CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

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To: Codex Contact Points
Interested International Organizations

From: Secretariat,
Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme,
E-mail: codex@fao.org,
Fax : +39 06 57054593)
Viale delle Terme di Caracalla,
00153 Rome, Italy

Subject: DISTRIBUTION OF THE REPORT OF THE SIXTH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (REP12/CF)

The Report of the Sixth Session of the Codex Committee on Contaminants in Foods is attached. It will be considered by the Thirty-fifth Session of the Codex Alimentarius Commission (Rome, Italy, 2-7 July 2012).

PART I: MATTERS FOR ADOPTION BY THE 35TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Standards and Related Texts at Step 8 and 5/8 of the Procedure

1. **Draft Maximum Levels for Melamine in Food (*Liquid infant formula)*** (para. 58, Appendix V); and
2. **Proposed Draft Maximum Levels for Total Aflatoxins in Dried Figs and Associated Sampling Plan** (para. 82, Appendix VI).

Other matters for adoption

3. **Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods** (para. 22, Appendix II);
4. **Revision of the *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001)** (para. 38, Appendix III); and
5. **Revised Definiton of Contaminant** (para. 38, Appendix IV)

Governments and international organizations wishing to submit comments on the above documents should do so in writing, ***preferably by e-mail***, to the above address, **before 15 May 2012**.

PART II: REQUEST FOR COMMENTS AND INFORMATION

6. **Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA** (para. 163, Appendix IX)

The Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has been endorsed by the Codex Committee on Contaminants in Foods as indicated in para. 163 and presented in Appendix XI of this Report. Submission of comments and/or information is requested as follows:

- Comments on substances that are already included in the Priority List (information on data availability of those substances should also be submitted where applicable); and/or
- Nomination of new substances for the Priority List (information on details of new substances, expected timeline for data availability should also be submitted).

For the second bullet point, it is requested to fill in the form as contained in Appendix XII of this Report.

Governments and international organizations wishing to submit comments and/or information on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) should do so in writing, ***preferably by e-mail***, to the above address, **before 31 January 2013**.

APPENDIX II

PROPOSED RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

SECTION 1. SCOPE

1. This document addresses the applications of risk analysis principles by the Codex Committee on Contaminants in Foods (CCCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For urgent matters that may pose human health risk and for matters that are not in the terms of reference of JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, or FAO/WHO *ad hoc* consultations..

2. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

3. This document also applies to contaminants and toxins in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health. This excludes feed[1] additives, processing aids and agricultural and veterinary chemical residues that are the responsibility of other relevant Codex committees.

SECTION 2. GENERAL PRINCIPLES OF CCCF AND JECFA

4. CCCF is primarily responsible for recommending risk management proposals for adoption by the CAC.

5. JECFA is primarily responsible for performing the risk assessments upon which CCCF and ultimately the CAC base their risk management recommendations.

6. CCCF and JECFA recognize that interaction between risk assessors and risk managers is critical to the success of their risk analysis activities. CCCF and JECFA should continue to develop procedures to enhance interaction between the two bodies.

7. CCCF and JECFA should ensure that their contributions to the risk analysis process involve all interested parties, are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.

8. JECFA, in consultation with CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria should be used by CCCF in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum requirements for data availability have been met when preparing the draft agendas for meetings of JECFA.

SECTION 3. CCCF

COMMUNICATION WITH JECFA

9. CCCF's risk communication with JECFA includes prioritizing substances for JECFA assessment with a view to obtaining the best quality risk assessment for contaminants and toxins in food and feed.

10. CCCF shall consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- CCCF's Terms of Reference;
- JECFA's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e., magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations.

11. When referring substances to JECFA, CCCF shall provide a clearly defined scope for the risk assessment request, background information and explain the reasons for the request when chemicals are nominated for evaluation.

