# IAM PAPER ON “SAMPLING IN CODEX STANDARDS – HOW IT SHOULD BE TREATED”

***Comments from the International Dairy Federation (IDF)***

The International Dairy Federation wishes to thank the IAM for preparing this paper and for the opportunity to comment. We strongly believe that an adequate appreciation of the principles and the limitations by involved stakeholders is crucial for a proper implementation.

Four alternative approaches are presented and, with the exception of pragmatic sampling, the paper gives the impression that these approaches are equally valid and could be used interchangeably. However Acceptance Sampling is still the only valid approach for the purpose of sampling inspection, but the other approaches have application in other areas as indicated in the more detailed comments below. We suggest that this should be stated explicitly in the document.

We note further that the paper suggests it may be possible to combine elements of the UfS approach with the current AcS approach laid down in Codex, and we would encourage the authors to further expand on how this might be done practically while maintaining the principles of scientific robustness and fairness to all parties.

Acceptance Sampling

Acceptance sampling is the scientifically recognised approach for sampling inspection. The field has a long history and the topic has been rigorously debated. Acceptance sampling is based on the theory of probability - not all ‘units’ in a lot will be inspected, but a sampling plan can be chosen so that the risks of incorrect decisions, of the acceptance of poor quality product, or the rejection of good product, can be controlled to allow no more risk than required.

* A greater understanding of Acceptance Sampling is needed, at least before an informed choice on the approach to be adopted by Codex can be decided.
* In our view, an understanding of the concepts is all that is required for the majority of users. These concepts are relatively easy to understand, without any need to understand the theory and there are, for example, a wide range of computer-based tools available to assist with the selection and operation of sampling plans.
* CAC GL-50 is possibly overly complicated, and there may be a need to prepare a simpler guide for less-technical users, in the same way the Codex Committee on Food Hygiene has done recently.
* CAC GL-50 is not comprehensive; there are others types of sampling plans available, including plans that handle measurement error.
* The development of any new sampling plans to address gaps in CAC GL-50 and the current literature should be carried out in accordance with the principles of acceptance sampling.

We note that an explicit figure for Uncertainty from Sampling is not required to decide whether a lot is acceptable (e.g. in sampling plans based on inspection by attributes) but where such a figure is available, the ‘sigma method’, already documented in CAC GL-50, shows how it can be used.

Total Uncertainty Approach

Although this option has been presented in several discussion documents at recent sessions, no formal statement of the proposal has been presented nor has any statistical demonstration, by way of Operating Characteristics or their derivation, been provided for review by CCMAS to provide assurance this approach will perform satisfactorily. Indeed the Procedural Manual suggests that this information should be provided prior to any decisions about the adoption of this approach:

*Similarly a commodity committee should, whenever possible, provide information to the Committee on Methods of Analysis and Sampling for each sampling plan relating to the scope or field of application, the type of sampling (e.g. bulk or unit), sample sizes, decision rules, details of plans (e.g. “Operating characteristic” curves), inferences to be made to lots or processes, levels of risk to be accepted and pertinent supportive data. Procedural Manual Section II: Elaboration of Codex texts*

We note that this text does not appear to be quoted in the paper.

We note also that there are no references to any standards published by ISO or other authoritative standards for the application of combined uncertainty to sampling inspection; indeed the discussion document suggests that the methodology is still under development, which we feel is a somewhat unsatisfactory situation.

Further, the material presented thus far contains several apparent anomalies that have yet to be explained:

* Results lying considerably outside specification limits might not cause rejection of product.
* Larger allowances are made when less precise measurements are made, thereby rewarding poorer measurement.
* Larger allowances are made for Uncertainty from Sampling for more variable product where there is greater potential for product to fall outside specification.

Finally we would mention that measurement uncertainty does appear to have a role in legal metrology, where the ‘null hypothesis’ of compliant must necessarily be assumed. However this is not useful for sampling inspection, because of the nature of the producer-consumer relationship.

Pragmatic Sampling

This approach is not scientific and, in accordance with the general principles of Codex, should not be considered. This approach was discussed at some length during the development of the General Guidelines on Sampling CAC GL-50 (2004) and rejected at the time for the same reason.

