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SAMPLING PLANS FOR BULK MATERIALS/HETEROGENOUS LOTS INCLUDING MYCOTOXINS

(Prepared by the EWG led by New Zealand and co-chaired by Germany)

Codex Members and Observers wishing to submit comments on the recommendations in this document should do so as instructed in CL 2026/6-MAS available on the Codex webpage/Circular Letters: <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

Introduction

1. The 44th Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS44, 2025) considered the review of sampling plans in CXS 234-1999 and a proposal to develop a discussion paper on sampling plans for bulk material, including mycotoxins.
2. This document includes information on the proposal to develop a discussion paper on sampling plans for bulk materials, including mycotoxins. For information on the review of sampling plans in CXS 234-1999, see CX/MAS 26/45/10.
3. With regard to the development of sampling plans for lots consisting of bulk material/heterogenous lots, including mycotoxins, there was discussion on the background, including the interest that had been expressed by delegates at previous sessions of CCMAS in acceptance sampling plans for lots consisting of bulk materials and inhomogeneous lots.
4. This work was proposed to address, but not be limited to:
 - The number of increments in CXS 234-1999 may lead to pockets of possibly harmful contamination being missed
 - Usually, a single composite sampling is tested, meaning that the contamination levels within the lot are averaged out, the final result may be less than the acceptance limit, and possibly below the detection limit of the test method even if potentially harmful pockets of contamination are present in the lot.
 - Bayesian approaches may be more appropriate than risk-based approaches so a method for calculating various (Bayesian) risks may be required.
5. CCMAS44 agreed to continue developing the discussion paper on sampling plans for bulk materials / heterogeneous lots, including mycotoxins, including proposed plans for consideration by CCMAS45, and to inform the Codex Committee on Contaminants in Food (CCCCF) of this decision. It was also noted the work should be conducted in close collaboration with CCCC.
6. This document includes the following appendices:
 - Appendix I: Discussion paper on the “Acceptance sampling plans for bulk materials for inhomogeneous lots with a special focus on mycotoxins”
 - Appendix II: EWG participants

EWG registration and consultation

7. EWG registration was sent out using the CCMAS EWG online platform. There were 18 Members and three Observer registered. The list of participants is in Appendix II.

8. New Zealand and Germany worked closely to develop the discussion papers and included consideration of comments provided to CCMAS44.
9. Consultation with the EWG was sent out in December 2025 using the online platform. This included the discussion paper “Acceptance sampling plans for bulk materials for inhomogeneous lots with a special focus on mycotoxins” along with a proposed recommendation to CCMAS45 to include this discussion paper as an annex to the *General Guidelines on sampling* (CXG 50 – 2004) with an outcome to provide guidance to Codex commodity committees and other users such as competent authorities on the design of sampling plans for bulk materials, with a focus on plans for mycotoxins.
10. The EWG was advised of discussions with the Codex Secretariat on how to formally include CCCF in this process and subsequently an informal process was initiated to seek comments from CCMAS country delegates through discussion with their CCCF country delegate colleagues.
11. The EWG was asked to consider a proposal that CCMAS45 develop this discussion paper as an annex to CXG 50 – 2004 to provide guidance to Codex commodity committees and other users such as competent authorities on the design of sampling plans for bulk materials, with a focus on plans for mycotoxins. This is the only way that the document can be included formally in the Codex system. Information documents have no status and are not preferred.
12. Consultation closed in January 2026. A meeting was held with experts from Canada and subsequently a detailed submission was provided. Japan also provided a substantial submission.
13. Technical comments on the discussion paper were included in the review and update of the paper.
14. General questions were asked about the value of revising sampling plans for homogeneous lots, whether the intent is to replace the plans in the *General standard for contaminants and toxins in food and feed* (CXS 193-1995), and whether this process is feasible.
15. One country expressed a view on the need to advise CCCF (as agreed at CCMAS45) and that it was not the role of CCMAS to design sampling plans on behalf of CCCF and that the proposed new work to add an annex to CXG 50 was not acceptable without following the step process.
 - It was clarified that consultation would take place with CCCF following CCMAS45.
 - On the role of CCMAS to design sampling plans: Generally, commodity committees lack the expertise to be able to design sampling plans without assistance from CCMAS or external consultants. Similar issues exist with methods of analysis but in that case commodity committees routinely refer to CCMAS for advice. The terms of reference for CCMAS provide for this support:
 - to elaborate sampling plans and procedures, as may be required;
 - to consider specific sampling and analysis problems submitted to it by the Commission or any of its committees.
 - On the process for new work: If this is agreed at CCMAS45 it will follow the process set out in the *Codex Procedural Manual*.
16. Input from the respondents was used to prepare the discussion paper. In summary, the paper presents a review of the sampling plans in CXS 193, in which several shortcomings are identified. It is proposed that new work is initiated to continue this work that will include the development of methodologies for the design of sampling plans for bulk materials based on alternative approaches.

Conclusion

17. The EWG has undertaken its work in accordance with its terms of reference, and a discussion paper has been developed as contained in Appendix I. New work is required for the development of guidance as identified in the discussion paper as a possible annex to CXG 50-2004.

Recommendations

18. CCMAS45 is invited to:
 - i. consider whether to initiate new work for the development of general guidance for acceptance sampling plans for bulk materials for inhomogeneous lots with a special focus on mycotoxins taking into account the discussion paper in Appendix I; and if so, whether this guidance should take, i.e. an annex to CXG 50-2004 or other to support development of sampling plans; and
 - ii. Inform CCCF (and other relevant committees) of discussions and request their views on the need for, and possible scope of, such guidance.

DISCUSSION PAPER: ACCEPTANCE SAMPLING PLANS FOR BULK MATERIALS FOR INHOMOGENEOUS LOTS WITH A SPECIAL FOCUS ON MYCOTOXINS

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Executive summary

Background

- Sampling plans for mycotoxins in bulk commodities, as described in CXS 193, are based on statistical parameters derived from studies conducted on lots known to be contaminated.
- Because these lots were not randomly selected and cannot be considered representative of a broader population, the resulting parameters may not be suitable for plans intended for partially contaminated or inhomogeneous lots.
- Information regarding the consumer's and producer's risks associated with the current plans is lacking, and available tools may understate these risks.

Subject of the present discussion paper

- Review the theoretical foundations underlying the current sampling plans, particularly those originally developed by Whitaker.
- Evaluate the relationship between the plans in CXS 193 and the broader body of work on which they are based (scientific articles, statistical parameters, and the FAO tool).
- Outline methodological approaches that could be used for the evaluation of existing plans, including the use of utility-based frameworks that consider both risks and costs.
- The present discussion paper does not provide new sampling plans.

Objectives of potential future work (subject to CCMAS agreement)

- Evaluate available data in order to explore approaches to characterizing inhomogeneity and deriving prior information.
- Evaluate existing sampling plans with respect to consumer's and producer's risks and costs.
- Prepare practical guidance on the evaluation and design of sampling plans for bulk materials, with a focus on mycotoxins (e.g. for commodities for which no plans currently exist), including applications of utility-based approaches.

Terms of reference:

The following was decided/noted in CCMAS44 (§§118 and 119 in REP25_MASe):

- Further work on a discussion paper on the development of sampling plans for bulk materials/heterogeneous lots, including mycotoxins, including proposed sampling plans for consideration by CCMAS45, and to inform CCCF of this decision.
- It was noted that work on sampling plans for bulk materials/heterogeneous lots, including for mycotoxins, should be conducted in close collaboration with CCCF, as was the possible need for CCMAS to provide support to commodity committees in their review of sampling plans was also noted.
- The EWG was re-established, chaired by New Zealand and co-chaired by Germany, working in English only.

If the proposed work is approved in CCMAS45, the Codex Committee on Contaminants in Food (CCCF) will be advised and consulted.

Cover note

This discussion paper discusses the need for further work on acceptance sampling plans for bulk materials. An acceptance sampling plan consists of (i) requirements regarding sampling and sub-sampling procedures (number of increments or items, aggregate sample size, laboratory sample size, test portion size, etc.) and (ii) a rule for the acceptance or rejection of an inspected lot. For a comprehensive discussion of acceptance sampling (and of the relationship between acceptance sampling and conformity assessment), the reader is referred to Section 2 in the General Guidelines on Sampling CXG 50-2004 and to Section 5.3 in the Information Document for CXG 50.

For convenience, the term *bulk sampling* will be used to mean *acceptance sampling for lots consisting of bulk material*.

1 Introduction

During the work on the *General guidelines on sampling* (CXG 50-2004) [1], several delegations expressed interest in a review of the current approaches used for acceptance sampling plans for mycotoxins and for more general information on the design of acceptance sampling plans for inhomogeneous lots, including the development of an app to assist with their design.

The present document presents the results of a preliminary review of the need for further work and a concrete proposal regarding what this further work should achieve.

1.1 Data basis

The plans described in the *General Standard for contaminants and toxins in food and feed* (CXS 193-1995) [2] were developed on the basis of statistical parameters which were calculated from data from lots known to be contaminated. Moreover, the estimation procedure assumes homogeneity (see the discussion in Section 5.5). This raises the question whether such parameters constitute a suitable foundation for plans for partially contaminated/inhomogeneous lots. Indeed, on the basis of purely theoretical considerations, these parameters cannot be expected to accurately characterize lots with a high mean contamination which is unevenly distributed in the lot where most of the parts of the lot have no contamination and a small number of parts have a high contamination. Section 6 provides a brief discussion of the disparity between the risks calculated via these parameters and the risks calculated via a statistical model which reflects inhomogeneity. One of the objects of the further work would be a more systematic characterization of such disparities. Accordingly, it is proposed to develop a statistical characterization of inhomogeneity (and any other relevant statistical parameters) on the basis of more representative (random) data. Indeed, there are many quite extensive and representative data sets which can be used as a basis for bulk sampling plans. These data sets did not exist when the statistical parameters underpinning the current CXS 193 plans were calculated. Annex B provides a preliminary overview and comparison of data sets which have already been made available.

