Peanuts, aflatoxin, and the U.S. origin certification program

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Abstract

The European Union (EU) reviewed the U.S. Origin Certification Program (OCP) to test U.S. export peanuts for aflatoxin at origin and indicated that the OCP provides a similar level of assurance as the EU Directive concerning aflatoxin testing in various commodities. EU member countries that choose to use the OCP are not precluded from conducting random testing of lots for aflatoxin at the port of entry. For domestic use, the U.S. Department of Agriculture (USDA) requires three 22 kg laboratory samples to average less than 15 total ng/g for acceptance. The EU requires one 30 kg laboratory sample to test less than 15 total ng/g (8B1) for raw peanuts destined for further processing and three 10 kg laboratory samples to all test less than 4 total ng/g (2B1) for consumer-ready peanuts sold for direct human consumption. The U.S. proposal to the EU was to use the official USDA 22 kg sample for raw peanuts or divide the USDA 22 kg sample into three 7.3 kg samples for consumer-ready peanuts. In addition the U.S. provides copies of official USDA grade and aflatoxin certificates for traceability and all aflatoxin test results for verification. The origin certification program will reduce lots rejected at the port of entry, reduce the disruption in supply, reduce economic losses, and maintain EU standards for consumer safety. The origin certification program is an example of an agreement between two countries that is mutually beneficial to both while maintaining high standards for consumer safety.

Keywords: aflatoxin, peanuts, sampling, origin certification
1. Introduction

Approximately 90 countries have regulations that establish maximum aflatoxin limits in food and feed products (Food and Agriculture Organization, 1997). Regulations and limits vary from country to country. For example, the U.S. Food and Drug Administration (FDA) have a limit of 20 ng of total aflatoxin per g of product (ng/g) while Canada has a limit of 15 ng/g total aflatoxin. Member governments, working through the CODEX system, are attempting to harmonize mycotoxin limits and sampling plans for products moving in international trade. Currently Codex has established an aflatoxin limit of 15 ng/g total aflatoxin for raw shelled peanuts destined for further processing and a sampling plan that requires a 20 kg sample for analysis (Codex Alimentarius Commission, 1999).

When food and feed products are shipped in the international market from one country to another, the exporter will sample the lot at origin and the importer will sample the lot at the port of entry to determine if aflatoxin concentration in the shipment is within the maximum limit established by the importing country. The exporter wants to minimize the number of lots rejected at the port of entry by the importer. The importer doesn’t want to accept a shipment with an aflatoxin concentration greater than the maximum limit. Because of the heterogeneity of aflatoxin contamination and the variability associated with the aflatoxin test procedure (sampling, sample preparation, and analysis), lots can be misclassified by both the exporter and importer (Whitaker and Park, 1993) constituting an economic loss and a potential health risk to the consumer. If the sample from a shipment tests greater than the legal limit at the port of entry, the shipment is usually rejected causing additional disruption of supply to the importer.

In the United States, about 30% of the peanut production is exported (Carley and Fletcher, 1995). Collectively, countries of the European Union are the largest importers of U.S. peanuts (Carley and Fletcher, 1995). Because rejecting lots at the port of entry causes a large economic loss to U.S. exporters and a disruption of supply to the EU importers, the U.S. peanut industry worked with European authorities to develop an Origin Certification Program that allows for U.S. peanuts to be tested for aflatoxin and certified

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1 Codex Alimentarius is jointly administered by the UN Food and Agriculture Organization and the World Health Organization. Codex establishes standards for food moving in international trade. The standards are meant to protect the health of consumers and ensure fair practices in the food trade.
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they meet EU aflatoxin regulation prior to export. The Origin Certification Program implemented with several Member governments of the EU and the U.S. is described below.