Auto-control

While we appreciate the attempt to give a comprehensive overview of options for developing sampling plans, we believe that currently there is not enough detail to evaluate this proposal. The procedure suggested in the document appears *ad hoc* and is not supported in the literature. Again, the procedure would have to be formally documented and a statistical evaluation carried out to show that it was a viable alternative. However, we note that there is no need for a process to be in a state of statistical control for specifications to be met, or vice versa. Auto-control has been used where AQL levels are in the ppm level, and measurement uncertainty is very small, but this situation seems unlikely to occur for most parameters on most foodstuffs.

***Comments from Petra Gowik (FRG)***

## 1 Introduction

We are not comfortable with the argumentation in the IAM Sampling Paper and hence cannot endorse its main conclusions. In these notes, we present the reasons why we reject or disagree with the views and arguments put forward in the IAM Sampling Paper.

## 2 Main criticism: Acceptance sampling vs. Estimation of the total uncertainty from both Analysis and Sampling

We would like to focus on two of the approaches to sampling discussed in the IAM Sampling Paper:

* Acceptance Sampling (AcS)
* Estimation of the total uncertainty from both Analysis and Sampling (UfS)

We take the basic direction proposed in the IAM Sampling Paper regarding these two approaches to be defined in the two recommendations on pp. 11 and 12.

These recommendations read as follows:

IAM Sampling Paper recommendation regarding AcS approach:

*That acceptance plans are only developed for specific system [sic] by those who fully appreciate their significance and associated difficulties and that the consequence of reducing the number of units taken from a lot area [sic] clearly appreciated.*

IAM Sampling Paper recommendations regarding UfS approach:

It is recommended that Codex:

* *Notes the publication of the EURACHEM/EUROLAB/CITAC/Nordtest Guide on the “Estimation of Measurement Uncertainty Arising from Sampling” and the Nordtest handbook.*
* *Discusses the issue of uncertainty and sampling and decides whether it should develop recommendations in the area in the same way that it already has for [Analytical] Measurement Uncertainty.*
* *Discusses whether sampling uncertainty should be taken into account when a lot is assessed for compliance with a Codex specification.*
* *Considers whether it should prepare Guidance for Codex Committee Committees on uncertainty from sampling.*

The reasons why we do not endorse these recommendations are presented in the following two sections (Sections 2.1 and 2.2). In Section 2.3, we also comment on the Strengths & Weaknesses analysis of UfS and AcS found on pages 5 and 6 of the IAM Sampling Paper.

### 2.1 Consumer and producer risks not only relevant for AcS approach but also for UfS approach.

The first issue we would like to discuss is the question of “*the consequence of reducing the number of units from a lot*”, to use the phrasing from the recommendation regarding the AcS approach quoted above. This issue is raised several times in the IAM paper, and concerns the “*high probability of accepting defective items, especially for small batches, that is not appreciated by some regulators*” (discussion of the weaknesses of the AsC approach on page 6).

We agree that there is a high probability of accepting defective items (false negative rate) at low sample sizes, and this point is very aptly illustrated in the table on page 10 of the IAM Sampling Paper (which can be directly constructed on the basis of the information presented in Chart A and Charts B-R from ISO 3951-1).

The gist of the matter, however, seems to us to lie in the fact that in the AcS approach, the false negative and false positive rates constitute the starting point for the determination of the AQL and the sample size. This approach thus compels the user to be aware of the consumer and producer risks (i.e. of false negative and false positive rates). If the desirable risk levels are not attainable due to limitations on sample size occasioned by economical or other constraints, the user will at least remain aware of the ensuing unsatisfactory risk levels.

In our opinion, the emphasis on consumer and producer risks which characterizes the AcS approach is essential for any viable approach to sampling. We are concerned that, in the IAM Sampling Paper, the high “percentage of defectives which will be accepted 10 % of the time” is construed as a weakness of the AcS approach, rather than as an inevitable consequence of the sample size. Indeed, if the consumer and producer risks were computed for the UfS approach, it would be found that they would be essentially the same. The only difference is that, in the UfS approach, it is not required to compute these risks, and the user often remains unaware of them. If, in the framework of the UfS approach, the false negative and false positive rates ensuing from the application of a particular rejection criterion for lots were computed, they would, by and large, be *the same* as in the AcS approach. In other words, what we see as a shortcoming of the UfS approach (i.e. the failure to emphasize the need to compute the false negative and false positive rates) is put forward as a virtue.

