionofImportOperationsandPolicy/ucm013670.htm>) for Regulatory Action Guidance. In addition to these resources, criteria and actions relevant to this compliance program are listed below.

A. Aflatoxin

IOM Sample Schedule 6 provides instructions on sample sizes for Initial/surveillance and follow-up sampling for aflatoxins. A Surveillance sample is a sample collected in reduced amounts (to lower costs) to determine if there is an aflatoxin problem with the product. This sample is not large enough to be considered representative of the lot, and, therefore a follow-up sample must be collected for regulatory purposes. See Sample Reporting section below for further instructions.

The following Compliance Policy Guides (available online at http://www.fda.gov/ora/compliance_ref/cpg/default.htm) are applicable when recommending legal actions against products collected under this program:

- Section 527.400 **Whole Milk, Low Fat Milk, Skim Milk - Aflatoxin M₁** (CPG Section 527.400)
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074482.htm>
- Section 570.200 **Brazil Nuts - Adulteration with Aflatoxin** (CPG Section 570.200)
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074594.htm>
- Section 570.375 **Aflatoxin in Peanuts and Peanut Products** (CPG Section 570.375)
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074598.htm>
- Section 570.500 **Pistachio Nuts - Aflatoxin Adulteration** (CPG Section 570.500)
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074601.htm>
- Section 555.400 **Foods, Adulteration with Aflatoxin** (CPG Section 555.400)
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074555.htm>

The following MOUs with USDA are in effect:

Peanuts and Peanut Products, Brazil Nuts and Pistachio Nuts:
MOU 225-11-0008

A complete copy of the MOU can be obtained by contacting the Office of the Chief of Staff, Office of the Executive Secretariat (OES), (301)

796-4520 or from the following website:

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm247114.htm>.

Immediately notify the Office of International Affairs, HFG-1, at (301) 827-4480, when informed of export lots of corn identified by USDA as appearing to be actionable, so that appropriate follow-up can be initiated.

Domestic Products Only

The Home District must report analytical results on compliance samples that exceed CPG limits to the responsible firm and to cooperating State Liaisons within their Districts.

When milk samples exceed the CPG limits for aflatoxin M₁, dairy feed should be sampled under the appropriate Center for Veterinary Medicine (CVM) programs to determine the source of the contamination.

Initiate appropriate follow-up action consistent with CPG 527.400, for dairy products under this compliance program, and for dairy feed using the instructions contained in the appropriate CVM compliance program (CVM compliance programs can be found at:

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/ucm112583.htm>,
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/ucm113409.pdf>).

If the district has a situation in which an aflatoxin reconditioning is required, please contact Chief of the Product Adulteration Branch in the Office of Compliance, Division of Enforcement, CFSAN, at 240-402-2439.

B. Patulin

Consult the following Compliance Policy Guide when recommending follow up actions for products collected under this program:

Section 510.150: Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074427.htm>

Identity of patulin must be confirmed by liquid or gas chromatography/mass spectrometry for all domestic and import samples.

Mycotoxins Not Addressed in Compliance Policy Guides

C. Fumonisin, Deoxynivalenol, Ochratoxin A

When reporting results for fumonisin and deoxynivalenol, lab findings in the original analysis above the level noted in part IV of the program for fumonisin require that the laboratory perform a check analysis and confirmation.

If the findings are confirmed, the complete analytical packet should then be forwarded to the district compliance branch in order for the home district compliance branch to prepare a regulatory recommendation for submission to the Division of Enforcement, Office of Compliance at CFSAN, through the Agency's Compliance Management System (MARCS-CMS). For imported products, districts should prepare a recommendation for Detention Without physical Examination (DWPE) for future shipments of the product and submit to ORA/Division of Import Operations.

Lab findings above the levels noted in the program for ochratoxin A should be sent to the mycotoxin program monitor via email for evaluation. The mycotoxin compliance program monitor will provide the information to the Office of Food Safety and the Division of Enforcement who will jointly determine whether the results warrant a check and confirmatory analysis to support a potential follow-up action. Lab findings at or below levels stated in the compliance program require no further action.