1.2 Apparent inconsistency between CXS 193 plans and their theoretical foundation

The plans in CXS 193 are ostensibly based on statistical parameters describing various sources of variation in the lot, see Table 1 in Annex IV.A and Table 3 in Annex V of CXS 193. These statistical parameters were calculated on the assumption of lot homogeneity. Similarly, the expressions which consider laboratory sample size, test portion size, etc. also assume lot homogeneity. By contrast, the CXS 193 plans require a large number of incremental samples (typically between 50 and 100), apparently working under the assumption of lot inhomogeneity. Thus, there seems to be an inconsistency between the CXS 193 plans and the theoretical framework which underpins them. However, since the design of the plans in CXS 193 implicitly accounts for inhomogeneity through the large number of incremental samples, the criticism of the Whitaker approach expressed in this discussion paper does not directly affect the soundness of the current CXS 193 sampling plans.

1.3 The risks associated with the CXS 193 plans have not been evaluated

The FAO tool (<https://tools.fstools.org/mycotoxins/>) allows a calculation of the probability of acceptance at different mean concentration levels, and thus a calculation of risks. However, since the number of increments cannot be taken into consideration in the FAO tool, the risks associated with the CXS 193 plans cannot be properly evaluated using that tool. In order to illustrate this point, consider the following example. For total aflatoxin in peanuts (20 kg laboratory sample and 100 g test portion) the FAO tool estimates a 0.26% chance of accepting a lot with a true concentration of 150 µg/kg (i.e. 10 times ML). The plan in CXS 193 requires 100 increments. If only 1% of increments are contaminated, the probability of having no contaminated increment in the aggregate sample (and thus a test result of 0 µg/kg resulting in lot acceptance) is 37%¹. This is clearly quite different from the 0.26% probability of acceptance from the FAO tool. This example shows that the proportion of contaminated increments in the lot and the number of increments required in the plan plays a fundamental role in the risks associated with any given plan.

1.4 The utility approach may allow a reduction in the workload

If prior information² is available, it is possible to optimize the efficiency of acceptance sampling plans via the utility function approach. This approach allows a simultaneous consideration of both risks and costs. If prior information shows that contamination is evenly distributed throughout the lot, then the utility approach may allow a considerable reduction in the number of increments. Conversely, if prior information indicates sparsely

¹ This is obtained by calculating the probability of taking a noncontaminated increment 100 times, i.e. $0.99^{100} = 0.37$

² Prior information may be available in the form of a statistical characterization of data obtained from previous lot inspections or experiments conducted to monitor inhomogeneity within and between lots. This statistical characterization of available data is one of the objectives of the further work proposed in the present discussion paper.

distributed highly contaminated pockets, then the utility approach will result in an increased number of increments, maintaining acceptable risk levels.

1.5 Proposed future project / further work

It is proposed that the future work will

- Evaluate existing data sets in order to derive a statistical characterization of real-life lot inhomogeneity. This statistical characterization will then be used to calibrate the model used in the calculation of risks associated with sampling plans.
- Evaluate risks associated with current plans for mycotoxins (in particular, the plans provided in CXS 193).
- Develop an approach based on the concept of utility allowing a reduction in the workload of bulk sampling for inhomogeneous lots and allowing a comparison of the costs associated with increment-level testing versus aggregate sample-level testing, taking into account costs of wrong decisions.
- Develop an app allowing relevant calculations.
- Provide practical guidance for the design and evaluation of sampling plans, including tables with standard plans for the utility approach.

For simplicity, it is proposed that this project be limited to the case that lot acceptance is determined via a criterion expressed in terms of the lot mean rather than via the lot (or process) proportion nonconforming³.

2 Inhomogeneous lots

In section 3.2.4 of CXG 50 [1], it is stated that:

In these guidelines, the term 'homogeneous' does not mean that the characteristic of interest does not vary within the lot. Rather, the term 'homogeneous' means that it is possible to characterize the variation of the characteristic of interest within the lot by means of a single standard deviation. Homogeneity applies only to variables plans.

In the present discussion paper, we propose to narrow the definition of homogeneous lot as follows.

Working definition of lot homogeneity

A lot is considered homogeneous if the sampling variance (variation between laboratory samples, i.e. between laboratory sample-specific mean concentration values, see the glossary in Section 0) is the same in the following two scenarios:

- Scenario 1: the laboratory sample is obtained in one sampling step (as one large increment)
- Scenario 2: the laboratory sample is an aggregate sample obtained via 100 sampling steps (100 increments)

Indeed, in the case of a homogeneous lot, the sampling variance depends not on the number of increments but on the laboratory sample size. In order to reduce the sampling variance by a factor k , the laboratory sample size must be increased by the same factor.

Working definition of lot inhomogeneity

Conversely, in the case of an inhomogeneous lot, the sampling variance does not just depend on the sample size. Indeed, in general, it will also depend on the number of increments. For an inhomogeneous lot, as long as subsampling variation is negligible, the sampling variance may be reduced by the factor k by increasing the number of increments by the same factor. For inhomogeneous lots, increasing the sample size may have only a negligible effect on the sampling variance.

This is a pragmatic definition of inhomogeneity rather than a theoretical one. It is motivated, in part, by available reports and publications on study results. For example, see the abstract of Tittlemier et al. (2025)⁴:

“The results indicate that sampling during only a portion of a loading or unloading process can result in an aggregate sample that is not representative of the consignment and thus increase the risk of misclassifying a consignment as compliant.”

³ Proportion nonconforming is the lot quality characteristic in many of the plans for homogeneous lots consisting of discrete items considered in the General Guidelines on Sampling (CXG 50-2004).

⁴ Tittlemier, S. A., Blagden, R., Chan, J., Drul, D., Gaba, D., Huang, M., ... Tran, M. (2024). Contaminants and residues have varied distributions in large volumes of wheat. *Food Additives & Contaminants: Part A*, 42(1), 92–102. <https://doi.org/10.1080/19440049.2024.2417394>

Other examples can be found in Section 9 (Annex A).

Characterization of inhomogeneity for mycotoxins

In the case of mycotoxins, it is proposed to characterize lot inhomogeneity via four parameters:

1. The proportion of contaminated subdivisions⁵ within the lot (considering that the entire lot is divided into increment-sized subdivisions). This parameter can also be referred to as the *expected* proportion of contaminated increments.
2. Variation in mean concentration between contaminated increment-sized subdivisions
3. The variation in the proportion of contaminated kernels⁶ within a contaminated increment
4. The variation in concentration between contaminated kernels

Note: there may be other sources of lot inhomogeneity, such as variation between broader subdivisions (segments) within the lot⁷. However, in this discussion paper, we will focus on the four inhomogeneity sources listed above.

Note: while the mean lot concentration may not be an appropriate quality characteristic for inhomogeneous lots, the costs associated with obtaining a test result per increment may be prohibitive. Nonetheless, it may be useful to address the question whether screening/rapid tests can be applied in future work. In particular, the utility approach would allow testing costs to be balanced against the costs associated with accepting lots with undetected pockets of contamination.

Note: for a discussion of different error sources (including fundamental variability) in connection with measurement uncertainty, the reader is referred to the Information document to CXG 54 [20].

The reader is referred to the discussion in Sections 3.2.4, 3.2.5 and 3.2.6 in CXG 50 [1] for further background information.

The reader is also referred to Annex A for further discussion.

3 Classical approach

The “classical” approach for bulk sampling consists in partitioning the variation within the lot into different components such as between-segment variation and between-increment variation. As such, this approach is also referred to as the *variance component* approach and is described, among other places, in ISO 10725:2000 [5] (where the focus is reasonable cost rather than minimal risk) and in the Schilling & Neubauer textbook [6].

This approach can be described as follows:

$$\begin{aligned}
 &\text{Total variance within the lot} = \\
 &\quad \text{variance between segments} \\
 &\quad + \text{variance between increments within a segment} \\
 &\quad + \text{variance between test portions within the aggregate sample} \\
 &\quad + \text{analytical variance}
 \end{aligned}$$

The following should be noted:

- This type of approach makes sense if estimates of the different variance components are taken into account in the acceptance sampling plan (number of segments and increments, aggregate sample size, comminution factor, test portions size)
- This approach makes certain tacit assumptions (normal distribution, homogenous between-increment variance within each segment, etc.)
- The variance components must be estimated prior to the inspection of actual lots via specially designed studies. (Procedures for estimating the different variance components are described in ISO 11648-1:2003.)
- ISO 10725:2000 Acceptance sampling plans and procedures for the inspection of bulk materials [5] describes sampling plans for bulk materials based on the variance components approach. The plans described in ISO 10725 differ from more general implementations of this approach in that they require two aggregate samples.

⁵ A contaminated subdivision is a subdivision whose mean concentration > LOQ

⁶ A contaminated kernel is a kernel with nonzero mycotoxin content

⁷ See ISO 10725 [5]

- Procedures specifically relating to particulate matter are described, for example, in ISO 11648-2:2001.
- The variance components approach cannot be applied to partly contaminated, inhomogeneous lots (i.e. lots with mixed distribution).

4 Acceptance sampling plans in CXS 193

These plans have the following distinguishing features:

- Relatively high number of increments (often 100 per lot or subplot)
- No stratified sampling
- No segments
- Large lots are subdivided into sublots, and the acceptance sampling plan is implemented separately to each subplot

Let us consider an example from CXS 193. The acceptance sampling plan for total aflatoxins in a 250-tonne lot of shelled peanuts (maximum level: ML = 15 µg/kg⁸) is as follows:

- Divide the lot into five 50-tonne sublots
- For each subplot:
 - take one hundred 200 g increments
 - laboratory sample: 20 kg
 - test portion size (taken from the *ground and homogenized* laboratory sample): 100 g
 - decision rule: subplot is accepted if the test result is less than ML

Note 1: Reproducibility requirements for an analytical method are often expressed in terms of the Horwitz reproducibility⁹. For example, in Table 3 in Annex III, the precision requirement is “2 x value derived from the Horwitz equation.” The latter is provided as:

$$RSD_R = 2^{1-0.5 \cdot \log(c)}$$

Note 2: Many of the plans in CXS 193 are similar (or identical) to plans in EU CIR 2023/2782. For example, in Table 1 in Section D.2, the bulk sampling plan for a 250-tonne lot of shelled peanuts is identical to the one in CXS 193 described above. (The maximum level (ML) for total aflatoxin in peanuts is specified in Annex I of EU CR 2023/95 as 15 µg/kg, i.e. the same ML as in CXS 193.)