In short: we would have expected the IAM Sampling Paper to

* emphasize the importance of computing consumer and producer risks
* point out that the computation of these risks plays a central role in the AsC approach
* require that the UfS approach be expanded to include the computation of these risks

### 2.2 Is sampling uncertainty not taken into account in the AcS approach?

The second issue we would like to discuss is addressed a few times in the IAM Sampling Paper: namely, the question of whether the sampling uncertainty is taken into account in the AcS approach. In the IAM Sampling Paper, it is stated a few times that this is not the case, and that only analytical uncertainty is taken into account in the AcS approach. See for example the **Conclusions – comparison of approaches** Section on page 7:

“*1. Only in the UfS approach does the information from the validation step (e.g. on the portion of the measurement uncertainty from sampling and sample preparation) get reported to the user of the measurement results. (e.g. 15 ± 10 ng g-1, rather than just the analytical portion 15 ± 1 ng g-1)*

*2. The differences in terminology of the three approaches reflect deeper distinctions. For example, the ‘variability’ due to sampling in AcS produces ‘uncertainty’ in the measurement (of concentration) that is not reported to the user (i.e. producer, consumer or regulator)*

*3. The more realistic estimate of measurement uncertainty given by the UfS approach is essential to making reliable decisions and classifications on the acceptability of material for its intended purpose (e.g. safety of food for consumption). The methodology for using this uncertainty information in enforcement decisions is not yet agreed internationally, for example in deciding the acceptable levels of false positive (producer’s or seller’s risk) and false negative (consumer’s or buyer’s risk) classifications. However, the UfS approach will enable this methodology to be applied not just at the validation stage, but also in routine operation.*

*4. Both ARS and AcS consider sampling variability in the design of the initial sampling protocol, but don’t consider or express it as part of the measurement process. This has the advantage of apparent simplicity, but misleads the decision maker on the reliability of the classification decision. However, the AcS approach uses the equivalent of the UfS information, in moving the effective threshold value (e.g. to AQL)”*

In short, the IAM Sampling Paper’s position seems to be that the only approach in which information about sampling uncertainty is adequately taken into consideration, quantified and reported to the user is the UfS approach. This position seems to us to be inaccurate.

Indeed, the very producer and consumer risks (or, more generally, the OC curves) quantify and codify the information about sampling uncertainty in a manner which is relevant for the user. We would argue that providing a sampling variance in the framework of a variance decomposition (i.e. the UfS approach) does not constitute information which can easily be interpreted by the user. On the other hand, a diagram showing that a lot with $p$ % defective items will yield an acceptance of the lot with such and such probability is precisely the information which the user needs.

In the Annex we provide further details on the treatment of sampling uncertainty in the AcS method (ISO 3951 approach).

### 2.3 Comments on the analysis of Strengths & Weaknesses for UfS and AcS

In Sections 2.1 and 2.2 we pointed out that:

1. High consumer or producer risks are not a flaw of the AcS method, but rather an inevitable consequence of fit-for-purpose decisions (e.g. economic constraints on the sample sizes) and of the assumption of a normal distribution.
2. These high risks would also be found to attend decisions taken in accordance with the UfS approach. However, in the UfS approach, it is not required that these risks be computed.
3. These consumer and producer risks (or, more generally, the OC curves) constitute an estimate of sampling uncertainty, expressed in a manner which is relevant to the decision-maker.

We will now review how these three points apply to the Strengths & Weaknesses analysis of UfS and AcS found on pages 5 and 6 of the IAM Sampling Paper. In addition we will point out what, in our opinion, seem to be logical inconsistencies.