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[1] The terms "feed" refer to both "feed (feedingstuffs)" and "feed ingredients" as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 54/2004). For the purposes of these principles, feed refers only to food producing animals and does not cover feed for pet animals.

12. CCCF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.

13. CCCF may request JECFA to review any methods and guidelines being considered by CCCF for assessing maximum levels for contaminants and toxins. CCCF would make such request in order to obtain JECFA's guidance on the limitations, applicability and appropriate means for implementation of a particular method or guideline.

14. In cases where JECFA has performed a risk assessment and CCCF and ultimately CAC determines that additional scientific guidance is necessary, CCCF or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a decision on a risk management recommendation.

RISK MANAGEMENT

15. CCCF's risk management recommendations to the CAC with respect to contaminants and toxins shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).

16. CCCF's risk management recommendations to the CAC that involve safety aspects of food and feed standards for human health shall be based on JECFA's risk assessments, and shall take into account the relevant uncertainties and safety factors in the risk assessment and recommendations described by JECFA. When establishing its standards, codes of practice, and guidelines, CCCF shall clearly state when it applies any other legitimate factors, in addition to JECFA's risk assessment, in accordance with the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are taken into Account*, and specify its reasons for doing so.

17. CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA or other FAO/WHO expert consultations have performed a quantitative risk assessment, 2) meets the criteria established as a significant contributor to total dietary exposure for consumers (*as per the Codex Policy for Exposure of Contaminants and Toxins in Foods*) and 3) the level of the contaminant in food or feed can be determined through appropriate sampling plans and analytical methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

17bis CCCF may also set MLs in order to address and distinguish the justifiable presence of the substances from intentional unauthorized use in food and feed which may give rise to a human health concern.

18. CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum levels for contaminants and toxins in food and feed.

19. Before finalising proposals for maximum levels for contaminants and toxins, CCCF shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and toxins in food or feed and about other relevant technical and scientific aspects, as necessary to provide for a suitable scientific basis for its risk management proposals to CAC.

SECTION 4. JECFA

PREPARATION OF RISK ASSESSMENT

20. When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with CCCF and the Codex Secretariat to ensure that CCCF's work priorities are addressed in a timely manner. The JECFA Secretariat should give first priority to substances that present an emergency or imminent public health risk and then to substances that are known or expected problems in international trade.

RISK ASSESSMENT

21. The selection of JECFA experts to participate in any specific meeting should be made after a careful consideration of the necessary scientific competence and experience required for the assessment of the substances on the agenda and independence, taking into account gender and geographical representation to ensure that all regions are represented.

22. JECFA should provide CCCF with science-based risk assessments that include the four components of risk assessment as defined by CAC. JECFA should determine, to the extent possible, the risks associated with various levels of dietary exposure to contaminants and toxins. Because of the lack of appropriate information, however, this may be possible only on a case by case basis.

23. JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.

24. When evaluating dietary exposure to contaminants and toxins during its risk assessment, JECFA should take into account regional differences in food consumption patterns.

COMMUNICATION WITH CCCF

25. JECFA should strive to provide CCCF with science-based quantitative risk assessments in a transparent manner.

26. JECFA should provide CCCF with information on the applicability and any constraints, uncertainties and assumptions of the risk assessment to the general population, to particular subpopulations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of childbearing age and the elderly).

27. JECFA should provide to CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants and toxins in food and feed, which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods and feeds as may be relevant for the risk management recommendations of CCCF.

28. JECFA should communicate to CCCF the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCCF with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

29. JECFA should communicate to CCCF the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

30. JECFA's risk assessment output to CCCF is limited to presenting its deliberations and the conclusions of its risk assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius.

APPENDIX III

PROPOSED REVISED CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOOD AND FEED[1] WITH CHEMICALS

(CAC/RCP 49-2001)

1. This document deals with the major sources of environmental chemicals which may contaminate food or feed for food producing animals and constitute a hazard to human health and therefore, have been considered for regulation by CCCF/CAC. Apart from environmental contaminants, foods may contain chemicals used as pesticides, veterinary drugs, food additives or processing aids. However, since such substances are dealt with elsewhere in the Codex system, they are not included here.