Note 3: For some mycotoxin and commodity combinations, variance components are provided in the form of Horwitz variances. As an example, Table 1 from Annex IV.A is reproduced here:

Table 1: Variance components for aflatoxins in almonds, hazelnuts, pistachios and shelled Brazil nuts. The number of kernels in the laboratory sample is denoted n , the test portion size [g] is denoted m and the number of aliquots is denoted k . Aflatoxin concentration [µg/kg] is denoted c .

Component	Almonds	Hazelnuts	Pistachios	Shelled Brazil nuts
Sampling s_s^2	$\frac{7730}{n} \cdot 5.759 \cdot c^{1.561}$	$\frac{10\,000}{n} \cdot 4.291 \cdot c^{1.609}$	$\frac{8\,000}{n} \cdot 7.913 \cdot c^{1.475}$	$\frac{1\,850}{n} \cdot 4.8616 \cdot c^{1.889}$
Sample Preparation s_{sp}^2	$\frac{100}{m} \cdot 0.170 \cdot c^{1.646}$	$\frac{50}{m} \cdot 0.021 \cdot c^{1.545}$	$\frac{25}{m} \cdot 2.334 \cdot c^{1.522}$	$\frac{50}{m} \cdot 0.0306 \cdot c^{0.632}$
Analytical s_a^2	$\frac{1}{k} \cdot 0.0484 \cdot c^{2.0}$	$\frac{1}{k} \cdot 0.0484 \cdot c^{2.0}$	$\frac{1}{k} \cdot 0.0484 \cdot c^{2.0}$	$\frac{1}{k} \cdot 0.0484 \cdot c^{2.0}$

⁸ See Table 1 in Annex III of CXS 193.

⁹ The Horwitz reproducibility may not be representative of the performance of more modern analytical methods. We note that reference to the Horwitz reproducibility has been removed from Section 4.2.1.1 of COMMISSION IMPLEMENTING REGULATION (EU) 2023/2782. In CXS 193, the analytical variance reflects a reproducibility relative standard deviation of 22 percent, which is based upon Food Analysis Performance Assessment Scheme (FAPAS) data. A relative standard deviation of 22 percent is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22 percent is larger than the within laboratory variation measured in the sampling studies for the four treenuts.

The total variation (expressed as a variance) is then obtained as

$$s_{total}^2 = s_s^2 + s_{sp}^2 + s_a^2$$

Note 4: Plans for certain important mycotoxins and commodities are missing. For example, at the moment, there are no plans for Ochratoxin A (OTA).

5 Whitaker approach

5.1 Introduction

The theoretical framework underpinning the current plans in CXS 193 consists of a substantial body of work comprising a series of scientific publications and a webtool [3] (see Section 5.2). References [11][13][14][15][16] are examples of Whitaker's publications¹⁰.

We will use the term *Whitaker¹¹ approach* to refer to this framework.

Our comments on the Whitaker approach can be summarized as follows:

- The Whitaker approach is based on the “classical approach” or “variance components approach” described in Section 3. This approach assumes lot homogeneity, see Section 2 above. It could be argued that it was sensible for Whitaker and his fellow authors to make this assumption, e.g. because they believed that the mycotoxin concentration levels were homogeneous in the lots they had selected for their studies. Be that as it may, it is clear that the statistical parameters obtained on the basis of the assumption of homogeneity cannot be used as the basis for risk calculations for inhomogeneous lots.
- The plans in CXS 193 are ostensibly based on the Whitaker approach. See, for example, Table 1 in Annex IV.A and Table 3 Annex V in CXS 193. At the same time, the plans seem to assume lot inhomogeneity and thus require a large number of increments to be aggregated. Thus, there seems to be an inconsistency between the CXS 193 plans and their theoretical framework. In addition, the FAO tool does not allow the number of increments to be entered. See Section 5.2 and Section 5.5.
- The variance estimates which Whitaker and his fellow authors have calculated are based on data from selected lots known to be contaminated. In other words, these estimates cannot be considered representative of typical contamination patterns in the wider population of lots. In particular, these estimates are not suitable for the types of sparsely contaminated lots which may reasonably be expected to be prevalent. In particular, the Whitaker approach will not work for lots where most of the parts display no contamination at all and a small number of parts display high contamination levels. See Section 5.3.
- In the Whitaker approach, parameters are estimated using linear regression in the log variance versus log concentration domain. However, the linear relationship in the log-log domain is induced by the log transformation rather than reflecting a relationship between dispersion and concentration which is intrinsic to the data. See Section 5.4.
- In the Whitaker approach, variances are inversely proportional to sample or test portion size. From a statistical point of view, this is inappropriate for inhomogeneous lots. See Sections 2 and 5.5.

5.2 FAO tool

The FAO tool (version 1.1) [3] can be accessed via the following link:

<https://tools.fstools.org/mycotoxins/>

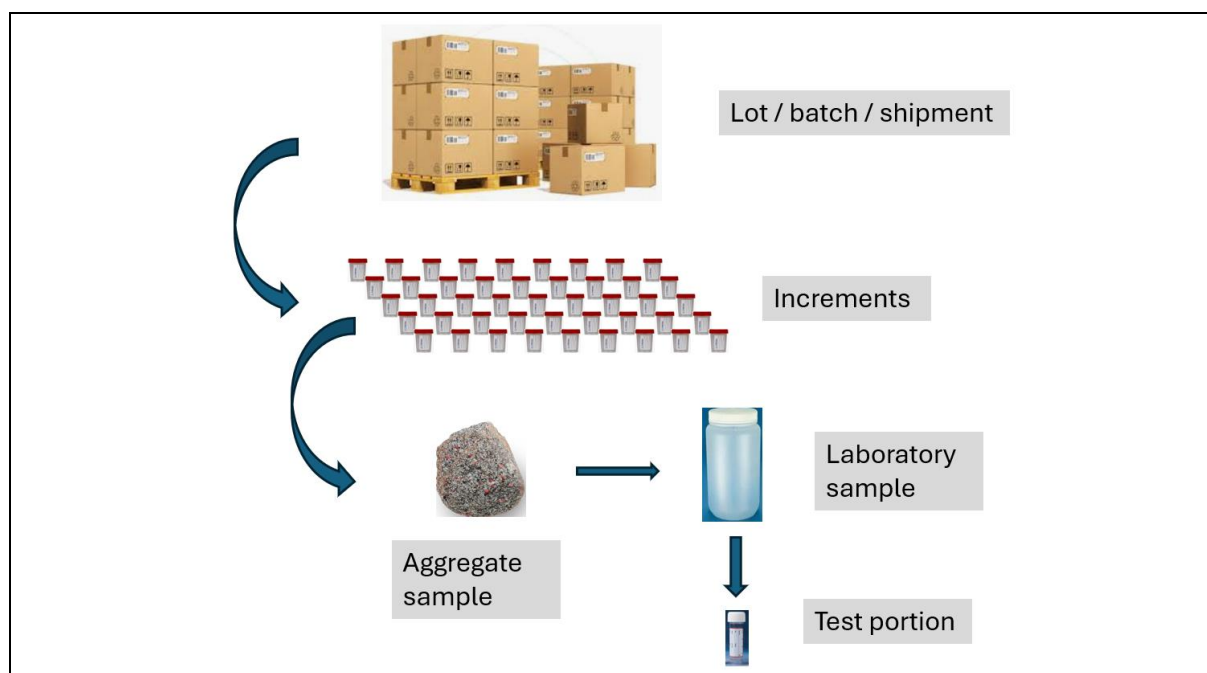
The design parameters for the acceptance sampling plan are as follows (see diagram below):

- Laboratory sample size – ns [kg]
This is converted to the number of kernels/particles via multiplication with count number per kg)
- Number of laboratory samples – scnt [#]
This allows attribute-like sampling plans with c = 0, i.e. all laboratory samples must meet the acceptance criterion
- Test portion size – nss [g]
Each laboratory sample is comminuted and a small test portion is taken from the comminuted laboratory sample
- Number of aliquots – na [#]
Final test result = mean across aliquots

¹⁰ A comprehensive list of Whitaker's scientific publications can be found here:

<https://mycotoxinresearch.wordpress.ncsu.edu/whitaker-publication-list/>

¹¹ The authors gratefully acknowledge Whitaker's numerous and valuable contributions to bulk sampling for mycotoxins which the future work proposed in the present discussion paper intends to build upon.

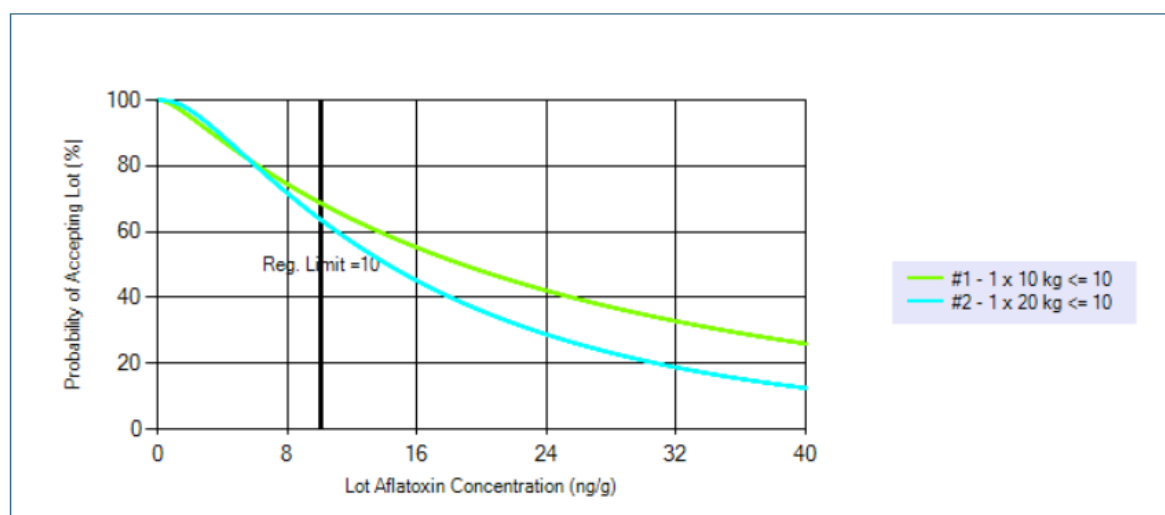
Figure 1: Bulk sampling stages

For a given mycotoxin, commodity and plan, the tool provides a variance analysis and OC curve.