|  |  |
| --- | --- |
| Strengths of the UfS approach according to IAM Sampling Paper (pages 5, 6) | Our comments |
| Gives a realistic estimate of the measurement uncertainty, which will make decisions on batch acceptance/rejection more reliable. | This depends on the way in which the uncertainty ranges are computed. In our opinion, this cannot be construed as an inherent strength of the UfS approach (see Section 3.3 below). |
| Enables the fitness-for-purpose of the measurements (& sampling) to be judged in terms of minimizing the overall costs of both measurement and incorrect regulatory decisions. | This depends on the way in which the uncertainty ranges are computed. Minimizing the overall costs of both measurement and incorrect regulatory decisions can also be achieved by using the AcS approach. We fail to see how this point constitutes a strength of the UfS approach as compared to the AcS approach (see point 1 above). |
| Inclusion of sampling quality control monitors on-going performance of samplers in routine application of the protocol, not just at validation. | Sampling quality control is also an issue of the AcS approach.  |
| Weaknesses of the AcS approach according to IAM Sampling Paper (page 6) | Our comments |
| The AcS approach underestimates the overall uncertainty of the measurement (excludes contribution from sampling), which will affect the reliability of decisions on batch acceptance/rejection. | * This is not correct: The AcS approach does not exclude the contribution from sampling (see point 3 above)
* This is also a direct contradiction with point 2 under Strengths (“Makes empirical estimates of variability arising from sampling,…)
 |
| Does not give the information on sampling variability (and hence larger measurement uncertainty) to the decision maker. | The AcS approach allows for information about sampling variability to be given to the decision maker in the form of consumer and producer risks (see point 3 above) |
| No way of checking on the quality of the actual implementation of the sampling protocol in routine operation. | We fail to see how this can be construed as a weakness of the AcS approach: The same could be said of any approach, and it depends on the way the approach is implemented. |
| Hard to devise correct protocol for heterogeneous material sampled in situ (e.g. un-mixed nuts in a container, or contaminated land). | We fail to see how this can be construed as a weakness of the AcS approach: The same could be said of any approach, and it depends on the way the approach is implemented. |
| Does not include potential financial losses that may arise from decision errors (caused by uncertainty) in calculation of final sampling protocol. | We fail to see how this can be construed as a weakness of the AcS approach: The same could be said of any approach, and it depends on the way the approach is implemented. |
| Gives rise to a high probability of accepting defective items, especially for small batches, that is not appreciated by some regulators. | The same can also be said of the UfS approach (see point 2 above) |

Finally, we are concerned that the IAM Sampling Paper addresses only 2 weaknesses altogether

Almost no weaknesses of the UfS approach are addressed. Are there really no serious weaknesses – apart from the fact that the “*methodology for including uncertainty from sampling in decision-making process (is) not yet agreed*”? It hardly seems tenable that there are no other serious weaknesses.

## Further comments

### 3.1 The question of a sampling bias (Key questions 5+7+8, page 1 of IAM Sampling Paper)

In our opinion, the concept “Sampling bias” can be somewhat misleading (see for example key questions (7) and (8)). Indeed, the presence or absence of a bias depends not only on the sampling procedure but also on the choice of statistical method applied in the evaluation of the data. For instance, if a stratified sampling procedure has been followed (as is frequently the case), the arithmetical mean will be considerably biased whereas the appropriate stratified mean will not. This shows that the presence or absence of a bias is not a property of the sampling procedure alone but rather of the combination of sampling procedure and statistical method.

For this reason, the answer to key question (5) should be: Yes, sampling must be considered as the first step in the measurement process rather than as a separate process.

### 3.2 The question of a representative versus appropriate samples (Key question 12, page 2 of IAM Sampling Paper)

In our opinion, the formulation of key question (12) is too vague: in particular, it seems to us the concepts “representative” and “appropriate” are not sufficiently well defined to allow concrete measures to be taken in terms of establishing useful practical guidance. The question of whether to use a representative or a pragmatic sampling (see page 2) suffers, in our opinion, from the same ill focus.

### 3.3 The issue of large sampling uncertainty

It should be noted that, in cases where the sampling uncertainty is large (say, relative standard deviations larger than 30 %), classical uncertainty ranges can be considerably misleading when the assumption of symmetrical ranges is erroneously made. Thus, in these cases, the UfS approach is fraught with substantial difficulties. By construction, the AcS approach is not affected by such problems.

## 4 Conclusion

We identified a large number of weaknesses, inconsistencies and inaccuracies in the arguments of the IAM paper. Apart from that we disagree with the views and arguments put forward in the IAM Sampling Paper.