2. The main objective of this document is to increase awareness of sources of chemical contamination of food and feed, and of source-directed measures to prevent such contamination. This means that measures recommended in the document may lie outside the direct responsibility of the food or feed control authorities and Codex.

3. National food or feed control authorities should inform relevant national authorities and international organizations of potential or actual food or feed contamination problems and encourage them to take appropriate preventive action. This should result in decreased levels of chemical contamination and, in the long term, could result in a decreasing need to establish and maintain Codex Maximum Levels for chemicals in food or feed.

4. Different approaches may be used to try and ensure that the levels of chemical contaminants in food and feed are as low as reasonably achievable and not above the maximum levels considered tolerable from a human health view.

Essentially, these approaches consist of

(a) measures to eliminate or control the source of contamination,

(b) processing to reduce contaminant levels, and

(c) measures to identify and separate contaminated (levels above ML) food that may ultimately enter the human food chain from food fit for human consumption.

(d) measures to identify and separate contaminated (levels above ML) feed that may ultimately enter the feed chain from feed fit for livestock feeding.

The contaminated food should be assessed as to its acceptability for human consumption.

By analogy, contaminated feed exceeding MLs should also be rejected for feed use unless the feed is treated to make it fit for animal consumption. In some cases, a combination of the above approaches must be used, for example, if emissions from a previously uncontrolled source have resulted in environmental pollution with a persistent substance, such as PCBs or mercury. When fishing waters or agricultural land become heavily polluted due to local emissions, it may be necessary to blacklist the areas concerned, i.e. to prohibit the sale of foods and feeds derived from these polluted areas and to advise against the consumption of such foods or use of such feeds.

5. Control of final products is unlikely to be enough to guarantee contaminant levels below established Maximum Levels. In most cases, chemical contaminants cannot be removed from food or feed and there is no feasible way in which a contaminated food batch can be made fit for human consumption or a contaminated feed batch can be made fit for animal consumption in respect of food safety. The advantages of eliminating or controlling food or feed contamination at source, i.e. the preventive approach, are that this approach is usually more effective in reducing or eliminating the risk of untoward health effects, requires smaller resources for food or feed control and avoids the rejection of food or feed.

6. Food and feed production, processing and preparation operations should be analysed with a view to identifying hazards and assessing the associated risks. This should lead to a determination of critical control points and the establishment of a system to monitor production at these points (i.e. the Hazard Analysis Critical Control Point or "HACCP" approach). It is important that care is exercised throughout the whole production-processing and distribution chain to ensure food safety and quality are maintained throughout..

7. Pollution of air, water and arable land can result in the contamination of crops grown for food or feed, food producing animals and surface and ground waters used as sources of water for drinking and food production and processing. The relevant national authorities and international organisations should be informed about actual and potential food or feed contamination problems and encouraged to take measures to:

- control emissions of pollutants from industry, e.g. the chemical, mining, metal and paper industries, and also from weapons testing.
- control emissions from energy generation (including nuclear plants) and means of transportation.

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1 The term "feed" refers to both "feed" and "feed ingredients" as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 054 2004). For the purposes of this Code of Practice, feed refers only to food producing animals, and does not cover feed for pet animals.

- control the disposal of solid and liquid domestic and industrial waste, including its deposition on land, disposal of sewage sludge and incineration of municipal waste.
- control the production, sale, use and disposal of certain toxic, environmentally-persistent substances, e.g. organohalogen compounds (PCBs, brominated flame retardants, etc.), lead, cadmium and mercury compounds.
- ensure that before new chemicals are introduced onto the market, and especially if they may eventually be released into the environment in significant amounts, they have undergone appropriate testing to show their acceptability from the health and environmental points of view.
- where possible, replace toxic environmentally-persistent substances by products which are more acceptable from the health and environmental points of view.

