PROSAFE meeting

Considerations for sampling used in future MS actions

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1. Comparison of sampling techniques

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1. Comparison of sampling techniques

✓ **Sample size based on binomial distribution**

The smallest sample size *n* which (after the inspection) delivers the fraction of defective items in the lot with level of confidence *LC* and margin of error *E*.

Formula: $$n = \frac{z_{LC}^2 \cdot p_p \left(1 - p_p\right)}{E^2}$$

Here:

- **z_{LC} is the z-value for level of confidence LC;**
- **p_p is prior knowledge of the fraction of defective items in the lot.**

1. Comparison of sampling techniques

✓ **Sample size based on test of hypothesis on a population proportion**

The smallest sample size *n* which (after the inspection) tells if the fraction of defective items in the lot (*p*) is bigger than a pre-specified value p_0 with probability α that in fact $p<p_0$ and probability β that $p>p_0$ but we fail to detect it.

Formula:

$$n = \left[\frac{z_{\alpha/2}\sqrt{p_0\left(1-p_0\right)} + z_{\beta}\sqrt{p_p\left(1-p_p\right)}}{p_p - p_0} \right]^2$$

Here:

- $z_{\alpha/2}$ **and** z_{β} **are z-values for** $\alpha/2$ **and** β**;**
- p_p **is prior knowledge of the fraction of defective items in the lot.**

1. Comparison of sampling techniques

✓ **Sample size based on statistical quality control**

The smallest sample size *n* such that there is probability 0.5 to detect a shift Δ in the fraction of defective items in the lot using *k*-sigma control limits (usually *k* =3).

Formula: $n = \frac{k^2}{\Delta^2} \cdot p_p \left(1 - p_p\right)$

Here:

- **p_p is prior knowledge of the fraction of defective items in the lot.**

1. Comparison of sampling techniques

✓ **Sample size based on ISO 2859-1**

In ISO 2859-1 the sample size depends on the following two parameters:

- **the size of the lot; and**
- **the inspection level (ISO 2859-1 suggests three inspection levels for general use and four inspection levels for special use).**

1. Comparison of sampling techniques

✓ **Sample size based on Bayesian statistics**

- **Bayesian statistics makes complete use of the previous data and previous knowledge about the product being inspected.**
- **Calculations (even of the sample size) are complicated and can be effectively done only by a computer and specialized software.**

1. Comparison of sampling techniques

✓ **Comparison of sampling techniques**

- **For appropriate choice of parameters techniques one and three (binomial distribution and statistical quality control) are completely equivalent (bring same sample size).**

- **For β = 1/2 sample size based on test of hypothesis on a population proportion is the same as in techniques 1 and 3. Choice β < 1/2 brings larger sample size but also more information. Is it worth and when?**

1. Comparison of sampling techniques

✓ **Comparison of sampling techniques**

- **ISO 2859-1 gives only tables and maximally limits the choice of parameters (only the inspection level).**

- **There are examples in the literature showing that the sample size obtained by Bayesian statistics and the one obtained by the previous techniques can be only 20-30% smaller, or even equal or bigger. Is it worth and when?**

1. Comparison of sampling techniques

✓ **Comparison of sampling techniques**

Conclusion:

- **By previous experience, we think that determination of the sample size by means of the binomial distribution meets the needs of market surveillance in most efficient way. This should be verified!**

- **Bayesian statistics, even not applied for sampling, still can be used for analysis of the results.**

2. Classification of Essential Requirements

Suppose:

- **the EUT (Equipment Under Test) has been attributed 3 ER's (Essential Requirements).**
- **The ER's are limited to electrical insulation only. Other risks are assumed not to be present in the EUT.**