We are concerned that the IAM Sampling Paper’s recommendation for the AcS approach fails to lay sufficient emphasis on the most important aspect of Acceptance Sampling: the fact that in this approach, producer and consumer risks – and thus the attendant risks of financial losses and food safety - play a central role. We are concerned that the IAM Sampling Paper does not recognize that sampling uncertainty is implicitly taken into account in the AcS approach, and that it is reported to the user in a very practical and relevant way; namely, as the producer and consumer risks, or more generally, as the OC curves. Finally, we are concerned that CCMAS shall decide on a “methodology for including uncertainty from sampling in decision-making process (which has) not yet (been) agreed” (cf. IAM Sampling Paper, p6).

Our intention is by no means to blindly embrace the AcS approach. In particular, we recognize the ISO 2859 and ISO 3951 standards are written in a manner which makes them relatively difficult to apply. Both standards use complicated terminology, fail to provide proper explanation of statistical procedures and use complicated tables and charts for decision-making. Therefore we suggest to develop more appropriate terminology, produce explanations for statistical concepts, simplify outdated procedures of decision-making and provide additional tools if needed. In the Annex some ideas are presented which could be used to support this work.

Currently both the ISO 2859 and the ISO 3951 standards are under revision, and we encourage member states to support this revision – which should include a thorough examination and description of uncertainty components. We also suggest preparing documents which describe more specifically and on a scientifically sound basis the differences and similarities between the different approaches in order to achieve an impartial appraisal of their respective advantages and shortcomings.

# Annex: Sampling uncertainty in the ISO 3951-1 standard

In the following, the manner in which sampling uncertainty is taken into consideration in the ISO 3951-1 standard will be explained.

### “s” method

Assume that a lower specification limit $L$ has been defined and that a sample of size $n$ has been drawn. The approach in the ISO 3951-1 standard consists in defining an *acceptability constant* $k$ in such a way that the criterion for accepting the lot or consignment, from which the sample was drawn, is:

$$\overbar{X}-kS\geq L,$$

where $\overbar{X}$ denotes the sample mean and $S$ denotes the sample standard deviation.

This is where sampling uncertainty comes in. Due to the random nature of the sample, it cannot be excluded that the sample misrepresents the lot or consignment, thus leading to an incorrect decision. Indeed, the computation of $k$ does not depend on the measured values obtained on the basis of the sample. Thus, once $k$ has been computed, different samples will yield different values for the quantity $\overbar{X}-kS$. Taking sampling uncertainty into consideration will thus consist in a description of the distribution of the values which the quantity $\overbar{X}-kS$ takes and, in particular, in the quantification of the probabilities of making incorrect decisions. There are two types of incorrect decisions:

* Accepting a consignment which does not meet the criterion (the consumer’s risk: $\overbar{X}-kS\geq L$ even though the true average of X lies below the specification limit L)
* Rejecting a consignment which meets the criterion (the producer’s risk: $\overbar{X}-kS<L$ even though the true average of X lies above the specification limit L)

In the ISO 3951-1, the starting point for taking sampling uncertainty into consideration thus consists in a decision as to which of the two types of risks to prioritize. In the “standard procedure” (see Section 13.1), the order of priority is:

1. Producer’s risk
2. Sample size
3. Consumer’s risk

(Procedures for other priority orders are also provided (see Section 13.1).)

It is assumed that the producer and the consumer have each defined a percentage of items nonconforming on the basis of which to establish the acceptance criterion:

* The consumer’s percentage of items nonconforming is called the “Limiting Quality”
* The producer’s percentage of items nonconforming is called the “Acceptance Quality Limit” (AQL)

(Once the Limiting Quality has been defined by the consumer, the producer can choose the AQL to be lower than the Limiting Quality so as to ensure a high probability of acceptance.)

If the producer’s risk is prioritized, the acceptability constant $k$ will be computed in such a way so as to ensure the producer’s risk is low (say, less than $5 \%$). Once this particular $k$ has been computed, it is possible to compute the consumer’s risk. Typically, the latter is deemed acceptable if less than $10 \%$. If, for the computed $k$, the consumer’s risk is too high, then it is possible to lower this risk by increasing the number of samples. The sample sizes corresponding to the code letters in the tables of the ISO 3951-1 standard were computed to ensure the criteria for both the producer risk (less than $5 \%$) and the consumer risk (less than $10 \%$) are met. In particular, tables B1, K1 and L1 provide the information discussed here:

* Table B1 provides the $k$ values (“acceptability constant”) corresponding to a particular AQL and sample size.
* Table K1 provides the corresponding consumer risks.
* Table L1 provides the corresponding producer risks.

