codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 16(c) **CX/FAC 05/37/23**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, the Netherlands, 25 – 29 April 2005

PROPOSED DRAFT SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN ALMONDS, BRAZIL NUTS, HAZELNUTS AND PISTACHIOS

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 28 February 2005** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl - ***preferably***), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org - ***preferably***).

BACKGROUND

1. The 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) agreed to commence work on the development of sampling plans for aflatoxins in almonds, Brazil nuts, hazelnuts, and pistachios, subject to approval as new work by the Codex Alimentarius Commission. The Committee also agreed that, once finalized, the sampling plans should be sent to the Codex Committee on Methods of Analysis and Sampling for endorsement.[1] The 36th CCFAC further agreed that a working group led by the United States with the assistance of Argentina, Brazil, Iran, EC, and the INC would prepare sampling plans for aflatoxins in almonds, Brazil nuts, hazelnuts, and pistachios for circulation, comments, and consideration by the next Session of the Committee. The 27th Session of the Codex Commission endorsed this new work of the CCFAC.[2]

2. Several sampling plans, appropriate for tree nuts, were evaluated. As a first approach, a sampling plan that uses a single 20 kg test sample with an accept/reject limit of 15 ng/g total aflatoxin is proposed for consideration by the 37th CCFAC. A key factor in finalizing the sampling plan would be CCFAC's recommendation on a maximum limit for aflatoxins in tree nuts. The proposed sampling plan is consistent with the sampling plan adopted for peanuts by the 24th Session of the Codex Commission.[3] The 20 kg test sample is comminuted in a vertical cutter mixer (VCM) type mill, a 100 g analytical subsample is removed from the comminuted test sample, and the aflatoxin is extracted and quantified using HPLC methods. If the sample test result is 15 ng/g total aflatoxin or less, the lot is accepted, else the lot is rejected. Sample selection methods, sample preparation methods, and analytical performance standards will be described at a later date once the maximum limit and a sampling plan design have been agreed upon by CCFAC.

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1 ALINORM 04/27/12, para. 149.
2 ALINORM 04/27/41, App. VI.
3 ALINORM 01/41, para. 138.

3. The performance of the proposed sampling plan is described in Annex I and is based upon sampling data to detect aflatoxin in almonds. Since data for the other tree nuts is still being gathered, it is suggested that the proposed sampling plan be considered for all four-tree nuts.

COMMENTS

4. Comments are requested on the technical feasibility, health protection effectiveness and promotion of fair trade practices of the proposed sampling plan.

ANNEX I

AFLATOXIN SAMPLING PLANS FOR TREE NUTS

Introduction

5. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and an accept/reject limit. The aflatoxin test procedure generally consists of three steps: sampling, sample preparation, and quantification. Aflatoxin sampling plan designs can vary tremendously depending on the objectives of an industry or regulatory agency. For aflatoxin sampling plans, sample size is usually the key issue. Generally, the sampling step is the largest source of error and large samples (or a large number of samples of a given size) are required to reduce the error associated with the aflatoxin test procedure (and thus reduce the exporters' and importers' risks) to acceptable levels. Examples of several aflatoxin sampling plan designs are described below.

i. The EU specifies a single 30 kg sample for raw shelled peanuts destined for further processing. The sample test results must be less than or equal to an accept/reject limits of 15 total ng/g and 8 ng/g B1 for the lot to be accepted.

ii. The EU specifies a single 30 kg sample for tree nuts destined for further processing. The sample test results must be less than or equal to an accept/reject limits of 10 total ng/g and 5 ng/g B1 for the lot to be accepted.

iii. The EU specifies three 10 kg samples for consumer-ready peanuts and tree nuts. All three 10 kg samples test results must be less than or equal to 4 ng/g total and 2 ng/g B1 for the lot to be accepted.

iv. Codex specifies a single 20 kg sample for raw shelled peanuts. The sample test results must be less than or equal to an accept/reject limits of 15 total ng/g for the lot to be accepted.

v. The U.S. Department of Agriculture specifies a sequential type plan consisting of three 22 kg samples for raw shelled peanuts destined for further processing. The accept/reject limits vary for each sample tested, but the final accept/reject limit for the average of all three-sample test results is 15 total ng/g.

vi. The U.S. Pistachio Industry is currently considering a sequential type-sampling plan consisting of three 10 kg samples for pistachio nuts. The accept/reject limits vary for each sample tested, but the final accept/reject limit for the average of all three-sample test results is 15 total ng/g.