For example, for aflatoxin in shelled almonds, and for one aliquot taken from one 100 g test portion taken from a 10 kg or a 20 kg laboratory sample, the OC curves are as follows.

Figure 2: OC curve from the FAO mycotoxin sampling tool. The green curve corresponds to a 10 kg laboratory sample and the blue curve to a 20 kg laboratory sample.

Probability of Accepting Lot of Almonds, Shelled (%) for various lot concentrations using sampling plans described in the Edit Plans Tab. For a complete description about operating characteristic curves see Sections 1.2 and 2.3 in the User Guide.



Note that at a mean lot aflatoxin concentration of 24 ng/g the probability of acceptance decreases from around 40% to less than 30% as the laboratory sample size is doubled. (For shelled almonds, CXS 193 requires a 20 kg laboratory sample size.)

Our comments on the tool:

- The tool does not allow the number of increments to affect the performance of a given plan. This makes it difficult to calculate the risks associated with a plan from, say, CXS 193.
- There is thus an inconsistency between the FAO tool and CXS 193, even though the plans in the latter are ostensibly based on the variance components which feed the calculations of the former.

5.3 Experimental basis

The calculations in the tool are based on a variance components model with pre-calculated estimates. The experiments and the calculations underlying these estimates are described in a series of scientific publications, see for example [11][13][14][15][16]¹². In order to shed some light on the estimation for the variance components, the design for aflatoxin (B₁, B₂, G₁ and G₂) in shelled corn will be briefly described, see Johansson et al. [15].

Test results from 18 lots (from 8 counties in North Carolina) suspected of being contaminated with aflatoxin were available.

There are three variance components: s_{sampling} , $s_{\text{sub-sampling}}$ and $s_{\text{analytical}}$. These three components are briefly described in the following table.

Table 2: Variance components

Variance component	Description
s_{sampling}	Random differences from one laboratory sample to another
$s_{\text{sub-sampling}}$	Random differences from one test portion to another (after the laboratory sample is comminuted). This component is also called the sample preparation component.
$s_{\text{analytical}}$	Random differences from one aliquot of test portion extract to another

The total variation is then obtained as

$$s_{\text{total}}^2 = s_{\text{sampling}}^2 + s_{\text{sub-sampling}}^2 + s_{\text{analytical}}^2$$

Subsampling and analytical events are conveniently combined via

$$s_r^2 = s_{\text{sub-sampling}}^2 + s_{\text{analytical}}^2$$

The variance components were estimated via two experiments.

Experiment 1

One sample (≈ 45 kg) was taken from each lot and divided into 32 test samples (≈ 1.13 kg per test sample). Each test sample was then comminuted and 50 g subsamples were taken¹³. Note that, translating this to the terminology of CXS 193, this means that

- the ≈ 45 kg sample plays the role of the composite or aggregate sample
- The (comminuted) 1.13 kg “test samples” play the role of the (comminuted) laboratory sample
- and the 50 g “subsamples” play the role of the test portion.

It should also be noted that the aim of the study was not to characterize the mean aflatoxin concentration of the lots. For this reason, questions such as whether the 45 kg sample is an aggregate sample and, if so, how many incremental samples were taken are not relevant to the study. Nonetheless, the lack of information on how the division of the 45 kg samples was performed as well as on how the subsampling from the 1.13 kg comminuted “test samples” was performed (i.e. equipment and procedure) constitute a limitation insofar as readers cannot judge whether these division/subsampling would result in a bias.

These data were used to calculate s_{total} and s_r . The sampling component was then obtained via

$$s_{\text{sampling}}^2 = s_{\text{total}}^2 - s_r^2$$

Experiment 2

Ten of the 50 g subsamples from experiment 1 were chosen. For each subsample, 15 replicate test results were obtained in order to calculate $s_{\text{analytical}}$.

The sub-sampling component was then obtained via

¹² A comprehensive list of Whitaker's scientific publications can be found here: <https://mycotoxinresearch.wordpress.ncsu.edu/whitaker-publication-list/>

¹³ The design in experiment 1 was an unbalanced nested design. The details are not of primary concern here, so the details are only mentioned here for the sake of completeness / convenient reference. For 16 of the 32 test samples, two 50 g subsamples were taken per test sample. For the remaining 16 test samples, one 50 g subsample was taken per test sample.

$$s_{sub-sampling}^2 = s_r^2 - s_{analytical}^2$$

Note: In these experiments, the lots were chosen because it was known they were contaminated. In other words, this is not a random sample. Therefore, the data set in this publication [15] is not relevant for modeling lot to lot variation of aflatoxin content.

5.4 Variance components as a function of mean lot concentration

For a given food type and mycotoxin, variance components and mean concentration were calculated for each lot. Then, separately for each variance component, a mathematical expression for the relationship between mean concentration and variance was then determined. This required the estimation of two parameters for each variance component, via a linear regression calculation performed on the basis of the following assumption:

$$\text{Variance} = a \cdot c^b \quad \text{Assumption 1}$$

where c denotes the mean lot concentration.

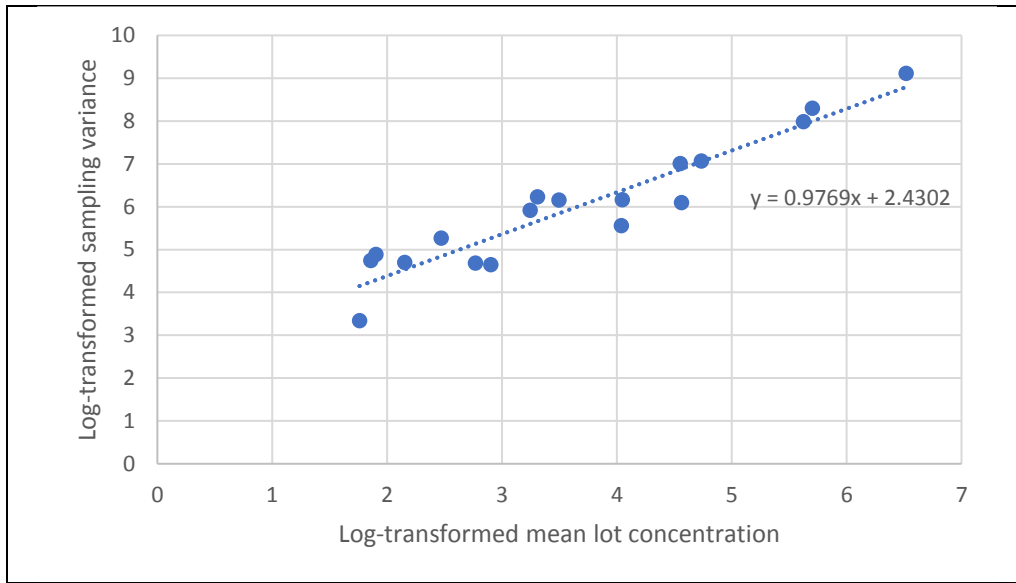
Indeed, on the basis of this assumption, we have

$$\log(\text{Variance}) = \log(a) + b \cdot \log(c) \quad \text{Equation 1}$$

In other words, Assumption 1 means that, on the logarithmic scale, variance is linearly related to concentration.

The following diagram shows a log-log plot for the sampling variance calculated from the 18 lots for aflatoxin in shelled corn.

Figure 3: Log-log plot for the sampling variance component for aflatoxin in shelled corn.



As can be seen from the above diagram, we have

$$\log(a) \approx 2.43 \text{ (and thus } a \approx 11.36)$$

and

$$b \approx 0.98$$

which is the value given in Equation 7 in the publication:

$$s_{sampling}^2 = 11.36 \cdot c^{0.98}$$

Our criticism of this approach is as follows:

- Let $s(c)$ denote the standard deviation at concentration c , let $RSD(c)$ denote the relative standard deviation at concentration c and let $v(c) = s^2(c)$ denote the variance at concentration c .
- Assume, as above, that $v(c) = a \cdot c^b$
- We then have $RSD(c) = \sqrt{a \cdot c^{b-2}}$

- For $b \approx 1$ (as above), this simplifies to $RSD(c) = \sqrt{\frac{a}{c}}$. This relationship does not fit well with the data (see Table 3, below).
- For $b \approx 2$ (as is the case for many of the estimates for the analytical component), this simplifies to $RSD(c) = \sqrt{a}$, i.e. a constant relative SD. This is not what is usually observed for the analytical component, where the RSD is typically higher at lower concentrations.
- The regression estimates depend on estimates of variance which are themselves subject to high statistical uncertainty.
- It is unrealistic to assume that these regression estimates—obtained on the basis of limited data—can be extrapolated to all data sets for a given food type and mycotoxin.

The following table allows a comparison of observed versus modelled ($s_{sampling}^2 = 11.36 \cdot c^{0.98}$) sampling RSD and variance values for the 18 lots for aflatoxin in shelled corn.

Table 3: Comparison of observed versus modelled sampling variance and RSD values for aflatoxin in shelled corn

Lot	Mean	Sampling variance		RSD	
		observed	modelled	observed	modelled
1	5,8	28,2	63,3	91,6%	137,1%
2	6,4	114,7	69,7	167,3%	130,4%
3	6,7	131,8	72,9	171,3%	127,4%
4	8,6	109,4	93,0	121,6%	112,1%
5	11,8	193,0	126,7	117,7%	95,4%
6	15,9	108,4	169,5	65,5%	81,9%
7	18,2	103,9	193,4	56,0%	76,4%
8	25,6	371,9	269,9	75,3%	64,2%
9	27,3	508,2	287,4	82,6%	62,1%
10	32,9	469,5	344,9	65,9%	56,4%
11	56,7	258,9	587,0	28,4%	42,7%
12	57,1	474,8	591,0	38,2%	42,6%
13	94,7	1106,8	968,9	35,1%	32,9%
14	95,6	444,5	977,9	22,1%	32,7%
15	113,8	1173,6	1159,4	30,1%	29,9%
16	276,9	2933,3	2763,9	19,6%	19,0%
17	298,9	4012,7	2978,3	21,2%	18,3%
18	676,6	9096,1	6616,3	14,1%	12,0%

Note: Figure 10 in [19] provides a comparison of modelled versus observed variance components for DON in wheat (bars B versus bars C).