As far as the actual computations are considered, the non-central t distribution plays an important role as can be read from the following equation:

$$P\left(\overbar{X}-kS\geq L\right)=P\left(\frac{\sqrt{n}\left(\overbar{X}-μ\right)}{σ}+\frac{\sqrt{n}\left(μ-L\right)}{σ}\geq k\sqrt{n}\frac{S}{σ}\right),$$

$$=P\left(T\_{n-1, δ}\geq k\sqrt{n}\right),$$

where $T\_{n-1, δ}$ denotes a random variable following a non-central t distribution with non-centrality parameter $δ$.

In the computation of the acceptability constant $k$, the producer’s risk is prioritized. The percentage of items nonconforming $AQL=P(X<L)$ can be written $AQL=P\left(\frac{X-μ}{σ}<\frac{L-μ}{σ}\right)=Φ\left(\frac{L-μ}{σ}\right)$.

For the non-centrality parameter, this implies

$$δ=\frac{\sqrt{n}\left(μ-L\right)}{σ}=-\sqrt{n}∙Φ^{-1}\left(AQL\right).$$

Finally, we have for the probability of acceptance:

$$P\_{a}=95 \%=1-F\_{n-1,δ}\left(k\sqrt{n}\right),$$

Where $F\_{n-1,δ}$ denotes the non-central t distribution function. The last equation can then be solved for $k$.

It can thus be seen that the computation of $k$ depends only on the choice of the $AQL$, on the sample size $n$ and on the producer’s risk.

The choice of the producer’s risk (e.g. 5 %) is the direct manifestation of sampling uncertainty (on the assumption that analytical uncertainty is negligible). If analytical uncertainty is not negligible, then the producer’s risk is caused by both sampling and analytical uncertainty. It should also be noted that the acceptance rule $\overbar{X}-kS\geq L$ depends indirectly on the sample standard uncertainty $u(\overbar{X})=S/\sqrt{n}$.

### “$σ$” method

The dependence of the decision rule on the sample standard uncertainty $u(\overbar{X})$ is more obvious for the “$σ$” method. For this method, the empirical standard deviation “S” is replaced by the theoretical (known) standard deviation “$σ$”.

The probability for acceptance for the “$σ$” method can be computed

$$P\left(\overbar{X}-kσ\geq L\right)=P\left(\frac{\sqrt{n}\left(\overbar{X}-μ\right)}{σ}+\frac{\sqrt{n}\left(μ-L\right)}{σ}\geq k\sqrt{n}\right),$$

$$=1-Φ\left(k\sqrt{n}-\frac{\sqrt{n}\left(μ-L\right)}{σ}\right),$$

In the computation of the acceptability constant $k$, again the producer’s risk is prioritized. Substituting the expression for the percentage of items nonconforming $AQL=Φ\left(\frac{L-μ}{σ}\right)$ (as above), we obtain $\frac{\sqrt{n}\left(μ-L\right)}{σ}=-\sqrt{n}∙Φ^{-1}\left(AQL\right).$

For the probability of acceptance we obtain:

$$P\_{a}=95 \%=P\left(\overbar{X}-kσ\geq L\right)=1-Φ\left(k\sqrt{n}+\sqrt{n}∙Φ^{-1}\left(AQL\right)\right).$$

The last equation can then be solved for $k$.

$$k\sqrt{n}+\sqrt{n}∙Φ^{-1}\left(AQL\right)=Φ^{-1}\left(1-P\_{a}\right).$$

$$k=Φ^{-1}\left(1-P\_{a}\right)/\sqrt{n}-Φ^{-1}\left(AQL\right).$$

As for the “s” method, $k$ thus depends only on $P\_{a}$, $AQL$ and on the sample size $n$. Again, the sampling uncertainty (in the absence of analytical uncertainty) is the sole source of random variability – and thus the producer’s risk is the acknowledged and controlled manifestation of the sampling uncertainty.

