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**CODEX
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INTERNATIONAL FOOD STANDARDS



CCCF19

19TH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Acceptance sampling plans for inhomogeneous
lots with an initial focus on mycotoxins

EWG Chair: New Zealand
EWG Co-Chair: Germany

Virtual pre-meeting on 9 October 2026 from 14:00 to 17:00 CEST
Supplementary material

Outline of Presentation

- Inhomogeneity
- Inhomogeneity-adjusted OC curve and utility approach
- Global producer's and consumer's risks
- Summary

Inhomogeneity

OC curves behind the CXS 193 sampling plans

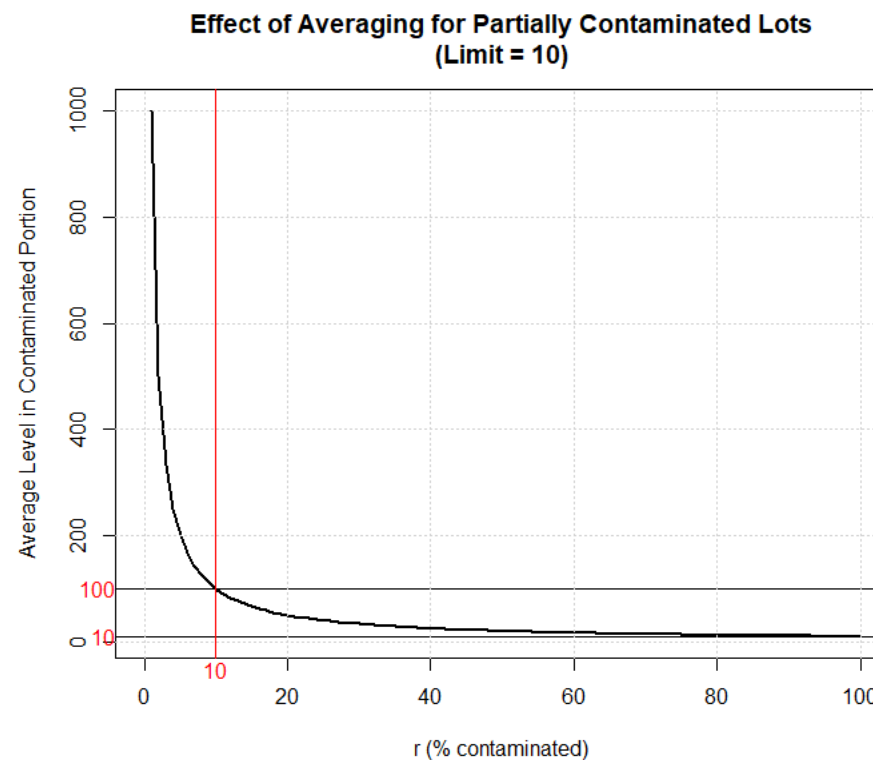
- The OC curves behind the CXS 193 plans account for the variability caused by the uneven distribution of mycotoxins among individual kernels (Whitaker et al.). They assume, however, that the lot is well mixed.
- They do not account for hotspots. Contamination may be concentrated in parts of the lot, so that most increments contain little or no mycotoxins while a few are highly contaminated.
- Even with large numbers of increments (e.g. 50 or 100), the risks of wrong decisions may therefore be considerably higher than the OC curves suggest.
- A realistic evaluation of these risks requires a model of lot inhomogeneity, in particular of the proportion of contaminated increments.
- The inhomogeneous distribution of mycotoxins, including the possible occurrence of high-contamination hotspots, is well documented (Smaoui et al., 2023).

	Lot accepted	Lot rejected
Lot is good	Correct decision	Producer's risk good lot rejected
Lot is bad	Consumer's risk bad lot accepted	Correct decision

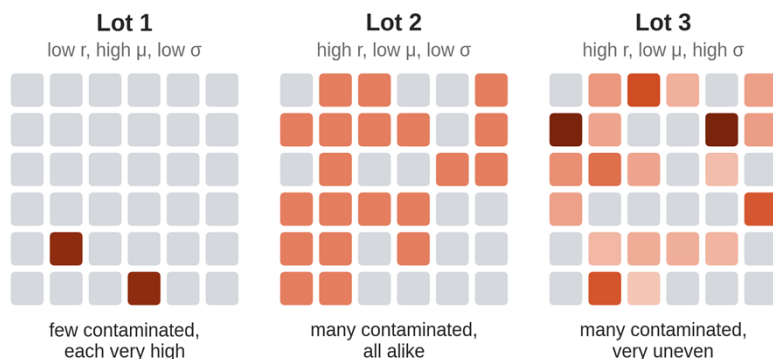
Aflatoxins Contamination in Feed Commodities: From Occurrence and Toxicity to Recent Advances in Analytical Methods and Detoxification - PMC

