codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 13 (b) **CX/FAC 06/38/21**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-eighth Session
The Hague, the Netherlands, 24 -28 April 2006

PROPOSED DRAFT SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN ALMONDS, BRAZIL NUTS, HAZELNUTS AND PISTACHIOS (N07-2004)

(At Step 3 of the Elaboration Procedure)

Prepared by the United States with the assistance of Argentina, Brazil, Iran, European Community and the INC

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the following subject matter are invited to do so **no later than 15 March 2006** 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, 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 as new work for the CCFAC.[2].

1 ALINORM 04/27/12, papa. 149.
2 ALINORM 04/27/41, App. VI.

2. At the 37th Session of the Codex Committee on Food Additives and Contaminants (CCFAC), the Working Group, led by the United States, presented a Proposed Draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil Nuts, Hazelnuts and Pistachios that was developed using uncertainty data for almonds. The presenter noted that uncertainty data for hazelnuts had been submitted and that additional work on the Sampling Plan depended upon future decisions concerning a maximum level and additional information on aflatoxin distribution in pistachios and Brazil nuts (inshell/shelled).[3] During the development of this plan, the drafters noted that it was necessary to have a value for the maximum level for aflatoxins in tree nuts. The 28th Session of the Codex Alimentarius Commission adopted at Step 5 a draft maximum Level of 15 ng/g for total aflatoxins in unprocessed almonds, hazelnuts and pistachios and advanced it to Step 6.[4] Therefore, a level of 15 ng/g continues to be the basis for statistical calculations required to develop the plan.

3. The Committee returned to Step 2 the proposed Draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil Nuts, Hazelnuts and Pistachios. It also agreed to request the electronic Working Group, led by the United States, to revise the document on the basis of new information becoming available in the future, for circulation and comments at Step 3, and consideration at the next Session. [5]

4. The revised sampling plan presented in this document for consideration by the 38th CCFAC is based on data for almonds and hazelnuts and uses a single 20 kg test sample with an accept/reject limit of 15 ng/g. This revised sampling plan for tree nuts is consistent with the sampling plan adopted for peanuts by the 24th Session of the Codex Commission.[6] A 20 kg test sample is taken from a lot and 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. This plan is applicable to unprocessed and processed almonds and hazelnuts assuming a maximum level of 15 ng/g total aflatoxins. If a maximum level other than 15 ng/g is considered by CCFAC for either unprocessed or processed nuts, then the sampling plan will have to be adjusted.

5. The performance of the proposed sampling plan is described in Annex I and is based upon sampling data to detect aflatoxin in almonds and hazelnuts. The performance of the proposed aflatoxin-sampling plan for tree nuts is similar for both almonds and hazelnuts. Since data for the other tree nuts is still being gathered, it is suggested that the proposed sampling plan continue to be considered for all four-tree nuts until research data can be collected for Brazil nuts and pistachios.

COMMENTS

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

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3 ALINORM 05/28/12, para. 143.
4 ALINORM 05/28/41, para. 76.
5 ALINORM 05/28/12, para. 144.
6 ALINORM 01/41, para. 138.

ANNEX I

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

(N07-2004)

(At Step 3 of the Elaboration Procedure)

Introduction

1. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and a 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 uncertainty and large samples (or a large number of samples of a given size) are required to reduce the uncertainty 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.

1) 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.

2) 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.

3) 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.

4) 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.

5) 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.

6) 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

2. 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 OC 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 OC curve for a specific sampling plan is constructed knowing the variability and distributional characteristics among replicated sample test results taken from a contaminated lot. The evaluation method was used by CCFAC to design and predict the performance of the aflatoxin-sampling plan for raw shelled peanuts destined for further processing. 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 raw shelled peanuts for aflatoxin.

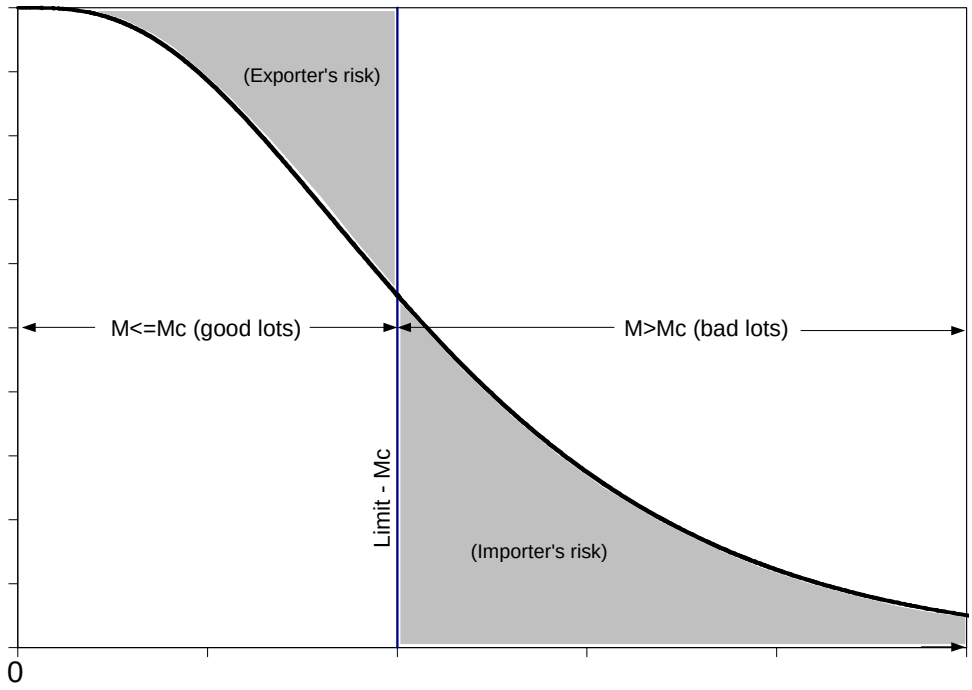

Figure 1. Example of an operating characteristic (OC) curve showing the importers' and exporters' risks associated with a sampling plan design.