D. Imports

If the district encounters problem importers, refer to Chapter 9 of the Regulatory Procedures Manual (RPM) that contains a section on Priority Enforcement Strategy for Problem Importers (<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucml179264.htm>).

The Center intends to focus enforcement efforts on problem importers to assure they assume appropriate responsibility for the commodities they import. The Center will routinely review import data to identify problem importers that may warrant increased observation and firm-based enforcement. CFSAN will consider field assignments to conduct additional sampling and analyses to meet detention criteria for detention Without Physical Examination (DWPE) actions. See the RPM (http://www.fda.gov/ora/compliance_ref/rpm/) for DWPE criteria and procedures.

The field import compliance or inspection branches should contact CFSAN's Office of Compliance, Division of Enforcement when they encounter such situations in their district.

PART VI - ATTACHMENTS, REFERENCES, AND PROGRAM CONTACTSATTACHMENTS

Attachment A - Mycotoxin Products for Sampling and Acceptable Product Codes

PROGRAM CONTACTS

Center Compliance Program Inquiries - Ms. Kaniz Shireen, Office of Compliance, Division of Field Programs & Guidance, Field Programs Branch, HFS-615, at (240)402-2775 or via email at Kaniz.Shireen@fda.hhs.gov.

Center Scientific Inquiries - Dr. Kathleen L. D'Ovidio, Office of Food Safety, Division of Plant Products and Beverages, Plant Products Branch, HFS-317, at (240)475-7175 or via email at Kathleen.D'Ovidio@fda.hhs.gov.

Dr. Anthony Adeuya, Office of Food Safety, Division of Plant Products and Beverages, Plant Products Branch, HFS-317, at (240)402-5759 or via email at Anthony.Adeuya@fda.hhs.gov.

Center Analytical Inquiries - Mr. Alex Krynitsky, Office of Regulatory Science, Division of Bioanalytical Chemistry, Chief, Bioanalytical Methods Branch HFS-717, at (240)402-2098, FAX (301)436-2332 or via email at Alex.Krynitsky@fda.hhs.gov.

Dr. Kai Zhang, Office of Regulatory Science, Division of Bioanalytical Chemistry, Chemist, Bioanalytical Methods Branch HFS-717, at (240)402-2318, FAX (301)436-2634 or via email at Kai.Zhang@fda.hhs.gov.

Center Regulatory Inquiries - Mr. Donald W. Greaves, Office of Compliance, Division of Enforcement, Manufacturing and Storage Adulteration Branch, HFS-607, at (240) 402-2057 or via email at Donald.Greaves@fda.hhs.gov.

ORA Import Operations Inquiries - Ms. Jennifer M. Gabb, Office of Regulatory Affairs, Office of Operations, Office of Enforcement and Import Operations, Division of Import Operations, Import Operations & Maintenance Branch, HFC-170, at (301)796-5920, FAX (301)827-4086 or via email at Jennifer.Gabb@fda.hhs.gov

ORA Investigations Inquiries - Ms. Lourdes Andujar, Office of Food & Feed Operations, Division of Food & Feed Program Operations and Inspections, Food & Feed Program Operations Branch, HFR-SE5570, at (787)729-9030 ext.9010, FAX (787)729-9035 or via email at Lourdes.Andujar@fda.hhs.gov.

ORA Mycotoxin Program Analytical Inquiries - Ms. Sarah Skorupsky, Office of Operations, Office of Regulatory Science, Food and Feed Scientific Staff, , at (240)402-4459 or via email at Sarah.Skorupsky@fda.hhs.gov.