Risks associated with acceptance criteria based on average levels

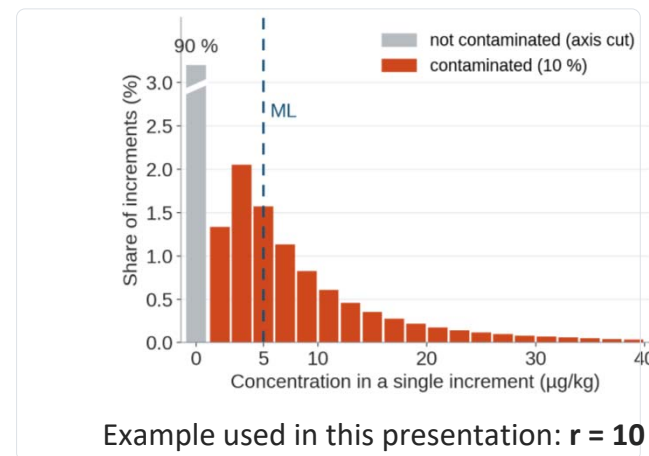
- **Lot mean of 10 ppb**
The black curve plots the mean level in the *contaminated portion of the lot* against the *percentage of contaminated increments*
- A lot “on the black curve” meets the acceptance criterion of 10 ppb for the lot mean.
- An acceptance rule based on the average level can lead to high local levels of contamination
- For example, at $r=10\%$ (percentage of contaminated increments, see vertical red line), the average level among contaminated increments is 100 ppb (see the horizontal black line).



Statistical model for inhomogeneity between increments



r — percentage of contaminated increments
 μ — mean concentration among contaminated increments
 σ — spread among contaminated increments (log scale)



Example used in this presentation: $r = 10\%$, $\sigma = 1$.
 Even a lot with mean concentration $\text{ML}/5$ contains increments with concentration $> \text{ML}$.

- The inhomogeneity model (ZILN) covers a large range of situations
- Where the laboratory sample size and the test portion size are known, the model allows explicitly accounting for kernel-level variability.
- Where this information is not available, kernel-level variability is not modelled separately but is included in the estimated inhomogeneity parameters.

Estimation of inhomogeneity parameters

Two parameters describe how a contaminant is spread across the increments within a given lot

The two inhomogeneity parameters r and σ can be estimated on the basis of

- lot- (sublot-)level data
- monitoring data
- Increment-level data would be useful – for verification of the estimation procedure.

For any given lot, subplot or sample, what we need is (in addition to the test result):

- the number of increments
- the LOD
- In addition (if possible): size of increments, laboratory sample and test portion, sampling protocol followed, etc.

The aim of data analysis

Characterizing inhomogeneity for a given combination of commodity and contaminant

For a given commodity and contaminant

- Obtain estimates for the inhomogeneity parameters, along with their confidence intervals.
- The aim is to take into consideration as many datasets as possible (different countries, years, etc.) in the estimation of the inhomogeneity parameters.
- Derive typical inhomogeneity scenarios or ranges of the inhomogeneity parameters
- Evaluate performance of existing sampling plans

Available data sets

All available data have already been statistically evaluated to characterize inhomogeneity

#	Country / source / name of data set	Contaminant (mycotoxin)	Commodity
1	Canada	OTA (Ochratoxin A)	Wheat/Durum
		DON (Deoxynivalenol)	
		EA (Ergot Alkaloids)	
2	Germany "monitoring data"	OTA	Wheat
		Aflatoxin	Various
3	USA	Aflatoxin	Maize
	EU		
4	Belgium	Aflatoxin (sum and B1)	Various
5	GEMS	Aflatoxin	Various
6	Brazil NCO_IAL	Aflatoxin and OTA	Various
7	Kenya	Aflatoxin	Maize
8	EU data complementing RASFF entries	Aflatoxin (sum and B1) and OTA	Maize

Inhomogeneity-adjusted OC curve and utility approach

Scenario

Based on OTA in wheat data from Canada

The calculations in the following slides are all based on the following scenario:

Inhomogeneity: worst-case scenario

- 10% of increments are contaminated
- Concentration of contaminated increments follows a lognormal distribution with $\sigma = 1$

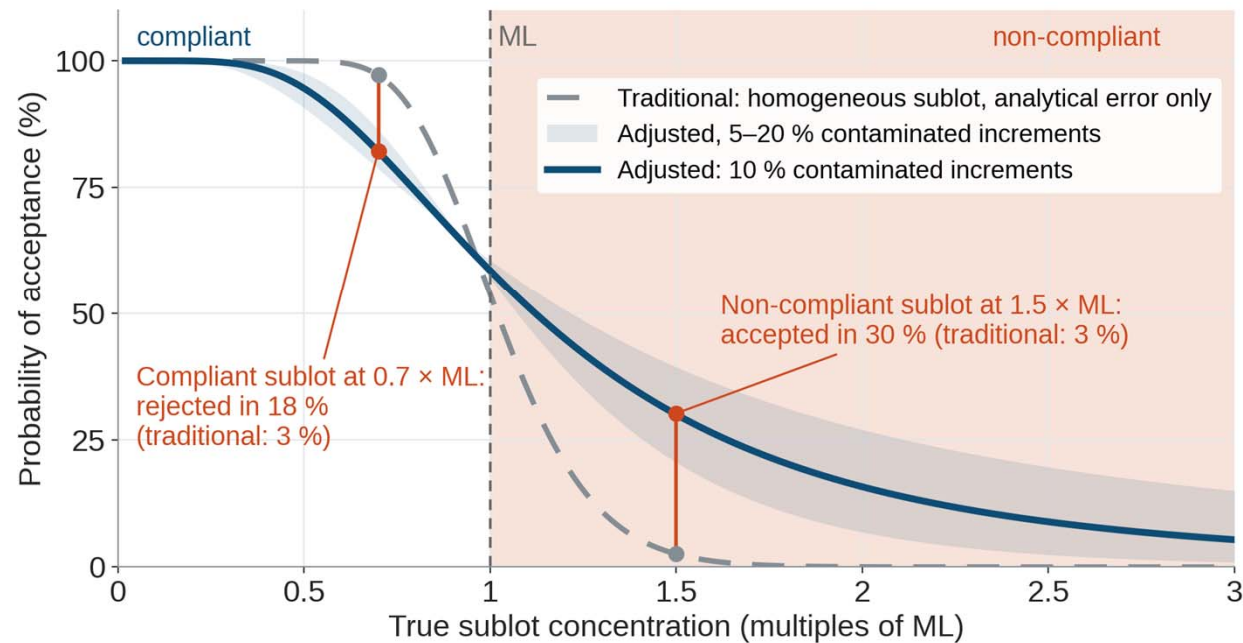
True mean concentration in the lot: optimistic scenario

- Lognormal with median = $ML/5$ (true mean concentration < ML with 95% probability)
- Variation between lots so that circa 5% of lots have a true concentration above ML

OC curve, adjusted for inhomogeneity

$$r=10\%, \sigma=1$$

OC curve for $n = 100$ increments

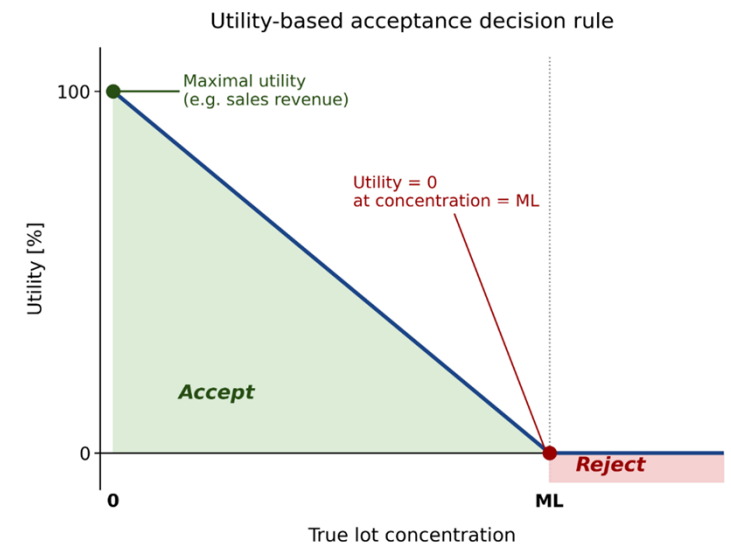


Complementing consumer's risk

Towards a utility approach

- Classical risks ignore how far the lot mean lies above or below the ML
- They should therefore be complemented by the damages caused by accepted lots.
- Assuming that damages are proportional to the true lot mean, they depend on the *mean concentration among accepted lots*.
- Utility [% lot value] = benefits – damages – costs