2. Origin certification program

In an Origin Certification Program (OCP), enforcement authorities in the importing country take into consideration the aflatoxin testing and certification that accompanies a shipment. Origin Certification doesn't preclude the possibility of aflatoxin testing and certification of shipments by importing authorities at the port of entry. In the specific case of the US OCP, consideration by the European Commission that the program provided a similar level of assurance enabled Member governments to take this into consideration in determining surveillance procedures. Specific memorandums of understanding agreed with several Member governments and their port/health authorities, provided the opportunity for peanut lots to be tested for aflatoxin in the U.S. by the U.S. Department of Agriculture (USDA). Under the program, specific procedures were outlined and agreed. Peanut lots tested and certified as complying with program provisions are consistent with EU aflatoxin regulations described in EU Directive 98/53 and Regulation 466/2001. A brief description of EU aflatoxin regulations is given below.


3 EU harmonized levels are in force for nitrates in lettuce and spinach and for aflatoxin in peanuts, nuts, dried fruits, cereals and milk. As of April 5, 2002, EU wide maximum levels will also apply for lead, cadmium, mercury and for 3-monochloropropane-1,2-diol (3-MCPD) in a wide range of food products, for aflatoxin in spices and for ochratoxin A in cereals and dried vine fruits. Maximum dioxin levels have been established for products of animal origin and vegetable oils. These levels will become mandatory as of July 1, 2002. The maximum levels for all of these contaminants are available in the annex to Commission Regulation 466/2001, amended by Commission Regulations 2375/2001, 221/2002, 257/2002, 472/2002 and 563/2002.
3. EU peanut aflatoxin regulations

EU aflatoxin regulations establishing maximum aflatoxin limits differ for raw peanuts destined for further processing (raw peanuts) and for peanuts destined for direct human consumption (consumer-ready, e.g. blanched peanuts). A brief description of the aflatoxin test procedure and maximum limits are given below. Unless stated, assume regulations apply to both raw and consumer-ready peanuts.

3.1 Sample selection

Sample selection equipment and procedures are to provide a representative (unbiased) laboratory sample for analysis. Depending upon lot size, many small incremental portions (as many as 100) of 300 g each, are collected from throughout the lot and pooled together to obtain an aggregate sample of 30 kg or greater.

3.2 Number of sample units

From the aggregate sample, remove one 30 kg laboratory sample (1x30) when sampling raw peanuts. For consumer-ready peanuts, divide the aggregate sample into three 10 kg laboratory samples (3x10).

3.3 Sample preparation

The laboratory sample is ground as finely as possible in a mill that provides as complete homogenization as possible.

3.4 Subsample size

A 100 g subsample is taken from each comminuted laboratory sample for aflatoxin extraction and quantification.

3.5 Analytical method

Analytical method that meets or exceeds established performance standards related to percent recovery, reproducibility, and repeatability or methods accepted by international agencies such as AOAC.
3.6 Accept/reject limit

The aflatoxin threshold value used to accept or reject peanut lots is equal to the EU maximum limit for raw and consumer-ready peanuts. For raw peanuts, the 30 kg laboratory sample has to test less than or equal to 8 ng/g B1 and 15 ng/g total aflatoxin. For consumer-ready peanuts, all three 10 kg laboratory samples have to test less than or equal to 2 ng/g B1 and 4 ng/g total aflatoxin. The shipment can fail on either B1 or total aflatoxin.

4. USDA aflatoxin control program

The peanut industry in the United States is unique among agricultural commodity industries in having a government operated marketing agreement for the control of aflatoxin. Prior to the 2002 crop year the USDA Marketing Agreement, administered by the Peanut Administrative Committee (PAC), defined procedures for the control of aflatoxin in peanuts (Dickens, 1977). With the new 2002 Congressional Farm Bill, PAC was abolished and a Peanut Standards Board (PSB) was established. The PSB is similar to PAC, but can only advise the Secretary of Agriculture concerning how peanuts are marketed in the U.S. Even though PAC was abolished, very few changes were made in the aflatoxin control program.

Figure 1 shows a flow diagram of the US peanut market system and the two locations where the USDA Market Agreement requires peanuts to be inspected for aflatoxin. First, farmers’ stock (FS) peanuts are inspected for the aflatoxin-producing fungi, *Aspergillus flavus*, when farmers sell their peanuts to a shelter at the buying point. Some shelters chemically test FS peanuts as part of their own in-house aflatoxin management procedures. Second, raw shelled peanuts are sampled and chemically tested for aflatoxin after the shelling process. Shelled peanut lots are not released by USDA into the domestic or export markets until the lot tests less than the maximum aflatoxin limit established by USDA.