ADDITIONAL REFERENCES

1. U.S. Food and Drug Administration, Compliance Policy Guide Sections 675.300, Moisture Damaged Grain, (CPG Section 675.300) (<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074695.htm>), 675.400, Rendered Animal Feed Ingredients, (CPG Section 675.400) (<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074717.htm>), and

683.100, Action Levels for Aflatoxins in Animal Feeds, (CPG Section 683.100)
(<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074703.htm>)

2. LMS Method - Code 050 (For Milk only).
3. DEIO Guide to Inspections of Manufacturers of Miscellaneous Food Products, Volume II, issued September 1996.
4. 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
Document issued on: June 29, 2010; Revised July 7, 2010

This document supersedes "Letter to State Agricultural Directors, State Feed Control Officials, and Food, Feed, and Grain Trade Organizations" issued on September 16, 1993

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/NaturalToxins/ucm120184.htm>

PART VII - CENTER RESPONSIBILITIES

PROGRAM EVALUATIONS

The Director, Office of Food Safety (OFS) has the responsibility to prepare periodic formal evaluations of this compliance program. When completed and cleared, the evaluation will be available for Agency personnel on CFSAN's OC Intranet site (<http://inside.fda.gov:9003/CFSAN/OfficeofCompliance/default.htm>). Additionally, the evaluation should appear on CFSAN's Internet website.

MYCOTOXIN PRODUCTS FOR SAMPLING AND ACCEPTABLE PRODUCT CODESFOODS FOR HUMAN USE ONLYDomestic and Import Products**Section 1 - Aflatoxins (see section 1b below for additional samples)**

<u>PRODUCT</u>	<u>PRODUCT CODES</u>
Bakery Products	03A to Y[[]][01-1& 99
Corn, shelled, whole kernel	02A[[]][01
Corn Flour (masa) or Meal (including Hominy Grits)	02B[[]][01 to 99
Cereals, Corn (including Ready to Eat, Quick Cook, Instant, and Grits)	05A or B[[]][01
Corn Grits, Brewers Corn Grits, Corn Flaking Grits	05B[[]][01
Hominy	24A or B[[]][61
Snack Foods ¹	07A or B[[]][02
Peanut Butter	23C[[]][07
Peanut Products, imitation	23N[[]][01
Peanuts, in shell, roasted	23A to H[[]][07
Peanuts, shelled roasted	23B to H[[]][07
Peanuts, toppings	23F[[]][07
Peanuts, in shell, raw (follow-up samples only)	23A[]B07
Peanuts, shelled, raw (follow-up samples only)	23B[]B07
Tree Nuts: (DO NOT COLLECT CASHEW NUTS)	
Almonds	23A to F[[]][01
Brazil Nuts	23A to F[[]][02
Hazelnut	23A to F[[]][06
Pecans	23A to F[[]][08
Pine nuts/pinon	23A to F[[]][09
Pistachios	23A to F[[]][11
Walnuts	23A to F[[]][12
Mixed Nuts (cashews excluded)	23A,Y[[]][99
Coconut, shelled	23A,Y[[]][99
Edible seeds:	
Pumpkin seeds	23K[[]][01
Sunflower seeds	23K[[]][04
Melon seeds	23K[[]][05
Ginger spice	28A to B[[]][19
Cayenne pepper spice (Flaked or ground)	28A 08 and 28B[[]][08
Rice, cultivate, whole grain (Brown)	02A[[]][05
Rice, wild, whole grain	02A[[]][06
Candy with nuts &/or seeds &/or fruit &/or coconut, &/or chocolate covered nuts &/or seeds &/or fruit &/or coconut -imports	33A to Y[[]][01-14 & 99
	34A to Y[[]][01-14 & 99

¹ Miscellaneous corn-based foods such as tacos, chips, cereals and similar products that are primarily corn are acceptable for collection. It is, however, preferable to collect the corn ingredients that will be used in these foods.

NOTE: Nut and seed pastes and similar ethnic foods such as coated peanuts, nut &/or seed snack mixes and nut &/or seed sugar/brittle candies containing nuts &/or seeds are susceptible to aflatoxin contamination and may be sampled.

Refer to PART III, section B (f) before collecting milk or milk products.