- benefits [% lot value] = probability of lot acceptance
- damages [% lot value] = $\beta \cdot \text{mean concentration among accepted lots} \cdot \text{probability of lot acceptance}$
 β is a slope parameter that depends on ML and on inhomogeneity
- costs [% lot value] = $g \cdot n + \text{analytical costs}$
 g is sampling costs per increment, and n is the number of increments



Utility = benefits – damages – costs

A brief overview – here the **damages** term

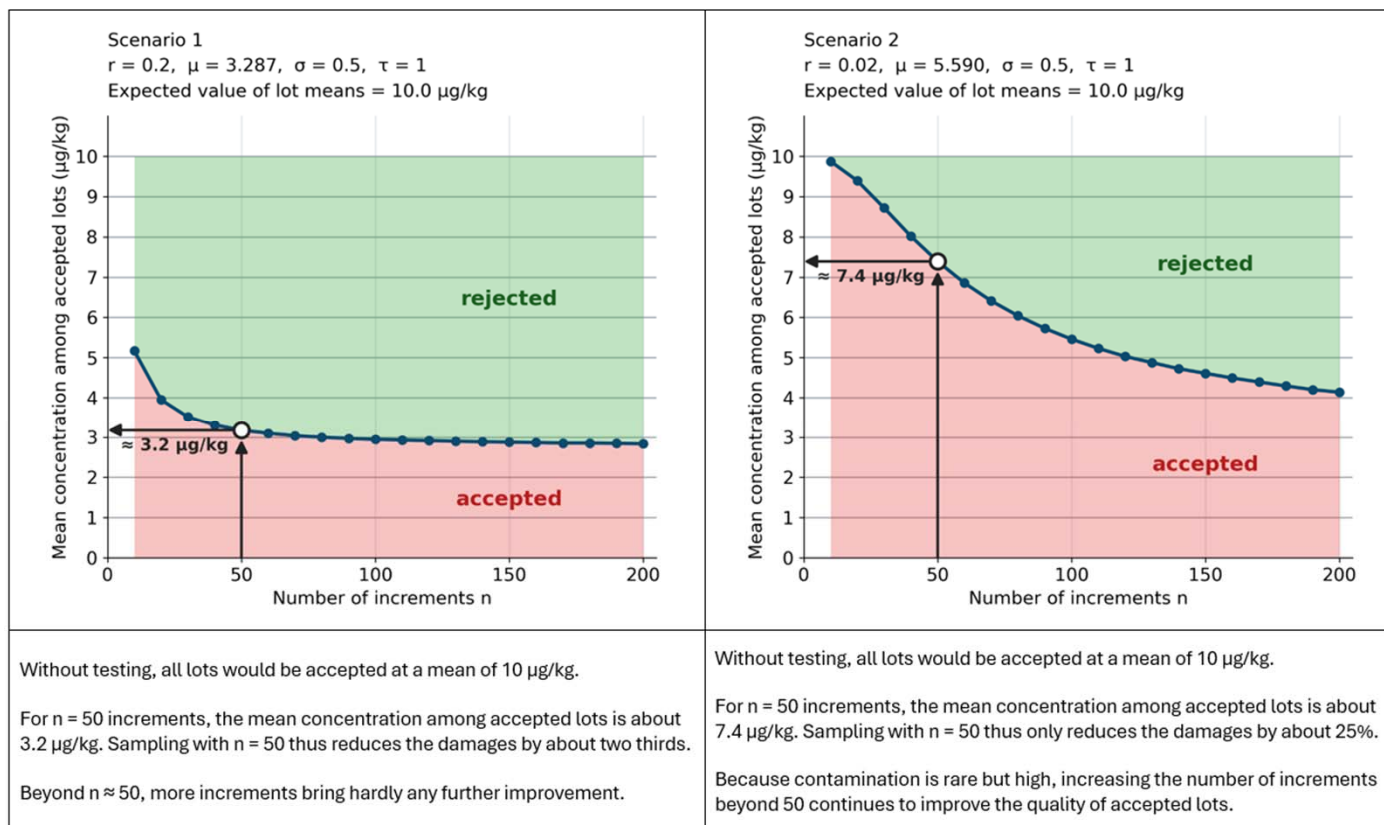
The damages depend on the *mean lot concentration among accepted lots*.