When farmers sell their peanuts at the buying point to a shelter, the lot is graded to determine the support price and the possible presence of aflatoxin (Whitaker, Dickens, and Giesbrecht, 1991; Davidson, Whitaker, and Dickens, 1982). There are about 400 inspection offices, operated by the Federal-State Inspection Service (FSIS), located at buying points throughout the peanut production region.
Figure 1. Flow diagram of the U.S. peanut marketing system.

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Segregation 1 peanuts are processed as either in-shell or raw shelled peanuts. Raw shelled peanuts account for about 75% of the total market (United States Department of Agriculture, 1994). The shelling processes includes removing foreign material, removing or separating the shell or hull from the kernels, separating shelled kernels into several commercial size categories, and removing damaged or discoloured kernels using electronic colour sorters. The USDA requires that all raw shelled lots must be graded and chemically...
tested for aflatoxin before being shipped to a manufacturer or exporter. There are about 40 inspection offices, operated by the FSIS, located at shelling plants responsible for selecting samples, grading the sample, and recording results. That portion of the grade sample used for aflatoxin analysis is transported to either a USDA lab or to a USDA-approved aflatoxin lab.

In the shelling plant, the FSIS uses automatic sampling equipment to select a 70 kg aggregate sample. The 70 kg sample is divided into a 4 kg grade sample and three 22 kg laboratory samples for aflatoxin analysis. The 4 kg grade sample is kept in the inspection office for processing and the three 22 kg laboratory samples are transported to either a USDA or USDA-approved aflatoxin lab for analysis. Each 22 kg laboratory sample is ground in a USDA hammer mill with a #14 screen that automatically removes an 1100 g subsample from the comminuted laboratory sample. USDA has approved the use of other types of mills, such as vertical cutter mixers, to grind the laboratory sample. Regardless of the type of mill used, an 1100 g subsample is always removed from the comminuted laboratory sample for aflatoxin extraction. Aflatoxin labs use AOAC-approved methods to extract aflatoxin from the subsample. Aflatoxin is quantified using thin layer chromatography, immunomassay, and high performance liquid chromatography methods. The USDA conducts proficiency checks on all labs about eight times a year.

The aflatoxin-sampling plan is a sequential design where either one, two, or all three 22 kg samples can be used to accept or reject a lot. If the first sample tests 8 ng/g or less, the lot is accepted with no further testing. If the first sample tests 45 ng/g or greater, the lot is rejected with no further testing. If the first sample tests between 8 and 45 ng/g, the second 22 kg sample is tested and the aflatoxin results are averaged with the first sample test result. If the average of the two samples is 12 ng/g or less, the lot is accepted with no further testing. If the average of the two samples is 23 ng/g or greater, the lot is rejected with no further testing. If the average of the two samples is between 12 and 23 ng/g, the third sample is tested and all three-sample test results are averaged. If the average of the three sample test results are 15 ng/g or less, the lot is accepted, otherwise the lot is rejected. The concept of the sequential design is that on the average fewer than 3 samples will be used per lot since lots with either low or high aflatoxin concentrations can be accepted or rejected with a high degree of certainty with one sample. USDA has used this sample design since 1975, but has lowered the accept/reject limits over time (Whitaker and Dickens, 1989). The USDA and the peanut
industry established an aflatoxin tolerance of 15 ng/g in 1990 that is lower than the current FDA guideline of 20 ng/g. All aflatoxin regulations are based upon total aflatoxin.

