Voluntary Aflatoxin Sampling Plan (VASP) USDA-Approved Laboratory Program

For purposes of providing a framework to assist laboratories in preparing for the USDA Agricultural Marketing Service (AMS) approval process, AMS has drafted a summary document that highlights the minimal requirements for the SOPs that will have to be provided. Since individual laboratories have their own format for SOPs, a specific format is not imposed. Laboratories should provide the SOPs currently in use in the laboratory – if the information is not sufficient for USDA purposes, additional information will be requested.

The following is not a complete description of the requirements but should give laboratories a sense of the requirements. Most laboratories should have these documents already written, and can review them to determine if any additional information is necessary.

VASP Protocol for EU Shipments: 15 kg total sample divided into 3 x 5 kg. Each sub-sample individually ground and analyzed; each result ≤ 2 ppb total aflatoxin.

VASP certificates can only be issued by USDA-approved laboratories. Laboratories who apply for approval and are able to provide the information contained in Section A may be granted interim authority to issue a VASP certificate while they are completing the USDA-approved laboratory program. At a minimum, laboratories issuing a VASP certificate must confirm use of sensitive analytical equipment (eg. HPLC) and either a dry or slurry grinder (e.g. VCM or Silverson mill) able to accommodate a minimum 5 kg sample.

Request for Standard Operating Procedures:

AMS will be requesting documentation in the form of Standard Operating Procedures demonstrating that the laboratory has the appropriate protocols and procedures in place to perform the necessary analyses.

Analytical Methodology
Include: step by step details to enable any qualified analyst in the laboratory, including newly hired individuals to understand and successfully follow the procedures. Include all control sample requirements. Also include any precautions to follow that are mentioned in the official method (critical control points), and precautions discovered in your own laboratory. Indicate the course of action that should be taken if unexpected results occur.

Quality assurance and quality control
Include: use of logbooks, standards, positive and negative controls, frequency of instrument calibration, temperature of equipment monitoring if necessary, sample storage, critical control points, etc.

Tracking and issuance of results
Include: logging in samples, laboratory designations, method of tracking samples, chain of custody, reporting results, delivering results to client, appropriate signature of responsible person.
Maintenance and repair of instruments and equipment
Include: maintenance log book, frequency of performance evaluation, frequency of professional servicing, labeling of broken instruments.

Calibration of instrumentation
Include: frequency of calibration, recording calibration information, corrective action.

Chemical handling, receipt and disposal
Include: logging in chemicals, frequency of preparation, storage requirements, handling precautions, pre-use testing, frequency of testing, discard times, and method of disposal.

Training and Training Documentation
Include: Procedures used to train personnel, documentation of the training procedures, and maintenance of training records.

Request for Validation Packet:
AMS will be requesting a validation packet demonstrating that the laboratory is capable of producing analytical results within the parameters specified by the method. AMS will be specifying the minimum number of samples that must be tested and what results should be obtained.

A description of the laboratory validation method and the analytical results along with appropriate documentation for this program will be requested. Since the AMS laboratory is currently validating the method, the specific protocol that will be used in the program cannot be provided at this time. However, once the protocol is finalized, labs participating in the approval process will be sent multiple samples to determine if the lab can do the analysis. Following successful completion of the analyses, labs will be visited by USDA/AMS to complete the approval process.

(a) All data submitted in the Validation Packet must have been generated by the analyst(s) who will be routinely performing the specified analysis. All Validation Packets must contain copies of the chromatograms signed by the analyst generating the data. A complete description of the protocol used to obtain the required data must be submitted.

(b) Minimum requirements of Validation Packet
Limit of Detection (LOD)
Limit of Quantification (LOQ)
Percent Recovery
Repeatability
Linearity
Estimation of Measurement of Uncertainty

Please address any questions to Sue Olson (209.343.3224) or Tim Birmingham (209.343.3222) at the Almond Board. If you are interested in participating in the USDA-Approved laboratory program for Almonds:
1. Send an email to bibrahim@almondboard.com indicating that you intend to participate in the program, which will enable the Board to follow up on applications.

2. Send a signed letter confirming your interest to:
Dr. D. Scott Lough, Program Manager
Aflatoxin in Almonds Approved Laboratory Program
USDA, AMS, S&T, TSB
National Agricultural Library, Room 401
10301 Baltimore Blvd.
Beltsville, Maryland 20705-2351
Scott.Lough@usda.gov

Dr. Lough will respond, providing any additional information that is required prior to sending the SOPs.