8. This Code should be read in connection with the *Code of Practice for Good Animal Feeding* (CAC/RCP 54-2004).

APPENDIX IV

PROPOSED REVISED DEFINITION FOR CONTAMINANT

"**Contaminant** means any substance not intentionally added to food ***or feed*** **for food producing animals**, which is present in such food ***or feed*** as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food ***or feed***, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter."

APPENDIX V

DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD:

LIQUID INFANT FORMULA (as consumed)

(At Step 8)

Product Name	ML (mg/kg)
Liquid infant formula (as consumed)	0.15

APPENDIX VI

PROPOSED DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN DRIED FIGS (INCLUDING SAMPLING PLAN)

(At Step 5/8)

Product Name	ML (µg/kg)
Dried Figs	10

Annex

SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN DRIED FIGS

DEFINITION

Lot - an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.

Sublot - designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

Sampling plan - is defined by an aflatoxin test procedure and an accept/reject level. An aflatoxin test procedure consists of three steps: sample selection of sample(s) of a given size, sample preparation and aflatoxin quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level.

Incremental sample – the quantity of material taken from a single random place in the lot or sublot.

Aggregate sample - the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.

Laboratory sample – the smallest quantity of dried figs comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.

Test portion – a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the aflatoxin for chemical analysis.

Ready-to-eat dried figs – dried figs, which are not intended to undergo an additional processing/treatment that have proven to reduce levels of aflatoxin.

Operating Characteristic (OC) Curve – a plot of the probability of accepting a lot versus lot concentration when using a specific sampling plan design. The OC curve also provides an estimate of good lots rejected (exporter's risk) and bad lots accepted (importer's risk) by a specific aflatoxin sampling plan design.

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers commercially classify dried figs mostly as "ready-to-eat" (RTE). As a result, maximum levels and sampling plans are proposed for only ready-to-eat dried figs.
2. The performance of the proposed draft sampling plan was computed using the variability and aflatoxin distribution among laboratory samples of dried figs taken from contaminated lots. Because the dried fig count per kg is different for different varieties of dried figs, the laboratory sample size is expressed in number of dried figs for statistical purposes. However, the dried fig count per kg for each variety of dried figs can be used to convert laboratory sample size from number of dried figs to mass and vice versa.
3. Uncertainty estimates (variances) associated with sampling, sample preparation, and analysis and the negative binomial distribution[1] are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans for dried figs.

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1 Whitaker, T., Dickens, J., Monroe, R., and Wiser, E. 1972. Comparison of the negative binomial distribution of aflatoxin in shelled peanuts to the negative binomial distribution. J. American Oil Chemists' Society, 49:590-593.

4. The analytical variance measured in the sampling study reflects within laboratory variance and was replaced with an estimate of analytical variance that reflects a reproducibility relative standard deviation of 22%, which is suggested by Thompson and is based upon Food Analysis Performance Assessment Scheme (FAPAS) data[2]. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for dried figs.

5. The issue of correcting the analytical test result for recovery is not addressed in this document. However, Table 2 specifies several performance criteria for analytical methods including suggestions for the range of acceptable recovery rates.

AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS

6. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and a maximum level. A value for the proposed maximum level and the aflatoxin test procedure are given below in this section.

7. The maximum level for "ready-to-eat" dried figs is 10 µg/kg total aflatoxins.

8. Choice of the number and size of the laboratory sample is a compromise between minimizing risks (false positives and false negatives) and costs related to sampling and restricting trade. For simplicity, it is recommended that the proposed aflatoxin sampling plan uses three 10 kg aggregate samples of dried figs.

9. The RTE sampling plan has been designed for enforcement and controls concerning total aflatoxins in bulk consignments (lots) of dried figs traded in the export market.