#### An alternative decision rule A for acceptance based on sample uncertainty and producer’s risk

With the following parameters:

* the sample average $\overbar{X}$ ,
* the sample uncertainty $u\left(\overbar{X}\right)=σ/\sqrt{n}$ ,
* the expanded uncertainty $U\_{A}\left(\overbar{X}\right)=Φ^{-1}\left(P\_{a}\right)∙σ/\sqrt{n}$ with the coverage factor $Φ^{-1}\left(P\_{a}\right)$ based on the producer’s risk (say, $P\_{a}=0.95=1-producer's risk$),
* the $AQL$ and
* the AQL process mean of the measured characteristic $μ\_{AQL}=L-σ∙Φ^{-1}\left(AQL\right)$ at which the fraction of nonconforming items equals AQL (by this definition of $μ\_{AQL}$ we have $AQL=Φ\left(\frac{L-μ\_{AQL}}{σ}\right)$),

the decision rule A is defined as follows: The lot will be rejected if the uncertainty interval $\overbar{X}\pm U\_{A}\left(\overbar{X}\right)$ is completely below the critical process mean $μ\_{AQL}$ without overlap, i.e. if $\overbar{X}$ is significantly higher than $μ\_{AQL}$, in other words, if the expected rate of non-conforming items is significantly higher than AQL. The lot will be accepted if $\overbar{X}+U\_{A}\left(\overbar{X}\right)>μ\_{AQL}$.

It can be shown easily that this decision rule A is equivalent to the ISO 3951-1 approach described above.

Indeed, the criterion

$$\overbar{X}+U\_{A}\left(\overbar{X}\right)>μ\_{AQL}$$

is equivalent to

$$\overbar{X}+Φ^{-1}\left(P\_{a}\right)∙σ/\sqrt{n}>L-σ∙Φ^{-1}\left(AQL\right)$$

and

$$\overbar{X}-σ∙\left(\frac{Φ^{-1}\left(1-P\_{a}\right)}{\sqrt{n}}-Φ^{-1}\left(AQL\right)\right)>L.$$

The expression in the brackets equals k, i.e. the decision rule for acceptance is equivalent with $\overbar{X}-σk>L, $and this is the approach in ISO 3951-1.

#### Another decision rule B for acceptance based on sample uncertainty and consumer’s risk

Another decision rule B based on consumer’s risk can be defined with the following parameters:

* the expanded uncertainty $U\_{B}\left(\overbar{X}\right)=Φ^{-1}\left(0.9\right)∙σ/\sqrt{n}$ with the coverage factor $Φ^{-1}\left(0.9\right)$ based on the consumer’s risk,
* the LQ process mean $μ\_{LQ}=L-σ∙Φ^{-1}\left(LQ\right)$ at which the fraction of nonconforming items equals the limiting quality LQ.

The lot will be accepted if the uncertainty interval $\overbar{X}\pm U\_{B}\left(\overbar{X}\right)$ is completely above the LQ process mean $μ\_{LQ}$ without overlap, i.e. the lot will be rejected if $\overbar{X}-U\_{B}\left(\overbar{X}\right)<μ\_{LQ}$.

LQ is defined in such a way that decision rule B is equivalent with decision rule A.

#### Example

Consider the sampling scheme described in Table C.1 (ISO 3951-1) for code letter H with n=12 samples. Let AQL = 1% the acceptance quality limit, $σ=2$ the standard deviation, and L = 20 the lower specification limit. Then k = 1.800 according to Table C.1 and LQ = 7.64% according to Table K.2 (ISO 3951-1).

With these parameters the AQL process mean $μ\_{AQL} $and the LQ process mean $μ\_{LQ}$ can be calculated as follows:

|  |  |
| --- | --- |
| **Decision rule A: based on producer’s risk** | **Decision rule B: based on consumer’s risk** |
| AQL=1%, $σ=2$, L = 20 | LQ=7.64%, $σ=2$, L = 20 |
| $$Φ^{-1}\left(AQL\right)=-2.326$$ | $$Φ^{-1}\left(LQ\right)=-1.430$$ |
| $$μ\_{AQL}=L-σ∙Φ^{-1}\left(AQL\right)$$ | $$μ\_{LQ}=L-σ∙Φ^{-1}\left(LQ\right)$$ |
| $μ\_{AQL}=24.65$ **(red line)** | $μ\_{LQ}=22.86$ **(red line)** |
| AQL | LQ |

In order to illustrate the decision rules, we assume the sample average over the 12 samples $\overbar{X}=23.8$.