2. Classification of Essential Requirements

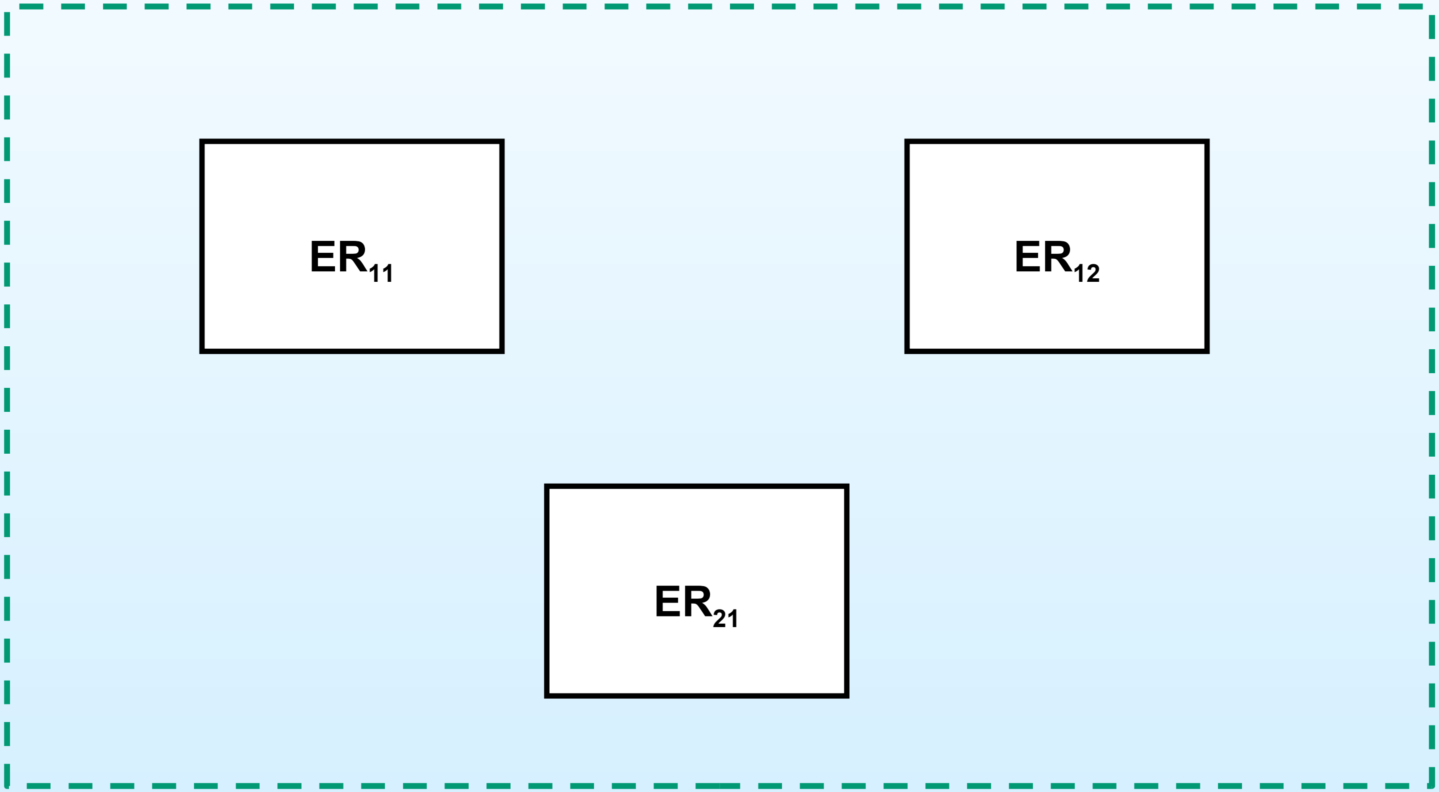


Figure: a typical electrical EUT

2. Classification of Essential Requirements

Classification of ER's (acc. DIN VDE 0800 T1)

- there are basically 2 ER‘s

ER electrical Theoretical	KU factor of insulation	Insulation level	Probability
ER1	3	BI	10exp-3
ER2	6	DI	10exp-6

BI= Basic Insulation, DI = Double insulation

2. Classification of Essential Requirements

In a typical EUTx on the market that will be assessed, practical values are e.g. as follows:

ER electrical actual	KU factor of insulation, actual	Insulation level actual	Probability of failure actual
ER11	3,5	>BI	10exp-3,50
ER12	4,02	>BI	10exp-4,02
ER21	6,01	>DI	10exp-6,01

Assumed life expectancy of equipment = 10exp5 h. (10 years),

KU = -logPa

2. Classification of Essential Requirements

- A KU level of lower then 6 is assumed to be unsafe.
- The lowest KU value attributed to the EUT is defining its safety level.
- For instance if it is a double insulated equipment and suppose 1 double insulation has 1 part bridged (broken down insulation) then the KU value of the double insulation has been reduced to 3.
- A level of 3 for the EUT is too low, so the equipment is potentially dangerous.