Lots that fail the USDA aflatoxin test can be reprocessed to reduce the aflatoxin content. Processing options include (a) sending the peanuts back through the shelling plant (remilling), (b) sending the peanuts to a blanching facility (the blanching process is a two step process where skins are removed from the kernel and damaged or discoloured kernels are removed from the lot using electronic colour sorters), and/or (c) crushing the peanuts for oil. Since 1990, a larger percentage of shelled peanut lots that exceed the USDA aflatoxin tolerance are sent to blanching facilities to reduce aflatoxin (Whitaker, 1997). The identity of all reprocessed lots is maintained and must pass the USDA aflatoxin test before entering the domestic or export market.

All lots, once they leave storage for the shelling plant, are given a USDA identification code (called positive lot identification). The aflatoxin values, grade, market type, market region, and sheller are recorded in a USDA database. Since 1974, approximately one million records have been recorded or stored for study by USDA and the peanut industry.

5. Origin certification agreement

The U.S. peanut industry, represented by the American Peanut Council, made a request to the European Commission (EC) to consider an Origin Certification Program. The U.S. proposed to minimize export uncertainty of peanut shipments by testing peanuts at origin for aflatoxin and to provide a certification that the peanuts met EU aflatoxin regulations. The EC reviewed the USDA aflatoxin control program and looked for three key factors: traceability, verifiability, and equivalency.

5.1 Traceability

When shelled peanut lots are formed in the shelling plant, they are given a unique identification code (positive lot identification) by the USDA. Documentation confirming lot identification, crop year, date processed, grade, market type, aflatoxin, handler, geographical location, and weight accompanies the lot throughout its processing, and is saved in a USDA database.
5.2 Verifiability

USDA conducts all official grading and aflatoxin tests on peanuts marketed in the U.S. The USDA operate approximately 400 inspections stations for farmers' stock peanuts, 40 inspection stations for shelled peanuts, and 16 USDA and USDA-approved aflatoxin labs nationwide. The USDA specifies procedures and equipment to be used by inspectors for grading and aflatoxin analyses. The USDA also requires that all equipment and procedures be evaluated and approved before official use. The USDA conducts proficiency checks on all labs about eight times a year.

5.3 Equivalency

The performance of the sampling plan used in the U.S. must provide similar performance to the EU sampling plan described above. This implies the sampling plan (aflatoxin test procedure and accept/reject limits) used in the U.S. should provide a similar level of assurance as the sampling plan defined in EU regulations. Because the USDA aflatoxin test uses automated sampling and three 22 kg samples, the U.S. OCP proposed to use a 22 kg sample in place of the 30 kg sample. The sample preparation, analytical methodology, and accept/reject limits would all be consistent with the Directive. Using methods developed by Whitaker, 1977, operating characteristic (OC) curves comparing the performance of sampling plans for raw peanuts using a 22 kg versus a 30 kg laboratory sample are shown in Figure 2. Operating characteristic curves comparing the performance of sampling plans for finished peanuts using three 7.3 kg laboratory samples versus three 10 kg laboratory samples are shown in Figure 3. The sample preparation, analytical method, and accept/reject limits are the same for both the U.S. and the EU sampling plans (vertical cutter mixer, 100 g comminuted subsample, and HPLC). The probabilities of accepting lots over a wide range of aflatoxin concentrations (OC curves) are similar but not exact. The OC curves reflect the uncertainty associated with sample size, sample preparation, and analytical method, but assume no biases are introduced with the sample selection techniques. The performances of the sampling plans were found to be similar because the U.S. uses automatic sampling equipment to take incremental samples from a moving stream of peanuts (versus a less representative manual probe sampling procedure which is used upon import).
Figure 2. Operating characteristic curves showing the performance of sampling plans that use a 30 kg and 22 kg sample to detect aflatoxin in shelled peanuts destined for further processing.