The uncertainty intervals and the final decision-making is as follows:

|  |  |
| --- | --- |
| **Decision rule A: based on producer’s risk** | **Decision rule B: based on consumer’s risk** |
| Producer’s risk = 0.05 | Consumer’s risk = 0.10 |
| Coverage factor: $Φ^{-1}\left(1-0.05\right)=1.645$ | Coverage factor: $Φ^{-1}\left(1-0.10\right)=1.282$ |
| $$U\_{A}\left(\overbar{X}\right)=Φ^{-1}\left(1-0.05\right)∙\frac{σ}{\sqrt{n}}=0.95$$ | $$U\_{B}\left(\overbar{X}\right)=Φ^{-1}\left(1-0.10\right)∙\frac{σ}{\sqrt{n}}=0.74$$ |
| Uncertainty interval: $\overbar{X}\pm U\_{A}\left(\overbar{X}\right)=23.8\pm 0.95$ (represented by green horizontal bar) | Uncertainty interval: $$\overbar{X}\pm U\_{B}\left(\overbar{X}\right)=23.8\pm 0.74$$(represented by green horizontal bar) |
| Decision:$$\overbar{X}+U\_{A}\left(\overbar{X}\right)=24.75>μ\_{AQL}=24.65$$Lot accepted (green bar not completely left from red line; still overlapping)  | Decision:$$\overbar{X}-U\_{B}\left(\overbar{X}\right)=23.06>μ\_{LQ}=22.86$$Lot accepted(green bar right from red line; no overlap)  |
|  |  |

It should be noted that both decision rules are close at the limit. This is true also for the acceptance criterion of the ISO approach,$ \overbar{X}-kσ>L$, as

$$\overbar{X}-kσ=23.8-1.8∙2=20.2>L=20.$$

If $\overbar{X}$<23.6, the three decision rules will come to a negative result, ie the lot will be rejected. This example demonstrates that the three decision rules are indeed equivalent, ie whether the lot will be accepted or not is not depending on the choice of the rule.

## Conclusion

1. The decision as to the acceptance of a lot according to the ISO approach for the $"σ$” method is equivalent with decision rule A. Decision rule A is based on a comparison of the sample average with the AQL process mean under consideration of the sampling uncertainty. The coverage factor is derived from the corresponding producer’s risk. Decision rule A is in line with the GUM. Sampling uncertainty is taken into account, and analytical uncertainty is assumed to be negligible.
2. The decision as to the acceptance of a lot according to the ISO approach for the $"σ$” method is also equivalent with decision rule B. Decision rule B is based on a comparison of the sample average with the LQ process mean under consideration of the sampling uncertainty. The coverage factor is derived from the corresponding consumer’s risk. Decision rule B is in line with the GUM. Sampling uncertainty is taken into account, and analytical uncertainty is assumed to be negligible.
3. The ISO approach for the $"σ$” method could easily be replaced by one of the decision rules A or B. Both rules take into account sampling uncertainty.
4. Sampling uncertainty for the process mean µ according ISO 3951-1 is computed $(\overbar{X})=σ/\sqrt{n}$ , where $σ$ denotes the true standard deviation of the variability between items.
5. Also the ISO approach for the $"s$” method takes into account sampling uncertainty. Coverage is derived from both producer’s and consumer’s risk.
6. The toolbox provided by ISO 3951 is very powerful and applicable for many different situations. It is statistically valid and can be applied also in situations
	1. when the uncertainty is very large (a situation which is critical for the UfS approach)
	2. when the analytical uncertainty is not negligible (since the last revision of the standard).
7. On the other hand, the ISO approach uses complicated terminology, fails to provide proper explanation of statistical procedures and uses complicated tables and charts for decision-making. It is therefore suggested to
	1. develop more appropriate terminology
	2. produce explanations for statistical concepts
	3. simplify outdated procedures of decision-making.