Our final—and perhaps most important—criticism is that the linear relationship in the log-log domain (log variance plotted against log mean) is an artefact of the log transformation itself. In order to clarify this, we start by rewriting the variance in terms of the relative standard deviation (RSD):

$$\text{Variance} = (RSD \cdot c)^2$$

Hence, we have

$$\log(\text{Variance}) = 2 \cdot \log(RSD) + 2 \cdot \log(c)$$

If we write $a = 2 \cdot \log(RSD)$, we thus obtain

$$\log(\text{Variance}) = a + 2 \cdot \log(c)$$

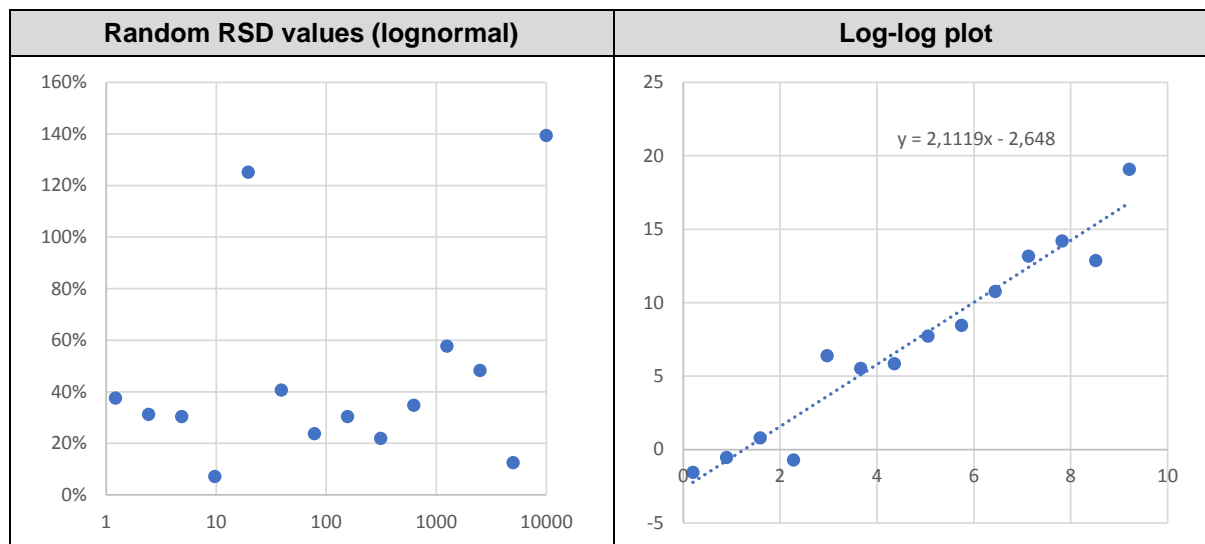
i.e. the very linear relationship which, in the Whitaker approach, is considered an empirically observed property of the data. Note that the slope is 2 independently of the value of RSD.

This can be seen in the following data set, where the RSD values are randomly generated as

$$RSD = 0.3 \cdot e^{0.8 \cdot z} \text{ with } z \sim \mathcal{N}(0,1)$$

The following figure provides the RSD values plotted against concentration along with the log-log plot. As can be seen, in the log-log domain, a linear relationship is observed even though the RSD values are lognormal random variates with no relationship whatsoever to the concentration.

Table 4: Random RSD values and log-log plot (log of the variance plotted against the log concentration). The linear relationship is clearly a mere artefact of the transformation rather than a property of the data.



In summary:

- The linear relationship in the log-log domain is an artefact of the transformation rather than a property of the data.
- The transformation will lead to a slope of 2

Note: the slope values for the sampling and sample preparation variances obtained via linear regression in the Whitaker approach differ from the value 2, see Table A in Annex II of the FAO tool User Guide [4]. The slope values of the analytical variance are often very close to 2.

5.5 Taking laboratory sample size into account

In the study described in the Johansson et al. article (see Section 5.3), the test sample size (corresponding to the laboratory sample size in CXS 193) was $m_0 \approx 1.13$ kg.

Let $s_{sampling,0}^2$ denote the sampling variance associated with laboratory sample of size m_0 .

The authors propose to take different laboratory sample size values into account as follows:

$$s_{sampling}^2 = \left(\frac{m_0}{m}\right) \cdot 11.36 \cdot c^{0.98} \quad \text{Equation 2}$$

where m denotes the laboratory sample size, expressed in kg. The rule expressed in Equation 2 is based on the assumption that if a sample of mass $m = k \cdot m_0$ is taken, then $s_{sampling}^2 = \frac{s_{sampling,0}^2}{k}$.

In ANNEX I of the User Guide of the FAO mycotoxins sampling tool [4], it is stated that “... statistical theory states that if you double sample size, the variance is reduced by half.”

As already discussed in Section 2, this assumption is not appropriate for inhomogeneous lots.

5.6 Probability of acceptance and OC curve

The calculation of the probability of acceptance is described in Section 7.3 and Section 7.4 of **ANNEX I – Theoretical Basis of Mycotoxin Sampling Tool** of the User Guide of the FAO mycotoxin sampling tool [4].

Of particular interest are the following quotes from Section 7.3:

To calculate an OC curve, it is important to be able to describe the mycotoxin distribution among individual particles in a bulk lot. However, it is too expensive and time consuming to measure the mycotoxin concentration among individual particles in a lot because it would take a very large number

of particles to construct the mycotoxin distribution among individual particles for a given lot concentration. If only one particle per 1000 particles is contaminated, one would have to measure hundreds of thousands of particles to describe the particle-to-particle mycotoxin distribution. Most of the particles would test less than the limit of detection of the analytical method.

Sampling studies—Whitaker et al. [13] and Whitaker et al. [14]—concerned with the detection of aflatoxin in shelled peanuts indicated that the aflatoxin distribution among laboratory samples taken from a given lot was not symmetrical, but was positively skewed. The experimentally determined mycotoxin distribution among the replicated sample test results (called the observed distribution) had a long tail to the right of the mean, the mean was greater than the median, and the variance was greater than the mean. One theoretical distribution, the negative binomial (NB), stood out among skewed distributions as a good candidate to simulate the characteristics mentioned above in the observed sample to sample distribution—Whitaker et al. [13]. The NB is a skewed distribution that allows for a high probability of low counts (particles with little to no mycotoxin) and a low probability of high counts (particles with high levels of a mycotoxin), and the variance has to be greater than the mean. The NB is also used to describe the distribution among particles where contagion is an issue.

A very useful characteristic of the NB distribution is that if the particle to particle distribution is NB with parameters mean c , variance s^2 , and shape parameter k , then the sample to sample distribution is also NB with parameters $n \cdot c$, $n \cdot s^2$, and $n \cdot k$ where n is number of particles in each sample. This characteristic of the NB distribution allows one to measure the variance and mean among replicate samples of size n [number of particles] and then compute the particle-to-particle distribution using the sample size n as a scale transformation. This is like having a statistical microscope to characterize the particle-to-particle distribution after measuring the sample-to-sample distribution—Whitaker et al. [13].

Note that the use of a single distribution to characterize the entire lot (here: the NB distribution) is not consistent with the consideration of inhomogeneous lots, see Section 2.

A specific example will now be considered. In CXS 193, the maximum level (ML) for aflatoxin (AFB1+AFB2+AFG1+AFG2) in maize grain (destined for further processing) is **15 µg/kg** in lots of at least 0.5 tonnes. The acceptance sampling plan is as follows (see Annex VI):

Laboratory sample size	Increment size	Test portion size
At least 5 kg	100 g	25 g

In the FAO mycotoxin sampling tool, the same plan is specified as follows:

Mycotoxin and commodity	Aflatoxin, corn, shelled (3000 kernels per kg)
Regulatory limit [ng/g]	15
Analytical variance type	Within lab
Laboratory sample size [kg]	5
Number of laboratory samples	1
Test portion size [g]	25
Number of aliquots	1
Accept / reject limit [ng/g]	15

In the tool, the variance at the regulatory limit (15 ng/g) is calculated as

Source	Variance [µg ² /kg ²]
Sampling	36.48
Sample preparation	78.16
Analysis	3.31
Total	117.95

The following table provides probabilities of acceptance values for three mean aflatoxin concentration levels, calculated

- via the FAO tool
- with the NB distribution
- with the compound gamma distribution

As can be seen, all the values agree quite well. Deviations are possibly due to the computational procedures used in the tool.

Table 5: Probability of acceptance values according to the FAO tool, the negative binomial model and the compound gamma model

Mean aflatoxin concentration in lot [ng/g]	Probability of acceptance [%]		
	FAO mycotoxin sampling tool	Statistical software (NB distribution)	Statistical software (compound gamma distribution as described in Johansson et al. [16])
5	93.61	94.14	93.39
15	59.62	60.77	56.26
30	17.16	18.55	18.39

6 Consumer and producer risks of CXS 193 plans

Underlying the CXS 193 plans and the Whitaker approach lies the tacit assumption that a certain level of risk is not exceeded. However, nowhere is it stated exactly what level of consumer's risk and what level of producer's risk are deemed acceptable. Accordingly, insofar as a risk-based approach is applied, the first step would be to state what risk levels are considered acceptable.

The main issue, however, is that the FAO tool cannot be used to calculate the risks of the CXS 193 plans correctly since the number of increments is not taken into account. For this reason, an R shiny tool was developed. Inhomogeneity within the lot and the number of increments of the acceptance sampling plan can be taken into consideration explicitly in the calculation of acceptance probabilities via consideration of the following four parameters (see Section 2):

- The proportion of contaminated subdivisions¹⁴ within the lot (considering that the entire lot is divided into increment-sized subdivisions). This parameter can also be referred to as the *expected* proportion of contaminated increments.
- Variation in mean concentration between contaminated increment-sized subdivisions
- The variation in the proportion of contaminated kernels¹⁵ within a contaminated increment
- The variation in concentration between contaminated kernels

This information is needed in order to correctly calculate the risks.

In order to illustrate this, we consider once again the acceptance sampling plan for maize grain (destined for further processing) from CXS 193.

¹⁴ A contaminated subdivision is a subdivision whose mean concentration > LOQ

¹⁵ A contaminated kernel is a kernel with nonzero mycotoxin content

The parameters for the calculation were as follows:

Table 6: Parameters for the calculation of the probability of acceptance. The values for the variation between increments, the variation between kernels and the fraction of contaminated kernels are somewhat arbitrary¹⁶.