KU level	Classification of risk (according EC guide)
>=6 and above	safe
>=3 to < 6	Low to medium risk
>=1 to <3	High risk
< 1	Serious risk

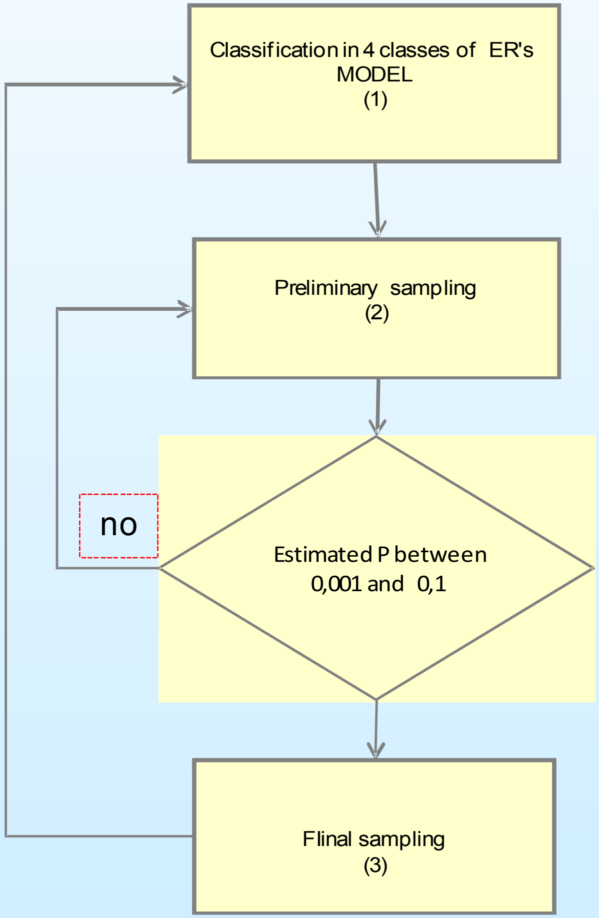
2. Classification of Essential Requirements

- **4 classes of risks (after preliminary sampling) and assignment of 4 levels of confidence.**

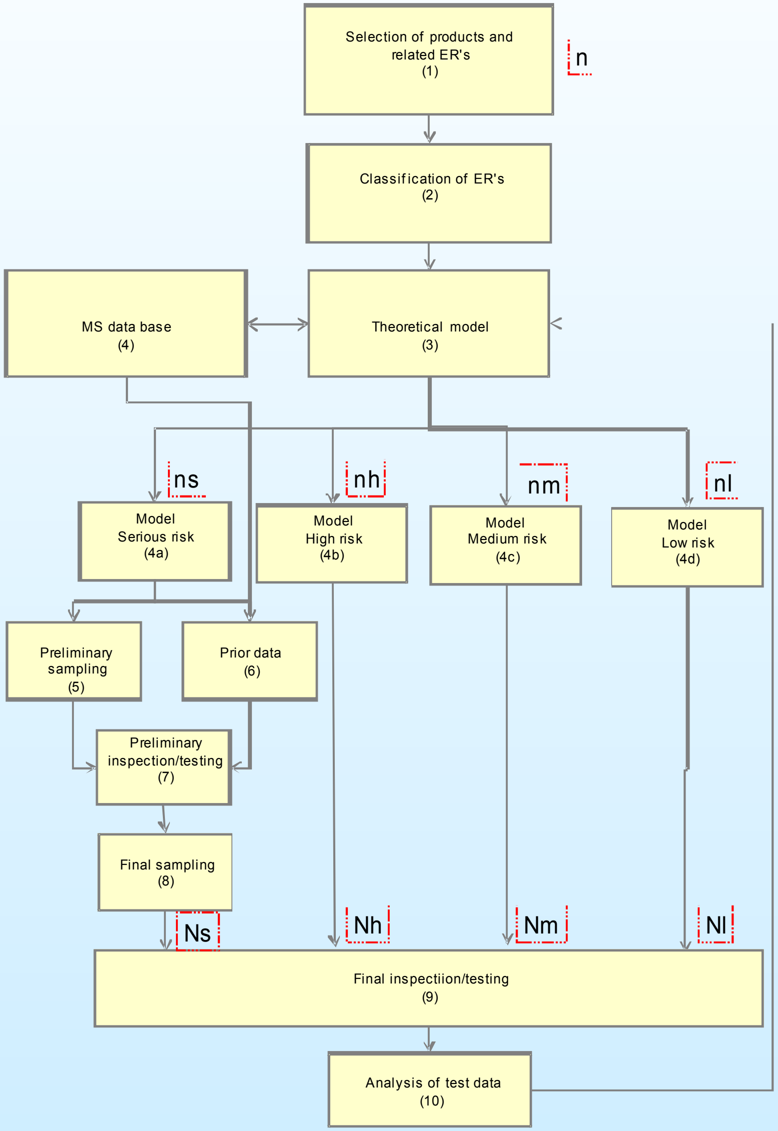
Curve	Classification of risk	Level of confidence (LC)
1	Serious	0,99865
2	High	0,95
3	Medium	0,9
4	Low (including rest of equipment)	0,8

3. Sampling procedure

Simplified flow chart (assuming sample size based on binomial distribution)



3. Sampling procedure



3. Sampling procedure

Explanations of the sampling procedure

(1) For harmonized products: the selection of market surveillance actions shall be based on technical legislation applicable to the product. For non-harmonized products the selection shall be based on <TBD>. The estimated number of products to be surveyed is n.