   Maximum level – 10 µg/kg total aflatoxins

   Number of laboratory samples – 3

   Laboratory sample size - 10 kg

   Sample preparation – water-slurry grind and a test portion that represents 55 g mass of dried figs

   Analytical method – performance based (see Table 2)

   Decision rule – If the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxins for all three 10 kg laboratory samples, then accept the lot. Otherwise, reject the lot.

   The operating characteristic curve describing the performance of the sampling plan for the ready-to-eat dried figs is shown in paragraph 46 at the end of this Annex.

10. To assist member countries implement the above Codex sampling plan, sample selection methods, sample preparation methods, and analytical methods required to quantify aflatoxin in laboratory samples taken from bulk dried fig lots are described in the following sections.

SAMPLE SELECTION

Material to be sampled

11. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 15 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 15 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 15 tonnes. It is recommended that a lot or a sublot should not exceed 15 tonnes.

12. Taking into account that the weight of the lot is not always an exact multiple of 15 tonnes, the weight of the sublot may exceed the mentioned weight by a maximum of 25%.

13. Samples should be taken from the same lot, i.e. they should have the same batch code or at the very least the same best before date. Any changes which would affect the mycotoxin content, the analytical determination or make the aggregate samples collected unrepresentative should be avoided. For example do not open packaging in adverse weather conditions or expose samples to excessive moisture or sunlight. Avoid cross-contamination from other potentially contaminated consignments nearby.

14. In most cases any truck or container will have to be unloaded to allow representative sampling to be carried out.

Incremental Sample Selection

15. Procedures used to take incremental samples from a dried fig lot are extremely important. Every individual fig in the lot should have an equal chance of being chosen. Biases will be introduced by sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

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[2] Thompson, M. 2000. Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing. J. Royal Society of Chemistry, 125:385-386.

16. Since there is no way to know if the contaminated figs are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

17. For lots less than 10 tonnes, the size of the aggregate sample is reduced so that the aggregate sample size doesn't exceed a significant portion of the lot or sublot size.

Number and Size of Incremental Samples for Lots of varying weight

18. The number of incremental samples to be taken from a lot (sublot) depends on the weight of the lot. Table 1 shall be used to determine the number of incremental samples to be taken from lots or sublots of various sizes. The number of incremental samples varies from 10 to 100 for lots or sublots of various sizes.

Table 1.Number and size of incremental samples composited for an aggregate sample of 30 kg[a] as a function of lot (or sublot) weight.

Lot or Sublot Weight [b] (T in Tonnes)	Minimum Number of Incremental Samples	Minimum Incremental Sample Size [c] (g)	Minimum Aggregate Sample Size (kg)	Laboratory Sample Size (kg)	Number of Laboratory Samples
15.0 ≥ T > 10.0	100	300	30	10	3
10.0 ≥ T > 5.0	80	300	24	8	3
5.0 ≥ T > 2.0	60	300	18	9	2
2.0 ≥ T > 1.0	40	300	12	6	2
1.0 ≥ T > 0.5	30	300	9	9	1
0.5 ≥ T > 0.2	20	300	6	6	1
0.2 ≥ T > 0.1	15	300	4.5	4.5	1
0.1 ≥ T	10	300	3	3	1

a/ Minimum aggregate sample size = laboratory sample size of 30 kg for lots above 10 tonnes

b/ 1 Tonne = 1000 kg

c/ Minimum incremental sample size = laboratory sample size (30 kg)/minimum number of incremental samples, i.e. for 10 < T ≤ 15 tonne, 300 g = 30000 g/100

19. The suggested minimum weight of the incremental sample is 300 grams for lots and sublots of various sizes.

Static Lots

20. A static lot can be defined as a large mass of dried figs contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the dried figs are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or sublot may not be accessible.

21. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

22. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

Equation 1:SF=(LT x IS)/(AS x IP).

23. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

24. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of dried figs as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

25. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the figs flow past the sampling point.

26. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

27. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

    Equation 2: S = (D x LT) / (T x V),

    where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

28. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed from Equation 3 as a function of S, V, D, and MR.

    Equation 3: SF = (S x V) / (D x MR).

29. Equations 2 and 3 can also be used to compute other terms of interest such as the time between cuts (T). For example, the time (T) required between cuts of the diverter cup to obtain a 30 kg aggregate sample from a 20,000 kg lot where the diverter cup width is 5.0 cm and the cup velocity through the stream 20 cm/sec. Solving for T in Equation 2,

    T = (5.0 cm x 20,000 kg)/(30 kg x 20 cm/sec) = 167 sec.

30. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2400 sec) and only 14.4 cuts (14 incremental samples) will be made by the cup through the lot (Equation 3). This may be considered too infrequent, in that too much product (1,388.9 kg) passes through the sampler between the time the cup cuts through the stream.

Packaging and Transportation of Samples

31. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

Sealing and Labelling of Samples

32. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLE PREPARATION

Precautions

33. Sunlight should be excluded as much as possible during sample preparation, since aflatoxin gradually breaks down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favor mold growth and aflatoxin formation.

Homogenization - Grinding

34. As the distribution of aflatoxin is extremely non-homogeneous, the laboratory samples should be homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

35. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small and the variability associated with sample preparation approaches zero. After grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.

36. The use of vertical cutter mixer type grinders that mix and comminute the laboratory sample into a paste represent a compromise in terms of cost and fineness of grind or particle size reduction[3]. A better homogenization (finer grind), such as a liquid slurry, can be obtained by more sophisticated equipment and should provide the lowest sample preparation variance[4].

Test portion

37. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 50 grams. If the laboratory sample is prepared using a liquid slurry, the slurry should contain 50 g of fig mass.

38. Procedures for selecting the 50 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 50 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 50 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.

39. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

Background

40. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific analytical method. The performance criteria established for analytical methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation (within lab), reproducibility coefficient of variation (among lab), and the percent recovery necessary for various statutory limits. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

Performance Criteria for Methods of Analysis

41. A list of criteria and performance levels are shown in Table 2. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Table 2: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration Range (ng/g)	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 110%	n/a
	>15	80 to 110%	n/a
Precision or Relative Standard Deviation RSD_R (Reproducibility)	1 to 120	Equation 4 by Thompson	2 x value derived from Equation 4
	>120	Equation 5 by Horwitz	2 x value derived from Equation 5
Precision or Relative Standard Deviation RSD_r (Repeatability)	1 to 120	Calculated as 0.66 times Precision RSD_R	n/a
	>120	Calculated as 0.66 times Precision RSD_r	n/a

n/a = not applicable

42. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values (expressed as a %) are calculated from equations 4 and 5 developed by Thompson[2] and Horwitz and Albert[5], respectively.

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3 Ozay, G., Seyhan, F., Yilmaz, A., Whitaker, T., Slate, A., and Giesbrecht, F. 2006. Sampling hazelnuts for aflatoxin: Uncertainty associated with sampling, sample preparation, and analysis. J. Association Official Analytical Chemists, Int., 89:1004-1011.

4 Spanjer, M., Scholten, J., Kastrup, S., Jorissen, U., Schatzki, T., Toyofuku, N. 2006. Sample comminution for mycotoxin analysis: Dry milling or slurry mixing?, Food Additives and Contaminants, 23:73-83.