<u>PRODUCT</u>	<u>PRODUCT CODES</u>
Milk, fluid	09C to E[] []01, 07, 09 to 11
Milk, concentrated	09C to E[] []03
Milk, nonfat dried	09C to E[] []16
Yogurt	09C to E[] []15
Cheese, natural	12A[] []01 to 61
Cheese products	12B[] []01 to 13, and 99
Frozen milk products	13A to G and Y[] []01 to 06, and 99

Section 1b - "SPECIAL SURVEILLANCE" PRODUCTS FOR AFLATOXIN ANALYSIS

<u>PRODUCT</u>	<u>PRODUCT CODE</u>
Sesame Seed	23K[] []02
Nutmeg	28A or B[] []30
Figs/Dates	21S or T[] []03 and 21G to J[] [];05-06 and 21H[] []16

Section 2 -- Patulin

<u>PRODUCT</u>	<u>PRODUCT CODES</u>
Apple Juice and Apple Juice Concentrate	20S[] []01

Section 3 -- Deoxynivalenol

<u>PRODUCT</u>	<u>PRODUCT CODES</u>
Whole wheat or white flour	02E[] []01
Wheat Bran and other milled wheat products for human consumption	02F[] []01
Wheat based prepared foods:	
Pretzels, baked or fried	07A or B[] []07
Pasta	04A[] []05
Bread	03A to E[] []12-13
Breakfast cereal derived from wheat:	
Ready to Eat	05A[] []04
Quick Cook	05B[] []04
Wheat based baby formula	40M to R[] []01-99
Baby Wheat Cereal	40B[] []06

Section 4 -- Fumonisin**PRODUCT****PRODUCT CODES**

Popcorn (unpopped)	02A[] [] 04
Cleaned corn aimed for masa flour production	02A[] [] 04
Dry milled corn bran	02B[] [] 99
Refer to Part III, 4.c. regarding the need to determine the fat content before collecting these products:	
Corn based breakfast cereals:	
Ready to Eat	05A[] [] 01
Quick Cook	05B[] [] 01
Baby Corn Cereal	40B[] [] 02
Corn flour (includes masa flour)	02B[] [] 01
Corn meal	02B[] [] 01 to 05, 07 thru 99
Corn Hominy Grits	02B[] [] 06
Flaking grits	05B[] [] 01
Corn Grits, Brewers Grits, Enriched Corn Grits, & Corn Meal Mush	05B[] [] 01
Corn Based Bakery Products	03A to E[] [] 04 & 99
Corn Based Snack Foods	07A to B[] [] 02, 07A to B[] [] 04; 07A to B[] [] 05, 33S[] [] 03

Section 5 -- Ochratoxin A**PRODUCT****PRODUCT CODES**

Barley (whole)	02A[] [] 02
Barley Malt	02J[] [] 01
Buckwheat flour	02G[] [] 02
Corn Meal (including hominy grits)	02B[] [] 01 thru 99
Oats (whole)	02A[] [] 03
Rye Flour	02G[] [] 10
Wheat kernels (whole)	02A[] [] 09
Whole wheat or white flour	02E[] [] 01
Cereals (barley)	05A or B[] [] 99
Cereals, (corn) (including Ready to Eat, Quick Cook, Instant, and Grits)	05A or B[] [] 01
Cereals (oat)	05A or B[] [] 02
Cereals (wheat)	05A or B[] [] 04
Cereals (rice)	05A or B[] [] 03
Coffee Beans	31A[] [] 01
Dried Beans/Peas	24B[] [] 02 thru 99
Raisins	20B[] [] 10
Fig, dried	21S or T[] [] 03
Ginger (Ground)	28B[] [] 19
Baby Cereals (barley, corn, oat, rice, wheat)	40B[] [] 01 to 06
Soya Based Baby Food Products	40A or B[] [] 99, 40C[] [] 25, 40Y[] [] 99, 40N or O or P[] [] 02

****Special Note:** Please use the correct product codes and collect only sample types listed above and in the SCOPE. Direct any questions to the Office of Compliance contact Ms. Kaniz Shireen or the Office of Food Safety mycotoxin compliance program manager Dr. Kathleen L. D'Ovidio. Contact information is found in Part VI, page 1.