(2) The classification of essential requirements shall be based on <TBD>. For electrical products it shall be based on KU values approach.

(3) A risk analysis shall be performed using the KU-values of the typical product. Estimation of number of products to be in classes: serious risk products (ns), high risk products (nh), medium risk products (nm) and low risk products (nl).

(4) Results of previous market surveillance actions will be stored in a MS data base (essential requirements test results).

(5) A preliminary sampling shall be performed if there are no data of previous assessments

(6) If prior data are available, these shall be used to define the sample size of the preliminary inspection/testing.

(7) Preliminary inspection/testing is performed.

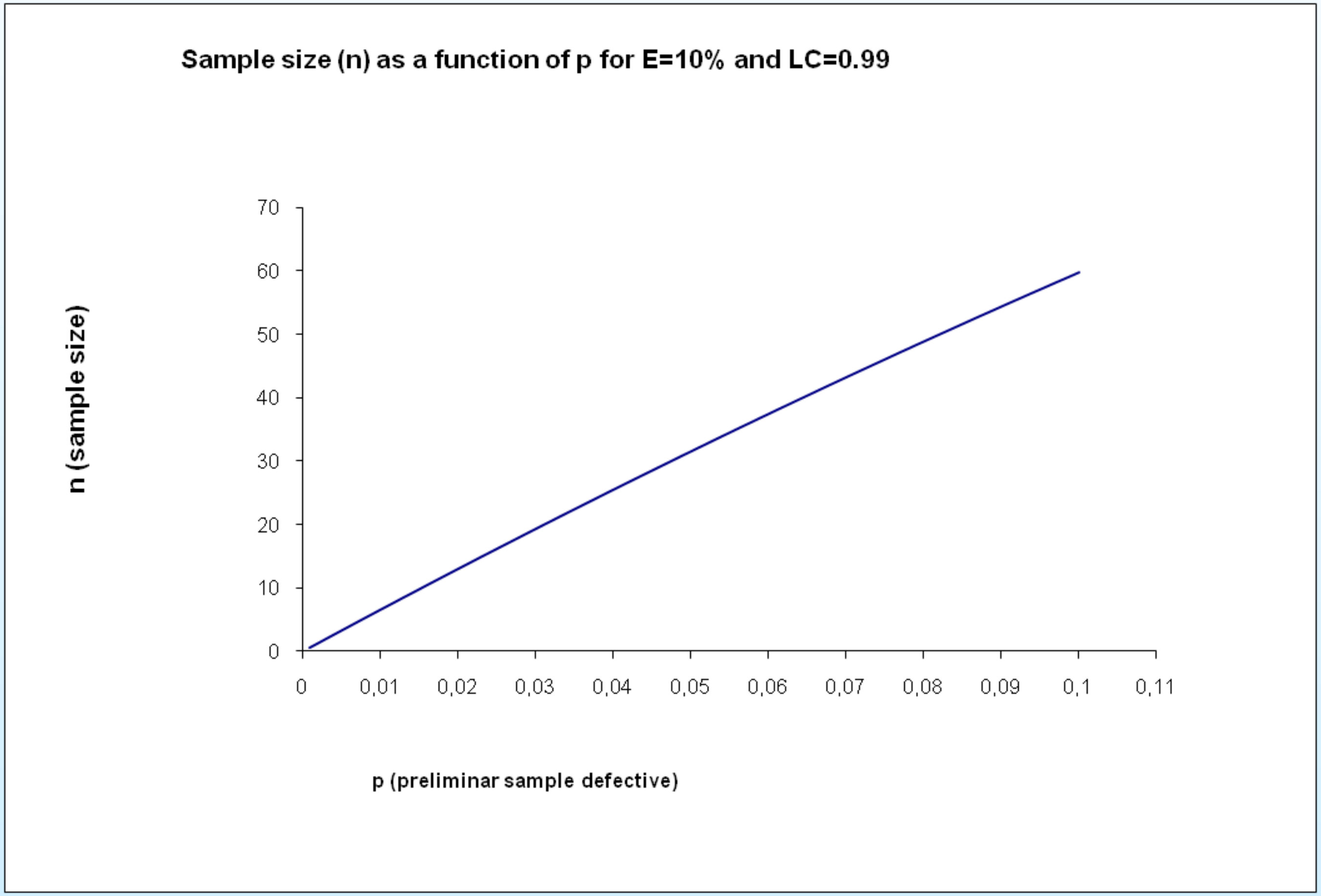
(8) A final sampling plan for all risk categories is calculated based on preliminary results

(9) Final inspection/testing is performed.