Equation 4: $RSD_R = 22.0$

Equation 5: $RSD_R = 45.25C^{-0.15}$

where:

- RSD_R = the relative standard deviation calculated from results generated
- under reproducibility conditions
- RSD_r = the relative standard deviation calculated from results generated under repeatability conditions = $0.66RSD_R$
- C = aflatoxin concentration or mass of aflatoxin to mass of dried figs (i.e. ng/g)

43. Equations 4 and 5 are generalized precision equations, which have been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

44. Results should be reported on the sample.

UNCERTAINTY, AS MEASURED BY THE VARIANCE, ASSOCIATED WITH THE SAMPLING, SAMPLE PREPARATION, AND ANALYTICAL STEPS OF THE AFLATOXIN TEST PROCEDURE USED TO DETECT AFLATOXIN IN DRIED FIGS

45. The sampling, sample preparation, and analytical variances associated with the aflatoxin test procedure for dried figs are shown in Table 3.

Table 3.Variances[a] associated with the aflatoxin test procedure for each dried figs

Test Procedure	Variances for Dried Figs
Sampling[b,c]	$S^2_s = (590/ns)2.219C^{1.433}$
Sample Prep[d]	$S^2_{sp} = (55/nss)0.01170C^{1.465}$
Analytical[e]	$S^2_a = (1/na)0.0484C^{2.0}$
Total	$S^2_t = S^2_s + S^2_{sp} + S^2_a$

a/ Variance = S^2 (t, s, sp, and a denote total, sampling, sample preparation, and analytical steps, respectively, of aflatoxin test procedure)

b/ ns = laboratory sample size in number of dried figs, nss =test portion size in grams of fig mass, na = number of aliquots quantified by HPLC, and C = aflatoxin concentration in ng/g total aflatoxins.

c/ Count/kg for dried figs averaged 59/kg.

d/ Sample preparation variance reflects a water-slurry method and a test portion that reflects 55 g fig mass.

e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson[2] (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the three dried figs.

OPERATING CHARACTERISTIC CURVE DESCRIBING THE PERFORMANCE OF THE DRAFT AFLATOXIN SAMPLING PLAN FOR READY-TO-EAT DRIED FIGS

46. The operating characteristic curve describing the performance of draft aflatoxin sampling plan for ready-to-eat dried figs is shown in Figure 1.

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5 Horwitz, W. and Albert, R. 2006. The Horwitz ratio (HorRat): A useful index of method performance with respect to precision. J. Association of Official Analytical Chemists, Int., 89:1095-1109.