Proposed Aflatoxin Sampling Plan Design for Tree Nuts

3. The proposed aflatoxin sampling plan for tree nuts can be described as follows:

1) a single 20 kg sample of shelled kernels is taken from the lot,
2) a VCM type mill is used to comminute the sample into a paste,
3) a 100 g analytical subsample is taken from the comminuted sample, *
4) HPLC analytical methods are used to quantify the aflatoxin in the analytical subsample, and

5) an accept/reject limit of 15 total ng/g aflatoxin is used to classify lots.

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.

* The performance characteristics of this plan may change if a subsample other than 100 g is taken.

Figure 2 shows two OC curves that describe the performance of the proposed sampling plan when sampling shelled almond and shelled hazelnut lots for aflatoxin. The OC curves were calculated using variability and distributional data specific to sampling shelled almonds and shelled hazelnuts for aflatoxin.

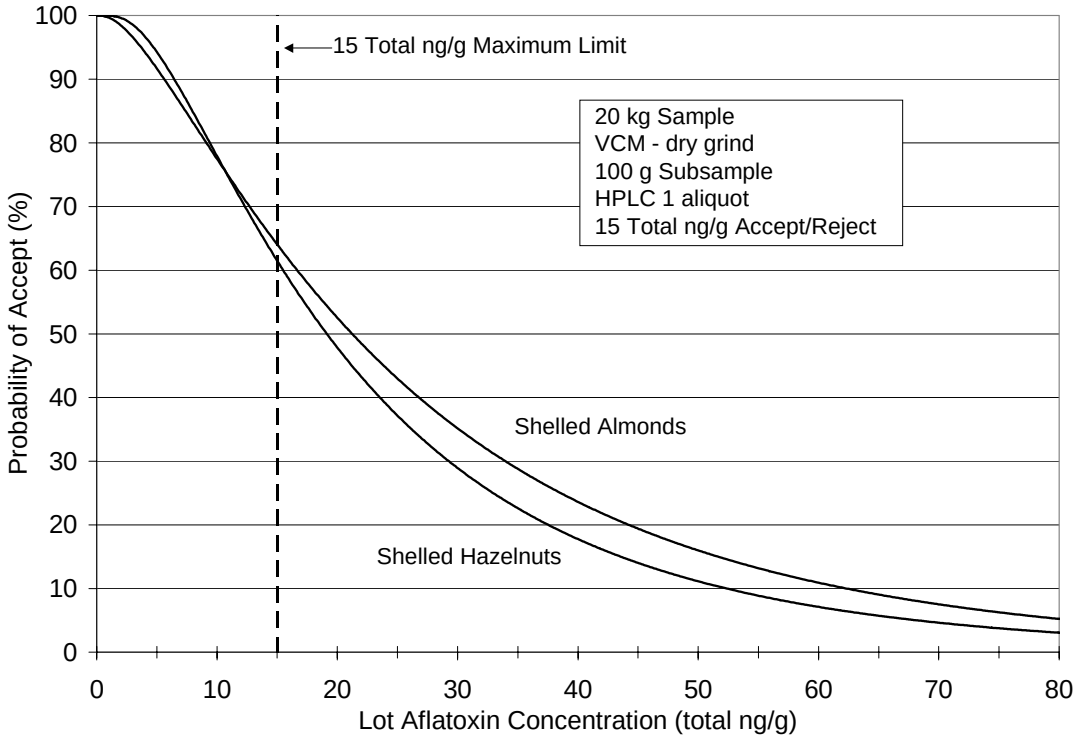

Figure 2. Operating characteristic curves that describe the performance of an aflatoxin sampling plan for almonds and hazelnuts that uses one 20 kg sample and a 15 ng/g accept/reject limit.

4. The two OC curves in Figure 2 are similar reflecting the fact that the variability and distributional data for shelled almond and shelled hazel nuts are similar. The OC curves for almonds and hazelnuts in Figure 2 shows that about 65 and 62%, respectively of the lots at 15 ng/g are accepted (35 and 38%, respectively are rejected) by the sampling plan and is based on an assumption that there is an equal probability of occurrence of any specific contamination level among lots tested with the sampling plan. However, actual contamination levels among lots sampled are usually skewed to the low concentrations. The sampling plan will reject most all lots above 80 ng/g. The chances of accepting lots at other concentrations by the proposed sampling plan can be determined from the OC curves in Figure 2.

5. Sample size has been expressed as sample mass or kg for convenience. Because the four tree nuts are physically different, the kernel count per unit mass will differ among the four tree nuts. For shelled almonds, a 20 kg sample contains about 15500 raw shelled kernels (77.5 kernels per 100 g). For shelled hazelnuts, a 20 kg sample contains about 20000 raw shelled kernels (100 kernels per 100 g). It is much easier to specify sample size and select a sample based upon mass instead of kernel count. However, sample-to-sample variability is dependent upon the number of kernels in the sample. As a result, the performance of the sampling plans depends on the number of kernels in the sample. If performance of a sampling plan that uses a 20 kg sample is significantly different among the four tree nuts, the mass of the sample associated with each tree nut may have to be adjusted so that the performance of the sampling plan for the four tree nuts is approximately the same. A simple conversion between mass and kernel count can be made knowing the count per unit mass for each type tree nut.

6. 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 aflatoxin-sampling plan for tree nuts. If either or both risks are considered too large, more samples of a given size or larger sample sizes can be used to reduce uncertainty. 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.