Figure 3. Operating characteristic curves showing the performance of sampling plans that use three 10 kg and three 7.3 kg samples to detect aflatoxin in consumer-ready shelled peanuts.
The origin certification procedures proposed by the U.S. included the following key points:

1. The first officially drawn USDA 22 kg sample continues to be used to meet USDA requirements.
2. Either the first or the second officially drawn USDA 22 kg sample may be used as the sample to meet EU certification.
3. USDA and USDA approved laboratories will analyze the sample using analytical methodologies that conform to the performance criteria established in the EU Directive.
4. The aflatoxin certificate, issued by a USDA or USDA approved laboratory, will include the following highlighted statement:
   - Meets EU Regulation 1525/98 and Directive 98/53. Sample consists of 22 kg, officially drawn by USDA/FSIS.
   - Results of the analyses for B1/Total aflatoxin (and methodology) will be provided:
     - 1x22 kg <= 15 ppb (8B1) if peanuts are to be further processed upon import.
     - 3x7.3 kg <= 4 ppb (2B1) if peanuts are for direct human consumption.
5. If a consignment is randomly inspected upon import, it may be assumed the peanuts will be for immediate consumption and therefore will be controlled on the 4 ppb (2B1) limits unless the sheller provides a statement with the official accompanying documentation that indicates the consignment is intended for further processing.

The EU reviewed the U.S. proposal, and indicated that Member governments can consider the OCP as an appropriate factor when assessing risk of aflatoxin contamination. Once the EU had finalized their review, the American Peanut Council approached EU Member governments and enforcement authorities to consider use of origin certification. Currently, memorandums of understanding have been completed with the U.K. Association of Port Health Authorities and the Dutch Port Health Authorities.
6. Practical considerations

Most European importers are requesting that peanut lots be analyzed and certified as consumer-ready rather than destined for further processing. This is largely due to increasing food safety concerns and demands for due diligence which are driving quality standards further down the supply chain. In this environment, origin certification takes on greater economic importance for U.S. exporters. Testing peanut lots at 4 ng/g total aflatoxin (2B1) leaves very little margin for error due to the large uncertainty associated with the aflatoxin test procedure and the heterogeneity of contamination.

As a result, a handler may screen potential lots for export using the aflatoxin test result from the first USDA 22 kg sample. If this sample tests 8 ng/g total aflatoxin or less (which would meet the EU’s limit for raw peanuts destined for further processing) or if the sample tests 4 ng/g total aflatoxin or less (which would meet the EU’s limit for consumer-ready peanuts) the second 22 kg sample is tested for aflatoxin to determine if the lot can be certified that it meets EU aflatoxin regulations for either raw or consumer-ready peanuts. As a result of the screening process, the U.S. is using an extra 22 kg sample to certify that lots meet EU regulations. The screening process effectively increases sample size and changes the performance of the U.S. aflatoxin test procedure as shown in Figures 4 and 5 for raw and consumer-ready peanut lots, respectively. The U.S. aflatoxin-sampling plan rejects more lots at all concentration so that a higher percentage of accepted lots have concentrations below the EU limit.

7. Summary and conclusions

The US origin certification program has allowed U.S. peanuts to be tested for aflatoxin at origin and be certified that the peanuts meet EU aflatoxin regulation. The EU review of the USDA aflatoxin control program determined that the procedures used by the U.S. provided a similar/equivalent level of assurance, were verifiable, and positive lot identification along with record keeping allows lots to be traced back to a handler. While the program does not preclude aflatoxin testing at the port of entry, it has provided enforcement authorities with a basis for determining that U.S. origin peanuts are a low risk commodity as compared to other imported foods.
Figure 4. Operating characteristic curves showing the performance of sampling plans that use a single 30 kg sample, a single 22 kg sample, and two 22 kg samples to detect aflatoxin in raw shelled peanuts destined for further processing.

Figure 5. Operating characteristic curves showing the performance of sampling plans that use three 10 kg samples, three 7.3 kg sample, and four (one 22 kg sample and three 7.3 kg samples) samples to detect aflatoxin in consumer-ready shelled peanuts.
The origin certification program was reviewed with enforcement authorities and the EU after one year. The consensus was that the system resulted in more efficient focusing of surveillance priorities while maintaining consumer safety standards. There has been an overall reduction in lots of U.S. peanuts rejected at the port of entry, fewer disruptions in supply, and lower economic losses associated with additional testing. The origin certification program is an example of an agreement between two countries that is mutually beneficial to both while maintaining high standards for consumer safety.

References