ML	15 µg/kg
Number of kernels per kg	3000
Lot size	25 tonnes
Laboratory sample size	5 kg
Number of increments	50
Increment size	100 g
Variation between increments (SD in natural log domain)	1
Variation between kernels (SD in natural log domain)	1
Fraction of contaminated kernels	Mean fraction across contaminated increments = 2 %, varying between 1% and 10% (90% prediction interval)
Test portion size	25 g
Comminution factor	1000 particles per kernel

The following table provides probability of acceptance values for different lot concentration and proportion of contaminated increment values. These can be compared with the values in

Table 5.

Table 7: Probability of acceptance values for different values for the lot concentration and the proportion of contaminated increments

Lot concentration [µg/kg]	Proportion of contaminated increments [%]	Acceptance probability [%]
5	0.1	95.6
15		95.2
30		94.8
5	1.0	89.6
15		74.3
30		64.1
5	10.0	98.0
15		60.9
30		26.1
5	100.0	100.0
15		54.6
30		0.0

Admittedly, a 0.1% proportion of contaminated increments is lower than expected (see Annex A for a selection of descriptions of inhomogeneity from the literature). Nonetheless, it is important to note that, in such a scenario, the lot will be accepted with a high level of probability no matter how high the mean concentration in

¹⁶ The future work proposed in the present discussion paper will include a much more detailed consideration of such prior information as input in risk or utility calculations, and of how to derive ranges of parameter values which are consistent with available data.

the lot. Furthermore, it should be noted that 100% proportion of contaminated increments corresponds to the case that the lot is homogeneous, so that a more classical statistical approach can be applied (such as the one implemented in the FAO tool).

The model described above (with the four parameters) will need to be calibrated via real-life data. This calibration will be part of the future work proposed. To this end, the preferred type of data would be increment-level data; however, in the absence of such data, composite-level data can be used to derive a realistic approximation.

7 Utility approach

7.1 Description of the approach

The development of a sensible utility approach in context of bulk sampling for inhomogeneous lots is a complex topic and the present section merely seeks to provide some preliminary considerations.

Even a high number of increments (e.g. 100 increments) may be insufficient to detect small pockets of potentially harmful contamination. The actual risks associated with a given sampling plan can only be reliably evaluated on the basis of prior information regarding the variation of analyte concentration within the lot and variation across lots, i.e. using Bayesian approaches.

The availability of such prior information immediately raises the question whether acceptance sampling plans can be optimized in terms of both risk and efficiency (i.e. reducing workload and costs while maintaining acceptable risk levels). This is addressed via the utility approach.

The definition of utility is as follows:

Utility for a lot which has been **accepted** = benefit associated with an accepted lot

minus damages¹⁷

minus testing and sampling costs

Utility for a lot which has been **rejected** = **minus** testing and sampling costs

Damages might include commercial losses, negative health impacts, costs associated with disputes and reputational loss. It should be noted that the calculation of the utility takes account of all scenarios encapsulated via the statistical codification of the prior information and is more accurately termed a calculation of “expected utility.”

Different damages functions can be specified, depending on the degree to which lot inhomogeneity should be penalized in the utility function. Depending on the prior information, the choice of damages function and the cost structure, the utility approach may result in plans such as “reject lot without inspection,” or, at the other extreme, plans requiring only few increments.

There is an additional issue that can be addressed by a utility-based approach: a purely risk-based framework only considers whether the mean exceeds the limit or not. A utility-based framework, by contrast, does not rely on this simple “exceedance” versus “no exceedance” distinction, but also considers the magnitude of any exceedance—for example, whether the subplot mean is ten times the limit or only 10% above it. This aspect becomes particularly important when there is considerable inhomogeneity within the lot.

Prior information is needed to develop plans based on the utility approach. Any such plan will thus display some sensitivity to the choice of parameters / prior information. The future work contemplated in the present discussion paper will include a characterization of this sensitivity.

7.2 Example

Consider the following scenario for aflatoxin concentration in lots of peanuts

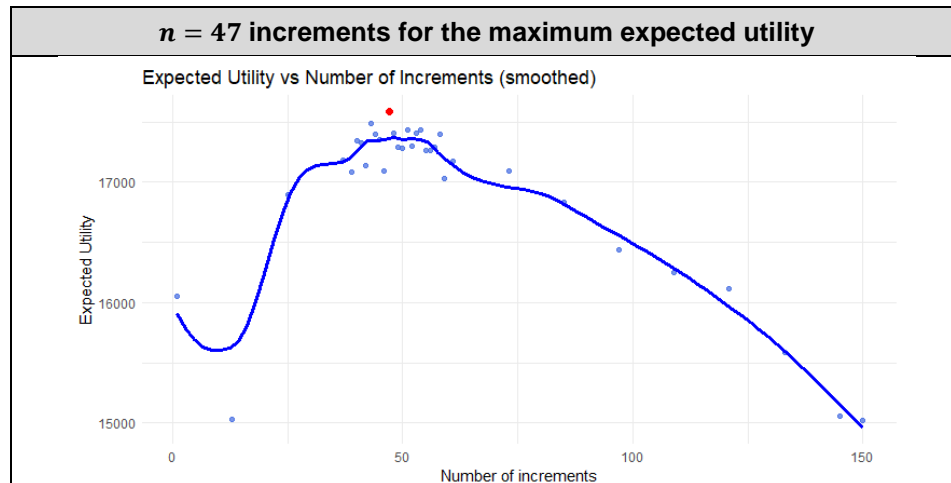
- Lot size: 50 tonnes
- Prior information regarding the variation of aflatoxin concentration between lots: lognormal distribution with mean concentration 10 µg/kg and with standard deviation (in the ln domain) 0.8 ln µg/kg.
- Prior information regarding the proportion of contaminated increments in a lot: 3%

¹⁷ In order to calculate the damages, we may require prior information regarding the variation of analyte concentration throughout the lot.

- Prior information regarding the variation of aflatoxin concentration between contaminated increments within a lot: lognormal distribution with standard deviation (in the ln domain) $0.3 \ln \mu\text{g/kg}$.
- Benefits per kg are $B = 1$ ($B = 1$ means that the sampling and test costs are expressed relatively to B)
- Sampling costs per increment are $C_S = 40 B$
- Test costs are $C_T = 200 B$

The following diagram provides a utility curve for this scenario calculated with the following damages function

Damages at concentration x is $\frac{x}{M}$ where M denotes the maximum level



8 Glossary

This section provides definitions for the main terms used in this paper. As far as possible, the terminology and definitions are consistent with those in ISO 17025, ISO 11648 and CXG 50.

Maximum level (ML)	A maximum level (ML) is a legally enforced upper limit for the concentration of a harmful fungal toxin (like aflatoxin, DON, patulin) in food and feed, set by regulatory bodies (e.g., EU regulations, Codex Alimentarius) to protect public health, based on toxicological risk assessments and intended to be as low as reasonably achievable (ALARA) while allowing safe trade.
Consumer	The term consumer denotes the party which purchases the lot and may apply to the importing country or to any operator in the food supply chain who purchases the lot, whether for further processing or for distribution or sale
Producer	The term producer denotes the party which sells the lot and may apply to a range of different operators in the food supply chain such as grower, supplier, exporting country, etc.
Consumer's risk (CR)	The probability of acceptance when the quality level of the lot is unsatisfactory (e.g. the mean concentration in the lot is greater than ML)
Producer's risk (PR)	The probability of non-acceptance when the quality level of the lot is acceptable (e.g. the mean concentration in the lot has a value less than the ML).
Bulk material	Amount of material within which component parts are not initially readily distinguishable on the macroscopic level
Lot (bulk material)	Quantity of bulk material under consideration for which specific characteristics are to be determined
Sublot (bulk material)	Definite part of a lot of bulk material to which a bulk sampling plan is applied (if the lot is too large)
Segment	Broader subdivision with the lot or sublot under inspection.
Sampling variance	Variation between laboratory samples, i.e. between laboratory sample-specific mean concentration values
Inhomogeneous lot	A lot in which the sampling variance depends on the number of increments rather than on the laboratory sample size.
Acceptance sampling	lot inspection in which decisions are made to accept or not to accept a lot based on the results of a sample or samples selected from that lot
Acceptance sampling plan	combination of requirements regarding the number of increments, the laboratory sample and test portion size, along with a lot acceptance criterion
Bulk sampling	Acceptance sampling for lots consisting of bulk material (rather than discrete items)
Bulk sampling plan	Acceptance sampling plan for lots consisting of bulk material (rather than discrete items)
Increment	amount of bulk material taken in one action by a sampling device
Incremental sample	
Aggregate sample	aggregation of two or more sampling increments taken from a lot
Composite sample	for inspection of the lot
Laboratory sample	subsample of the aggregate sample, which is sent to the laboratory for homogenization and testing
Test portion	part of the homogenized laboratory sample which is used for testing or for analysis at one time

Comminution	process in sample preparation whereby the particle size is reduced by crushing, grinding or pulverization
Comminution factor	Factor by which particle size is reduced in the comminution process

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9 Annex A: Characterization of inhomogeneity in the literature

Many authors have provided indications regarding the level of variation of local mycotoxin concentration within a lot. This section provides a compilation.

From Section 7.3 of **ANNEX I – Theoretical Basis of Mycotoxin Sampling Tool** of the User Guide of the FAO mycotoxin sampling tool [4]:

Research indicates that a very small percentage (less than 1%) of particles in a bulk lot is contaminated and that the mycotoxin concentration on individual contaminated particles can vary from low levels to extremely high levels. For example, Shotwell [7] and Cucullu [8] observed aflatoxin levels as high as 4×10^5 , 1×10^6 , and 5×10^6 ng/g on a single corn kernel, a single peanut kernel, and a single cotton seed, respectively.

From Coker et al. [9]:

It is evident [...] that systematically collected 100 g incremental samples of hand-picked selected (HPS) peanut kernels can contain as much as 200 times the mean aflatoxin content of the batch.

From Cucullu et al. [9]:

[...] contamination in a few unevenly distributed kernels could have caused this variability between subsamples. [...] As an example, individual assays of 50 slightly wrinkled peanuts from the seed stock showed that one peanut contained 1200 ppb aflatoxin B1 and 4 had only trace amounts and the rest were negative.