Performance Evaluation

6. From research studies, methods have been developed to evaluate the performance of mycotoxin sampling plan designs using operating characteristic (OC) curves. An OC curve describes the performance or the level of miss-classifications associated with an aflatoxin sampling plan for tree nuts. An example of an OC curve is shown in Figure 1. The curve estimates the probability of accepting (or rejecting) lots at a given lot aflatoxin concentration by a specific aflatoxin sampling plan design (sample size, sample preparation method, analytical method, and accept/reject limit). The shape (accept probabilities) of the OC curve is uniquely defined by the sampling plan design. The OC curve also gives an indication of the importers' risk (bad lots accepted) and the exporters' risk (good lots rejected) associated with a sampling plan design. The importers' and exporters' risks are shown in Figure 1.The evaluation method has been reviewed and sanctioned by an FAO/WHO Expert Consultation. Results of the review can be found in FAO/WHO Food and Nutrition Paper 55. The evaluation method was also used by CCFAC to design and predict the performance of the aflatoxin-sampling plan for raw shelled peanuts. The evaluation method assumes that no biases are associated with the aflatoxin test procedure. Biases are considered to be minimal when using the Codex guidelines established for sample selection, sample preparation, and analytical performance when sampling peanuts for aflatoxin.

7. The performance of the proposed sampling plan to detect aflatoxin in tree nuts was evaluated using variability and distributional data from an aflatoxin sampling study for almonds. The variability and distributional data reflects the following aflatoxin test procedure:

i. Aflatoxin distribution exists among individual raw shelled kernels.

ii. Selection of a 20 kg test sample from the lot

iii. Grinding the test sample in a vertical cutter mill to a paste.

iv. Removal of 100 g analytical subsample from the comminuted test sample.

v. Use of HPLC analytical method to quantify aflatoxin in the analytical subsample.

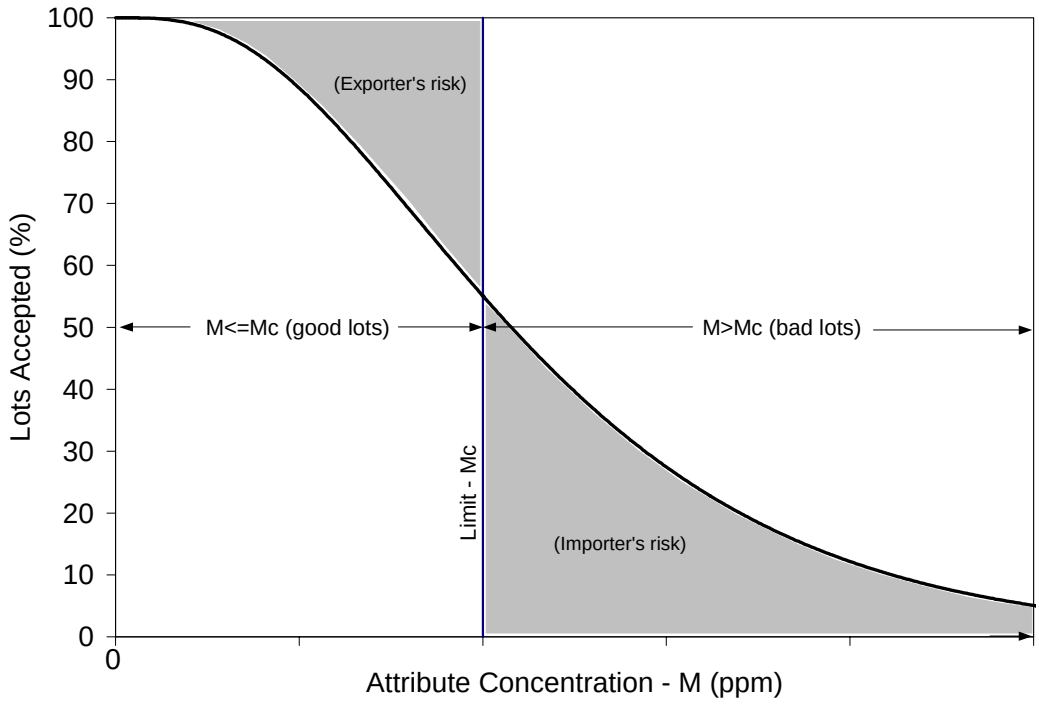

Figure 1. Example of an operating characteristic (OC) curve showing the importers' and exporters' risks associated with a sampling plan design.

Aflatoxin Sampling Plan Design for Tree Nuts

8. The proposed sampling plan uses a single 20 kg sample and an accept/reject limit of 15 total ng/g aflatoxin. The sampling plan design is simple and easy to implement. If the sample test result is 15 ng/g total aflatoxin or less, the lot is accepted, else the lot is rejected.