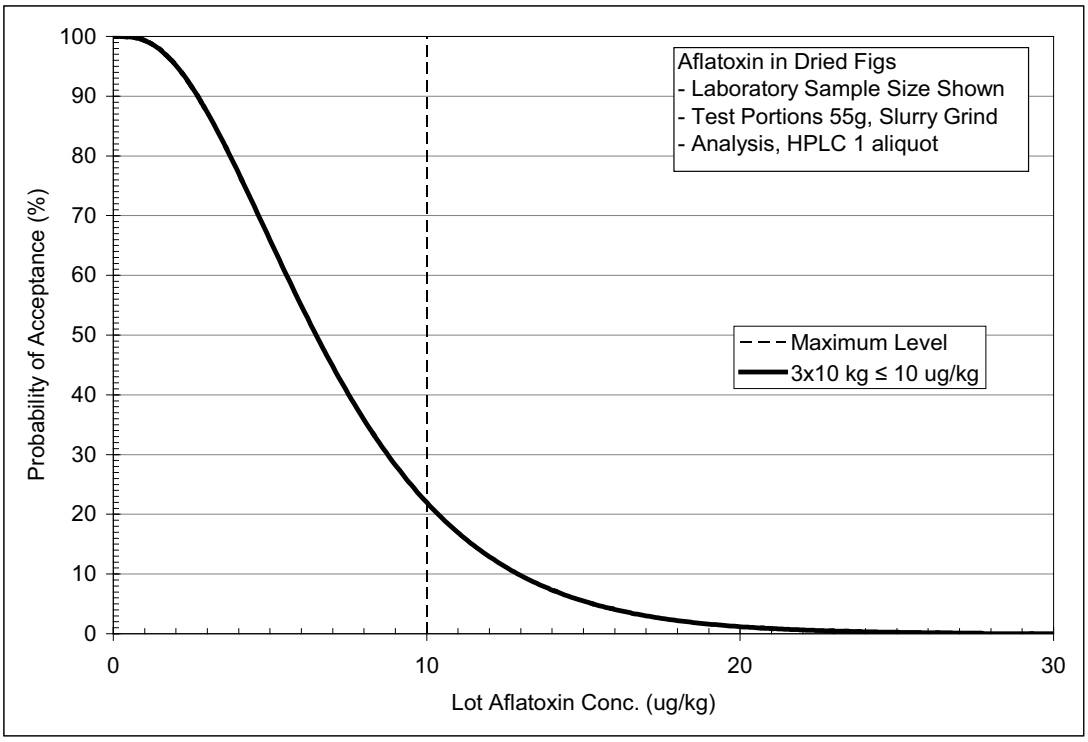

Figure 1. Operating characteristic (OC) curve describing the performance of the aflatoxin sampling plan for ready-to-eat dried figs using three laboratory samples of 10 kg each and a maximum level of 10 µg/kg total aflatoxins, water-slurry comminution method, test portion that reflects 55 g fig mass, and quantification of aflatoxin in a the test portion by HPLC.

APPENDIX XI

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA

Contaminants and naturally occurring toxicants	*Background and Question(s) to be answered*	*Data availability (when, what)*	*Proposed by*
3-MCPD esters	Full evaluation (toxicological assessment and exposure assessment)	Germany: occurrence data available Japan: subchronic toxicity test and occurrence end 2013 Surveillance data by summer 2013 (new method being developed) China: Total Diet Study on 3-MCPD esters available Canada: surveillance data available	Germany, supported by EC, Canada, Japan
Glycidyl ester	Full evaluation (toxicological assessment and exposure assessment) Bioavailability of free compounds	Japan: (analytical method under development) Surveillance in fats and oils Summer 2013 Subchronic tox studies summer 2013 USA: end 2012 as planned	Germany; USA
Pyrrolizidine alkaloids (PAs)	Identify most relevant PAs (occurrence and toxicity) for human health Full risk assessment Identify of data gaps Consideration of PAs in feed as it carries over from feed to animal products	All data collected by the eWG Australia: additional toxicological data end of 2013 EU: on-going occurrence data collection (DATEX unit of EFSA)	CCCF
Non dioxin-like PCBs	full risk assessment	Canada: data from total diet studies, monitoring data - available Netherlands: provides monitoring data to EFSA database Rep of Korea: monitoring data - available EU: to assure that EFSA data will be made available Belgium: total diet study available end 2012 Tunisia: monitoring data - available	Rep of Korea Canada
Cadmium	exposure assessment from cocoa and cocoa-product		Colombia

APPENDIX XII

Nomination of new substances for the Priority List of Contaminants and Naturally Occurring Toxicants for evaluation by JECFA

1. Basic information

1) Proposal for inclusion submitted by:

2) Name of compound; chemical name(s):

3) Identification of (additional) data (toxicology, metabolism, occurrence, food consumption) which could be provided to JECFA:

4) List of countries where surveillance data are likely to be available, and if possible list of contact person who could provide such data, including quality assurance information on the data.

5) Timeline for data availability:

2. Detail information

1) Whether or not the occurrence of the compound in commodities will have potential to cause public health and/or trade problems;

2) Whether or not commodities containing the compound are in international trade and represent a significant portion of the diet; and,

3) Commitment that a dossier (as complete as possible) will be available for evaluation by the JECFA.

4) Relevant justification and information on the following prioritization criteria[1]

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- Compliance with CCCF's Terms of Reference;
- Compliance with JECFA's Terms of Reference;
- Compliance with the Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and Criteria for the Establishment of Work Priorities;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e., magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations.

[1] Section 3, para.20 of the Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods (See Procedural Manual of the Codex Alimentarius Commission).