From Tittlemier and Whitaker [11]:

Mycotoxin testing is often used in trade to determine compliance with MLs. However, it is challenging to relate an analytical test result from a sample back to the volume from which it was taken because of the distributional and constitutional Inhomogeneity (Esbensen, 2020) of grain. Mycotoxin concentrations in a volume of commodities can vary with position (i.e. spatial distributional Inhomogeneity), particularly with localised fungal infections, such as those observed in damaged, less dense cereal grain kernels that contain higher concentrations of mycotoxins (Biselli *et al.*, 2008; Shotwell *et al.*, 1974; Tittlemier, 2022). Constitutional Inhomogeneity, as displayed in kernel to kernel, etc., differences in mycotoxin concentration, can span multiple orders of magnitude (Chavez *et al.*, 2022; Tittlemier, 2022; Trucksess *et al.*, 2009) and also complicate testing.

From Tittlemier et al. [12]:

[...] OTA is a particular challenge to analyse in many bulk commodities, including raw grains such as wheat, due to its inhomogeneous distribution throughout the bulk wheat mass.

This Inhomogeneity manifests itself in two ways. Firstly, via localised areas of elevated concentrations in bulk lots of wheat. This distributional Inhomogeneity was effectively demonstrated in a study by Biselli *et al.* (2008) in which a 26 tonnes lot of wheat in a truck was manually sampled and incremental and aggregate samples were analysed for OTA. A coefficient of variance of 200% was obtained from the incremental sample results and the OTA concentration determined in the aggregate sample did not agree with the averaged OTA concentration in the incremental samples.

In addition to the distributional Inhomogeneity, OTA concentrations amongst individual kernels of grain can also vary widely. This variation has been referred to as intrinsic Inhomogeneity. Differences in OTA concentrations measured on individual wheat kernels can span over two orders of magnitude (Tittlemier *et al.*, 2011; T.W. Nowicki and M.M. Roscoe, personal communication).

10 Annex B: Data basis

Representative data will be required in order to derive a more reliable statistical characterization of inhomogeneity in real-life lots and shipments, as required for risk and utility calculations. So far, Canada, Brazil and Germany have provided data sets which can be used to this end. The data from Canada and Brazil represent test results on aggregate samples from lots (the Brazil data are mainly from GEMS), whereas the data from Germany were obtained in monitoring programs. At the moment, no increment-level data are available.

Here is a brief overview of the data sets we have so far.

- German monitoring data: various mycotoxins and food types (2010-2025). Large data set (about 160 000 values). The measurement values were not obtained from aggregate samples from lots, but rather from sampled items from retailers. For this reason, each value can be considered to correspond to one incremental sample. Note that the sampling focus changes from year to year.
- Three data sets from Brazil (GEMS, NCO IAL and GTFC): Aflatoxin and OTA for the period 2011-2021.
- Aflatoxin in maize: very large data set (more than 1 000 000 data points)
- OTA monitoring data from Canada. Measurement values were obtained from aggregate samples representing individual consignments of raw grain, and sublots thereof. In addition, kernel-level data were recently made available.

The following tables provide a simple statistical characterization of these data sets (or subsets thereof) in terms of data size, percentage >LOD and maximum value. Where possible, mean value and standard deviation of the maximum values are provided.

In order to simplify the analysis of changes in contaminant concentrations over time, data were aggregated within three time periods:

- 2010-2014
- 2015-2019
- 2020 and after

Due to the large number of mycotoxins and food types in the German monitoring data set, only a small selection was considered for the statistical characterization in the following tables. Namely: Aflatoxin (total) and OTA, in each case 8 food types corresponding the highest values for the time periods with at least 50 data points.

It is clear from the structure of the data (many <LOD results¹⁸) that very advanced censorship-based statistical methods will be required.

¹⁸ Practice is not consistent: both LOD and LOQ are used as a limit. In nearly all cases, the actual value of LOD or LOQ is available.

Table 8: German monitoring data: Aflatoxin (total). Number of increments = 1.

Food	Time period	Number of data points	Percent > LOD	Max [µg/kg]	Mean ¹⁹ [µg/kg]	SD [µg/kg]	RSD
Brazil nut	2015-2019	112	29.5%	4.5	81.1	108.3	133.6%
	2020 and after	74	37.8%	157.7			
Date	2010-2014	105	1.0%	79.2	26.4	45.7	173.2%
	2015-2019	81	19.8%	0.0			
	2020 and after	105	14.3%	0.0			
Fig	2010-2014	714	11.8%	1329.5	677.3	922.3	136.2%
	2020 and after	109	21.1%	25.2			
Ginger	2020 and after	82	51.2%	41.9			
Hazelnut	2010-2014	87	56.3%	35.0	28.6	9.1	31.9%
	2020 and after	112	60.7%	22.1			
Kurkuma	2010-2014	56	67.9%	5.0	10.0	7.0	70.4%
	2020 and after	51	49.0%	14.9			
Peanut	2010-2014	72	4.2%	14.6	12.8	5.3	41.8%
	2015-2019	68	23.5%	16.9			
	2020 and after	106	0.9%	6.8			
Pistachio	2010-2014	101	11.9%	25.4	10.6	12.8	120.8%
	2015-2019	52	30.8%	3.7			
	2020 and after	85	17.6%	2.7			

Rest 50.7, Quinoa, 2020 and after, 48 values.

¹⁹ Where possible, mean value and standard deviation of the maximum values are provided.

Table 9: German monitoring data: OTA. Number of increments = 1.

Food	Time period	Number values	Percent > LOD	Max [µg/kg]	Mean ²⁰ [µg/kg]	SD [µg/kg]	RSD
Chickpea	2010-2014	4	0.0%		24.2	33.5	138.7%
	2015-2019	83	2.4%	0.5			
	2020 and after	73	5.5%	47.9			
Fig	2010-2014	934	26.2%	431.5	371.5	84.8	22.8%
	2020 and after	121	13.2%	311.6			
Paprika	2010-2014	120	86.7%	29.3	44.6	19.9	44.6%
	2015-2019	131	90.1%	37.4			
	2020 and after	73	84.9%	67.0			
Peanut	2010-2014	123	46.3%	49.9	17.6	28.0	159.4%
	2015-2019	81	23.5%	2.7			
	2020 and after	131	1.5%	0.1			
Pistachio	2010-2014	89	15.7%	23.3	64.9	92.4	142.4%
	2015-2019	103	6.8%	170.9			
	2020 and after	97	2.1%	0.6			
Rye	2010-2014	209	17.7%	38.4	24.3	18.9	78.0%
	2015-2019	89	41.6%	2.8			
	2020 and after	255	12.9%	31.7			
Tafelweintrube	2010-2014	1	100.0%	0.9	27.2	23.0	84.5%
	2015-2019	161	66.5%	37.4			
	2020 and after	132	46.2%	43.3			
Wheat	2010-2014	307	20.2%	31.1	12.7	16.2	127.8%
	2015-2019	249	8.0%	0.7			
	2020 and after	334	7.5%	6.2			
Rest		9890		191.5			
				(pulse, 2010-2014, just one value)			

²⁰ Where possible, mean value and standard deviation of the maximum values are provided.

Table 10: Brazil GEMS data. Aflatoxin (total). It known neither if data points represent test results from aggregate samples, nor how many incremental samples were taken.

Food	Time period	Number values	Percent > LOD	Max [µg/kg]	Mean ²¹ [µg/kg]	SD [µg/kg]	RSD
Brazil nut	2015-2019	50	32%	2.1	6.7	3.8	56.8%
Cashew nut	2015-2019	2555	3%	8.9			
Peanut, whole	2015-2019	380	22%	10.6			
Hazelnut	2015-2019	140	6%	5.2			
Maize	2015-2019	58	0%				
Rice	2015-2019	61	13%	14.1			
Rice flour	2015-2019	1781	3%	13.5			
Cereal-based products	2015-2019	94	0%				
Cocoa powder	2015-2019	79	5%	0.4			
Rest	2015-2019	121		0.6 (Fruit and fruit products)			

Table 11: Brazil NCO IAL data. Aflatoxin (total).

Food	Time period	Number values	Percent > LOD	Max [µg/kg]	Mean [µg/kg]	SD [µg/kg]	RSD
Herb. spice or condiment	2015-2019	46	65.2%	7.5			
Peanut. shelled	2010-2014	7	0.0%		276.8	109.4	39.5%
	2015-2019	46	60.9%	354.2			
	2020 and after	15	40.0%	199.4			
Rice	2010-2014	35	2.9%	3.9			

²¹ Where possible, mean value and standard deviation of the maximum values are provided.

Table 12: Brazil GTFC data. Aflatoxin (total).

Food	Time period	Number values	Percent > LOD	Max [µg/kg]
Cereal-based infant food	2015-2019	8	0.0%	
Whole rice	2015-2019	6	16.7%	0.3
Refined rice	2015-2019	6	0.0%	
Corn flour	2015-2019	15	0.0%	
Corn grains for processing	2015-2019	3	0.0%	
Mandioca	2015-2019	3	0.0%	

Table 13: Different countries. Aflatoxin (total) in maize.

Country	Time period	Number values	Percent > LOD	Max [µg/kg]
Canada	2010-2014	43	0.0%	
European Union	2010-2014	449	17.4%	27.4
	2015-2019	279	20.4%	226.0
Philippines	2010-2014	7	28.6%	14.8
Rwanda	2015-2019	1587	99.8%	207.7
Saudi Arabia	2010-2014	5	20.0%	9.9
	2015-2019	11	9.1%	5.1
Singapore	2015-2019	6	0.0%	
Thailand	2010-2014	14	0.0%	
	2015-2019	2	0.0%	
USA	2010-2014	573236	16.2%	9928.0
	2015-2019	470898	4.1%	8447.0

[I suggest combining Tables 14 and 15. These data sets together would reflect lot to lot variation.]

Table 14: Canada. OTA Cargo data. B Each value corresponds to a 10 kg laboratory sample obtained from an aggregate sample representing a systematically selected shipment. Between 200 and 800 increments per value (i.e. per aggregate sample).