Here:

Mean lot concentration among accepted lots for two different scenarios ($r = 20\%$ versus $r = 2\%$).

Mean lot concentration among all (accepted + rejected) lots = $10 \mu\text{g/kg}$

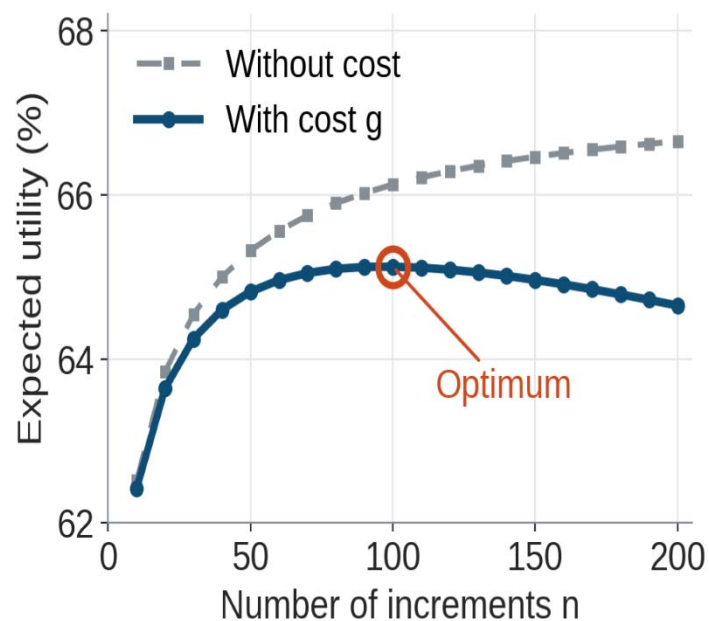
Utility is determined for a combination of contaminant and commodity and takes into account historical data.



Utility

As a function of the number of increments

Utility



- The utility approach is proposed primarily as a tool for the evaluation of plans.
- The utility approach can also be used to develop new plans
- Utility approach consists of 3 different elements
 - Utility curve
 - Inhomogeneity-adjusted OC curve
 - Global consumer's and producer's risks

Global producer's and consumer's risks

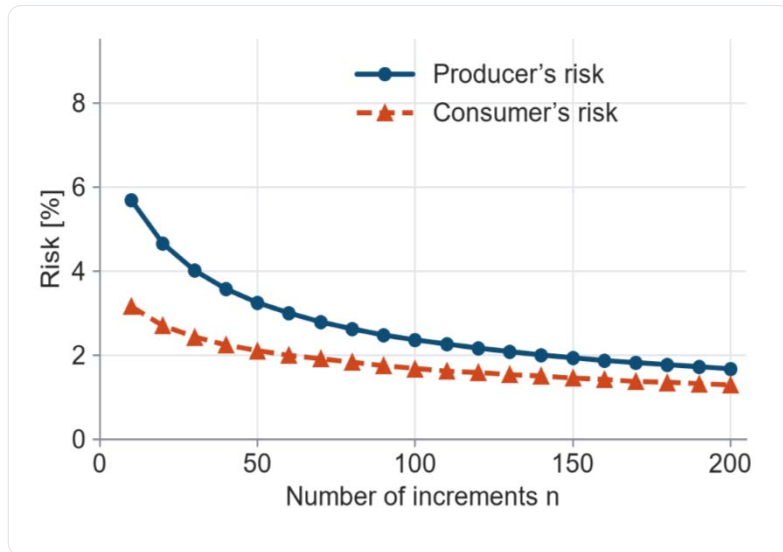
ISO risks versus global risks

ISO producer's and consumer's risks, even when adjusted for inhomogeneity, refer to a given true lot mean, which is never known. We therefore propose complementing them with global risks, calculated from distributions derived from historical data (for a given commodity and contaminant)

(Following the definitions of different risks in JCGM 106 and ISO DTR 24962.)