9. Figure 2 shows OC curve that describes the performance of the proposed sampling plan. The OC curve reflects the uncertainties associated with a single 20 kg sample, VCM to grind the sample, 100 g analytical subsample, HPLC analytical method, and an accept/reject limit of 15 ng/g total aflatoxin.

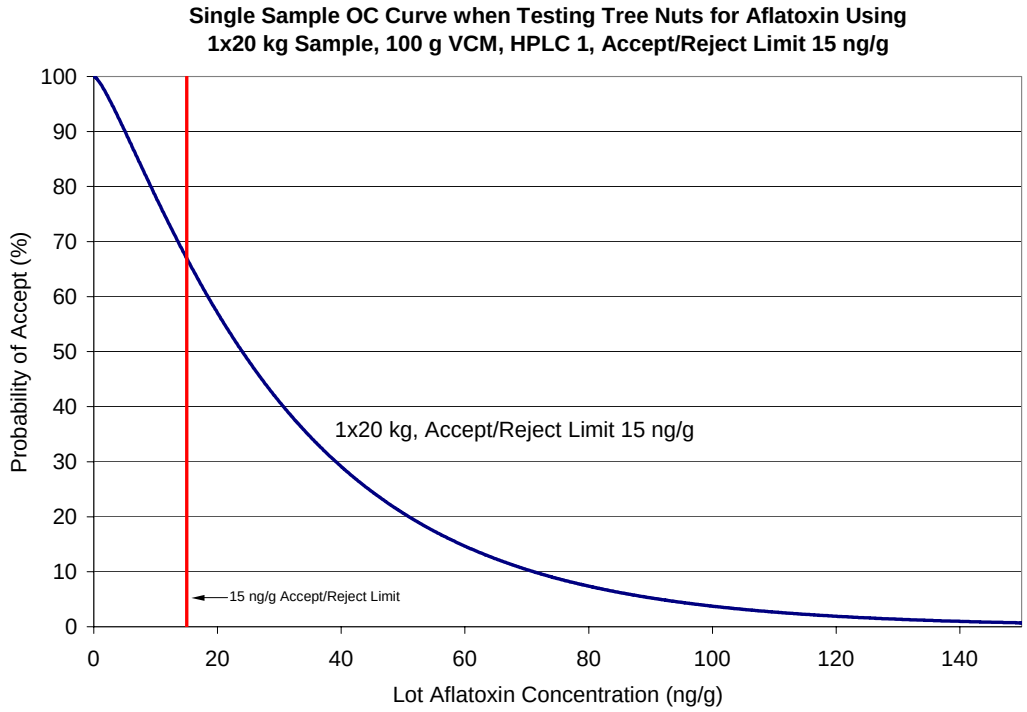

Figure 2. Operating characteristic curves that describe the performance of a single type- sampling plan for tree nuts that use one 20 kg sample and a 15 ng/g accept/reject limit.

10. The OC curve in Figure 2 shows that about 68% of the lots at 15 ng/g are accepted (32 % rejected) by the 20 kg sampling plan and is based on an assumption that there is an equal probability of occurrence of any specific contamination level in a lot. However, actual contamination levels are normally skewed to the low concentrations. The sampling plan will reject most all lots above 140 ng/g. The chances of accepting lots at other concentrations by the proposed sampling plan can be determined from the curve in Figure 2.

11. Sample size has been expressed in sample mass or kg for convenience. However, sample-to-sample variability is dependent upon the number of kernels in the sample. For almond, a 20 kg sample contains about 15500 raw shelled kernels (77.5 kernels per 100 g). The number of kernels per unit mass will differ among the four types of tree nuts. The sample size for tree nuts should be 15500-shelled kernels for the sampling plan. The 15500 shelled kernels will translate into different sample masses depending on the type of tree nut. A simple conversion can be made knowing the count per unit mass for each type tree nut.

12. Codex's philosophy, when it adopted the aflatoxin sampling plan for peanuts, was for the exporter and importer to share the risks associated with the sampling plan (Figure 1). The exporters' risk is defined as good lots rejected and the importers' risk is defined as bad lots accepted by the sampling plan. Risk sharing is usually accomplished by setting the accept/reject limit equal to the maximum limit. This approach (used by the Codex aflatoxin sampling plan for peanuts) was also used in designing the proposed sampling plan. If either or both risks are considered too large, the accept/reject limits can be reduced to smaller values and/or larger samples can be used to reduce uncertainty. Lowering the accept/reject limits will have the effect of reducing the importers' risk but increasing the exporters' risk. Increasing the size of the sample will reduce both risks. Choosing the appropriate sampling plan design requires balancing risk reduction and costs related to the sampling plan.