Grain	Time period	Number values	Percent > LOD	Max [µg/kg]	Mean ²² [µg/kg]	SD [µg/kg]	RSD
Barley	2010-2014	30	26.7%	2.8	5.9	2.7	45.6%
	2015-2019	50	18.0%	7.3			
	2020 and after	19	21.1%	7.7			
Durum	2010-2014	36	41.7%	4.9	4.1	0.7	17.3%
	2015-2019	85	36.5%	4.0			
	2020 and after	40	15.0%	3.4			
Oats	2015-2019	41	43.9%	4.2	3.7	0.6	16.3%
	2020 and after	16	18.8%	3.3			
Wheat	2010-2014	76	39.5%	4.1	5.7	1.4	25.2%
	2015-2019	222	41.4%	6.3			
	2020 and after	90	14.4%	6.8			

Table 15: Canada. OTA cargo data. Each value corresponds to a 10 kg laboratory sample obtained from an aggregate sample representing a targeted shipment. Between 200 and 800 increments per value (i.e. per aggregate sample).

Grain	Time period	Number values	Percent > LOD	Max [µg/kg]	Mean [µg/kg]	SD [µg/kg]	RSD
Barley	2010-2014	1	0%	1.8			
	2015-2019	35	3%				
	2020 and after	17	0%				
Durum	2010-2014	106	31%	5.9	5.7	0.7	11.6%
	2015-2019	494	15%	6.3			
	2020 and after	299	13%	5			
Wheat	2010-2014	195	28%	6	6.5	1.9	29.2%
	2015-2019	1187	19%	8.6			
	2020 and after	641	14%	4.9			

²² Where possible, mean value and standard deviation of the maximum values are provided.

11 Annex C: Overview of acceptance sampling plans in CXS 193

These tables are provided here for convenient reference.

11.1 Aflatoxins (total) in peanuts

Annex III in CXS 193. ML = 15 µg/kg

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
≤1 t	No subdivision	10	2000 g	20 kg	20 kg
>1–≤5 t	No subdivision	40	500 g	20 kg	20 kg
>5–≤10 t	No subdivision	60	333 g	20 kg	20 kg
>10–≤15 t	No subdivision	80	250 g	20 kg	20 kg
>15–≤25 t	1 subplot	100	200 g	20 kg	20 kg
≥25–≤100 t	Sublots of 25 t	100 for each subplot	200 g	20 kg for each subplot	20 kg
>100–<500 t	5 sublots	100 for each subplot	200 g	20 kg for each subplot	20 kg
≥500 t	Sublots of 100 t	100 for each subplot	200 g	20 kg for each subplot	20 kg

11.2 Aflatoxins (total) in almonds, hazelnuts and Brazil nuts (shelled)**Annex IV in CXS 193. ML = 15 µg/kg**

DFP / RTE	Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
DFP	<1 t	No sublots required (≤ 25 t)	10	2000 g	≥ 20 kg	1 × 20 kg
DFP	1–<5 t	No sublots required (≤ 25 t)	25	800 g	≥ 20 kg	1 × 20 kg
DFP	5–<10 t	No sublots required (≤ 25 t)	50	400 g	≥ 20 kg	1 × 20 kg
DFP	10–<15 t	No sublots required (≤ 25 t)	75	267 g	≥ 20 kg	1 × 20 kg
DFP Also: in-shell pistachios	≥ 15 t	Sublots ≤ 25 t	100 per (sub)lot	200 g	≥ 20 kg	1 × 20 kg
RTE	<1 t	No sublots required (≤ 25 t)	10	2000 g	≥ 20 kg	2 × 10 kg
RTE	1–<5 t	No sublots required (≤ 25 t)	25	800 g	≥ 20 kg	2 × 10 kg
RTE	5–<10 t	No sublots required (≤ 25 t)	50	400 g	≥ 20 kg	2 × 10 kg
RTE	10–<15 t	No sublots required (≤ 25 t)	75	267 g	≥ 20 kg	2 × 10 kg
RTE Also: in-shell pistachios	≥ 15 t	Sublots ≤ 25 t	100 per (sub)lot	200 g	≥ 20 kg	2 × 10 kg

11.3 Aflatoxins (total) in dried figs (ready to eat)**Annex V in CXS 193. ML = 10 µg/kg**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
>10–≤15 t	No sublots required (≤15 t)	100	300 g	30 kg	3 × 10 kg
>5–≤10 t	No sublots required	80	300 g	24 kg	3 × 8 kg
>2–≤5 t	No sublots required	60	300 g	18 kg	2 × 9 kg
>1–≤2 t	No sublots required	40	300 g	12 kg	2 × 6 kg
>0.5–≤1 t	No sublots required	30	300 g	9 kg	1 × 9 kg
>0.2–≤0.5 t	No sublots required	20	300 g	6 kg	1 × 6 kg
>0.1–≤0.2 t	No sublots required	15	300 g	4.5 kg	1 × 4.5 kg
≤0.1 t	No sublots required	10	300 g	3 kg	1 × 3 kg
>15 t	Sublots of 15 t	100 for each sublot	300 g	30 kg for each sublot	3 × 10 kg

11.4 Aflatoxins (total) in maize grain (destined for further processing)**Annex VI in CXS 193. ML = 15 µg/kg**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
≥1500 t	Sublots of 500 t	100 for each subplot	100 g	≥5 kg for each subplot	≥5 kg
>300—<1500 t	3 sublots	100 for each subplot	100 g	≥5 kg for each subplot	≥5 kg
≥100—≤300 t	Sublots of 100 t	100 for each subplot	100 g	≥5 kg for each subplot	≥5 kg
>50—<100 t	2 sublots	100 for each subplot	100 g	≥5 kg for each subplot	≥5 kg
20—<50 t	No subdivision	100	100 g	≥5 kg	≥5 kg
10—<20 t	No subdivision	60	100 g	≥5 kg	≥5 kg
3—<10 t	No subdivision	40	100 g	≥5 kg	≥5 kg
1—<3 t	No subdivision	20	100 g	≥5 kg	≥5 kg
0.5—<1 t	No subdivision	10	100 g	≥5 kg	≥5 kg
>0.05—<0.5 t	No subdivision	5	1000 g (to reach ≥5 kg)	≥5 kg	≥5 kg
≤0.05 t	No subdivision	3	1667 g (to reach ≥5 kg)	≥5 kg	≥5 kg

11.5 Aflatoxins (total) in flour/meal/semolina/flakes derived from maize**Annex VI in CXS 193. ML = 10 µg/kg**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
All lot sizes	No sublots	10	100 g (10 × 100 g)	1 kg	1 kg

11.6 Aflatoxins (total) in husked / polished rice and in sorghum grain (destined for further processing)**Annex VI in CXS 193. ML = 20 µg/kg for husked rice / ML = 5 µg/kg for polished rice / ML = 10 µg/kg for sorghum grain DTE**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
≥1500 t	Sublots of 500 t	100 for each subplot	100 g	≥5 kg for each subplot	≥5 kg
>300—<1500 t	3 sublots	100 for each subplot	100 g	≥5 kg for each subplot	≥5 kg
≥100—≤300 t	Sublots of 100 t	100 for each subplot	100 g	≥5 kg for each subplot	≥5 kg
>50—<100 t	2 sublots	100 for each subplot	100 g	≥5 kg for each subplot	≥5 kg
20—<50 t	No subdivision	100	100 g	≥5 kg	≥5 kg
10—<20 t	No subdivision	60	100 g	≥5 kg	≥5 kg
3—<10 t	No subdivision	40	100 g	≥5 kg	≥5 kg
1—<3 t	No subdivision	20	100 g	≥5 kg	≥5 kg
0.5—<1 t	No subdivision	10	100 g	≥5 kg	≥5 kg

11.7 DON in cereal grains (wheat/maize/barley) destined for further processing**Annex VII in CXS 193. ML = 2000 µg/kg**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
≥1500 t	Sublots of 500 t	100 for each subplot	100 g	≥1 kg for each subplot	≥1 kg
>300—<1500 t	3 sublots	100 for each subplot	100 g	≥1 kg for each subplot	≥1 kg
≥100—≤300 t	Sublots of 100 t	100 for each subplot	100 g	≥1 kg for each subplot	≥1 kg
>50—<100 t	2 sublots	100 for each subplot	100 g	≥1 kg for each subplot	≥1 kg
20—<50 t	No subdivision	100	100 g	≥1 kg	≥1 kg
10—<20 t	No subdivision	60	100 g	≥1 kg	≥1 kg
3—<10 t	No subdivision	40	100 g	≥1 kg	≥1 kg
1—<3 t	No subdivision	20	100 g	≥1 kg	≥1 kg
0.5—<1 t	No subdivision	10	100 g	≥1 kg	≥1 kg

11.8 DON in flour/semolina/meal/flakes from wheat/maize/barley**Annex VII in CXS 193. ML = 1000 µg/kg**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
All lot sizes	No sublots	10	100 g (10 × 100 g)	1 kg	1 kg

11.9 DON in cereal-based foods for infants and young children**Annex VII in CXS 193. ML = 200 µg/kg**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
All lot sizes	No sublots	10	100 g (10 × 100 g)	1 kg	1 kg

11.10 Fumonisin (FB1+FB2) in maize grain (unprocessed)**Annex VIII in CXS 193. ML = 4000 µg/kg**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
≥1500 t	Sublots of 500 t	100 for each subplot	100 g	≥1 kg for each subplot	≥1 kg
>300–<1500 t	3 sublots	100 for each subplot	100 g	≥1 kg for each subplot	≥1 kg
≥100–≤300 t	Sublots of 100 t	100 for each subplot	100 g	≥1 kg for each subplot	≥1 kg
>50–<100 t	2 sublots	100 for each subplot	100 g	≥1 kg for each subplot	≥1 kg
20–<50 t	No subdivision	100	100 g	≥1 kg	≥1 kg
10–<20 t	No subdivision	60	100 g	≥1 kg	≥1 kg
3–<10 t	No subdivision	40	100 g	≥1 kg	≥1 kg
1–<3 t	No subdivision	20	100 g	≥1 kg	≥1 kg
0.5–<1 t	No subdivision	10	100 g	≥1 kg	≥1 kg

11.11 Fumonisin (FB1+FB2) in maize flour and maize meal**Annex VIII in CXS 193. ML = 2000 µg/kg**

Lot weight	Weight/number of sublots	Number of increments	Weight/size increments	Weight/size of aggregate sample	Weight/size of Laboratory sample
All lot sizes	No sublots	10	100 g (10 × 100 g)	1 kg	1 kg

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