Global risks as a function of the number of increments

Scenario: lot concentration is below ML with 95% probability, $r=10\%$ and $\sigma=1$



Global producer's risk

Percentage of all lots which are both conforming (true mean concentration below ML) and rejected (FP)

Global consumer's risk

Percentage of all lots which are both nonconforming (true mean concentration above ML) and accepted (FN)

Without any inspection

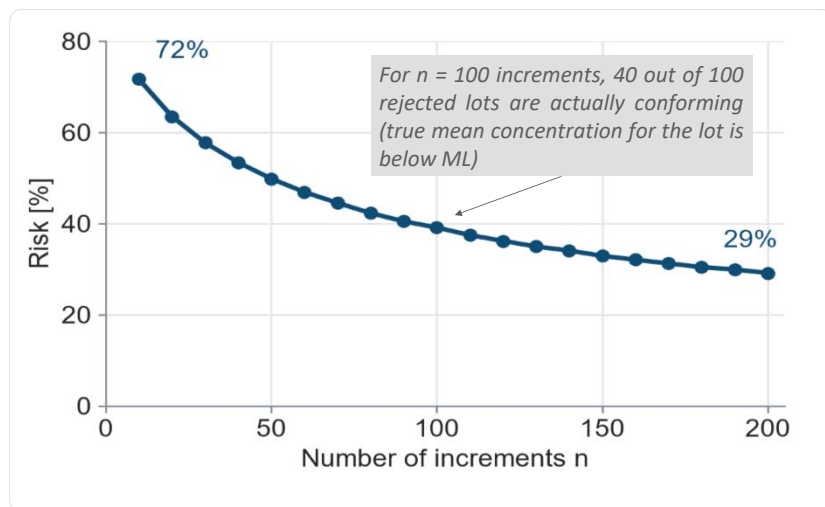
- the global producer's risk is zero (all lots — and thus all conforming lots — are accepted)
- the global consumer's risk equals the percentage of nonconforming lots, in our case circa 5%

Both global producer's and consumer's risks can be reduced by increasing the number of increments

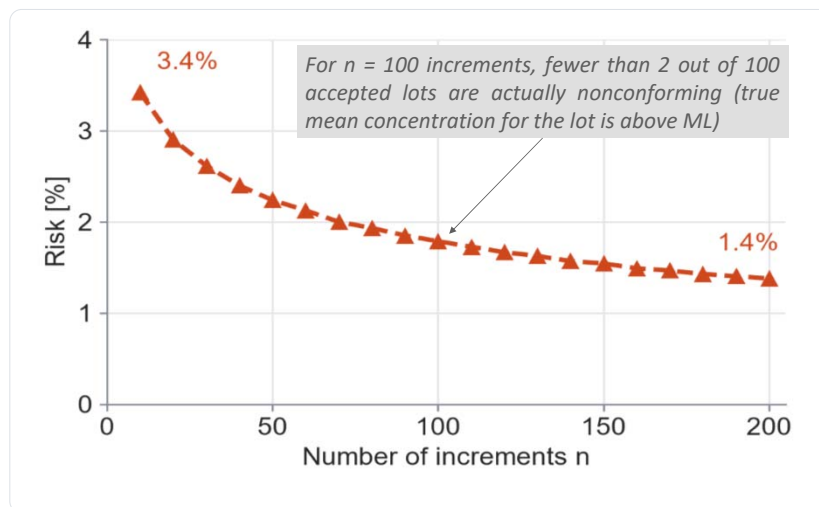
Conditional global producer's and consumer's risks

Scenario: lot concentration is below ML with 95% probability, $r=10\%$ and $\sigma=1$

Conditional global producer's risk



Conditional global consumer's risk



Note: in this scenario, there are not many lots with true mean values clearly above ML — that is why the conditional global producer's risk is so high and the conditional global consumer's risk is so low.

See ISO DTR 24962, soon to be published

Both global producer's and consumer's risks can be reduced by increasing the number of increments

Summary

Summary

- The OC curves behind the CXS 193 plans account for the variability caused by the uneven distribution of mycotoxins among kernels (Whitaker et al.), but assume a well-mixed lot and do not account for hotspots. We propose inhomogeneity-adjusted OC curves instead.
- The utility approach is proposed primarily for evaluating existing sampling plans (e.g. number of increments, increment sample size and test portion size). The utility is determined for a combination of commodity and contaminant. For commodity–contaminant combinations not yet covered, it can also support the design of new plans, which could be considered by CCCF for inclusion in CXS 193.
- Evaluation of sampling plans by:
 - inhomogeneity-adjusted OC curves
 - the expected utility of a plan
 - global consumer's and producer's risks
- Calculations are based on inhomogeneity parameters for each combination of commodity and contaminant, derived from historical data.



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