(10) Analysis of results is validated using the theoretical model and outcomes are added to the MS data base.

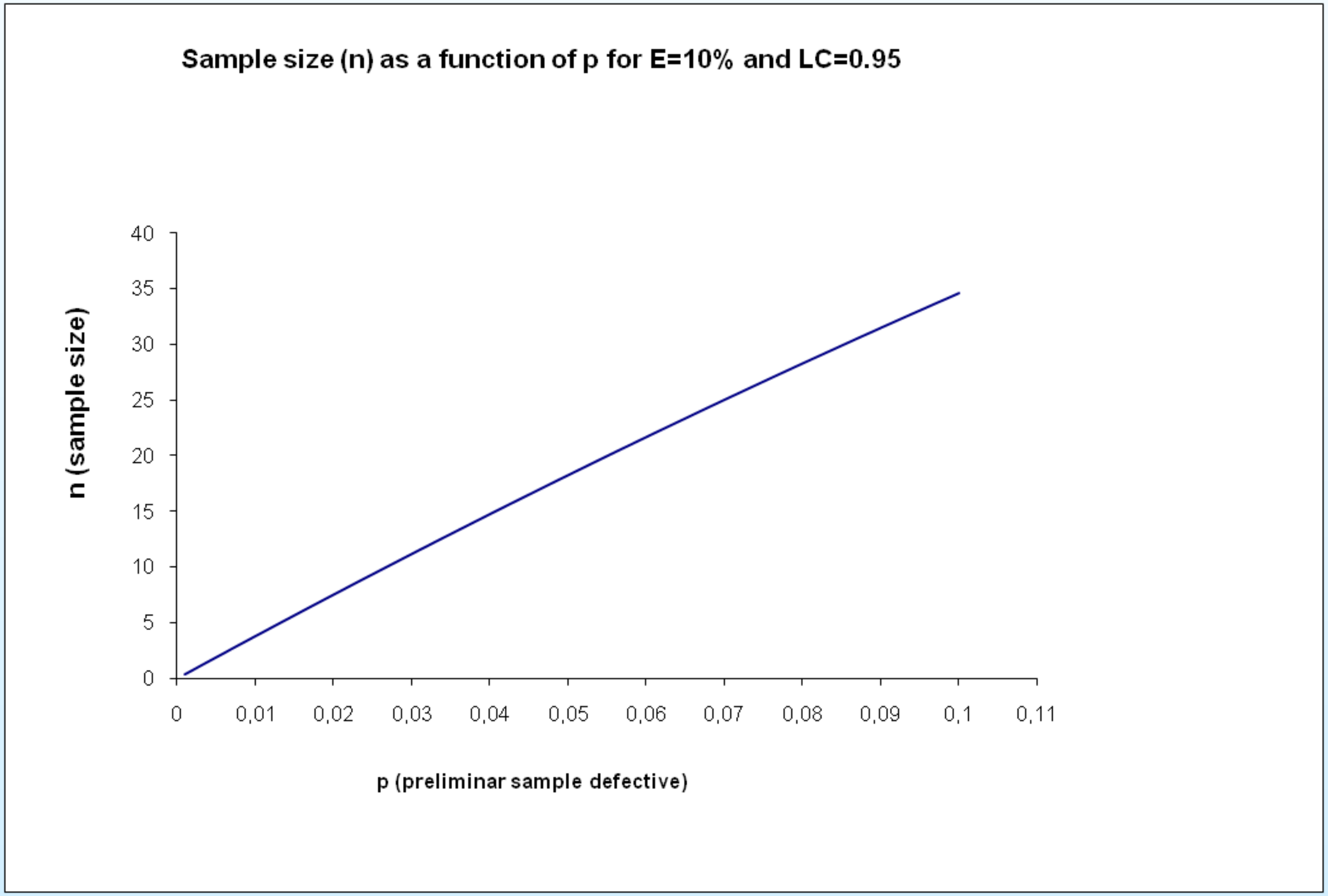
3. Sampling procedure

Sample size for E=10% and LC=0.99



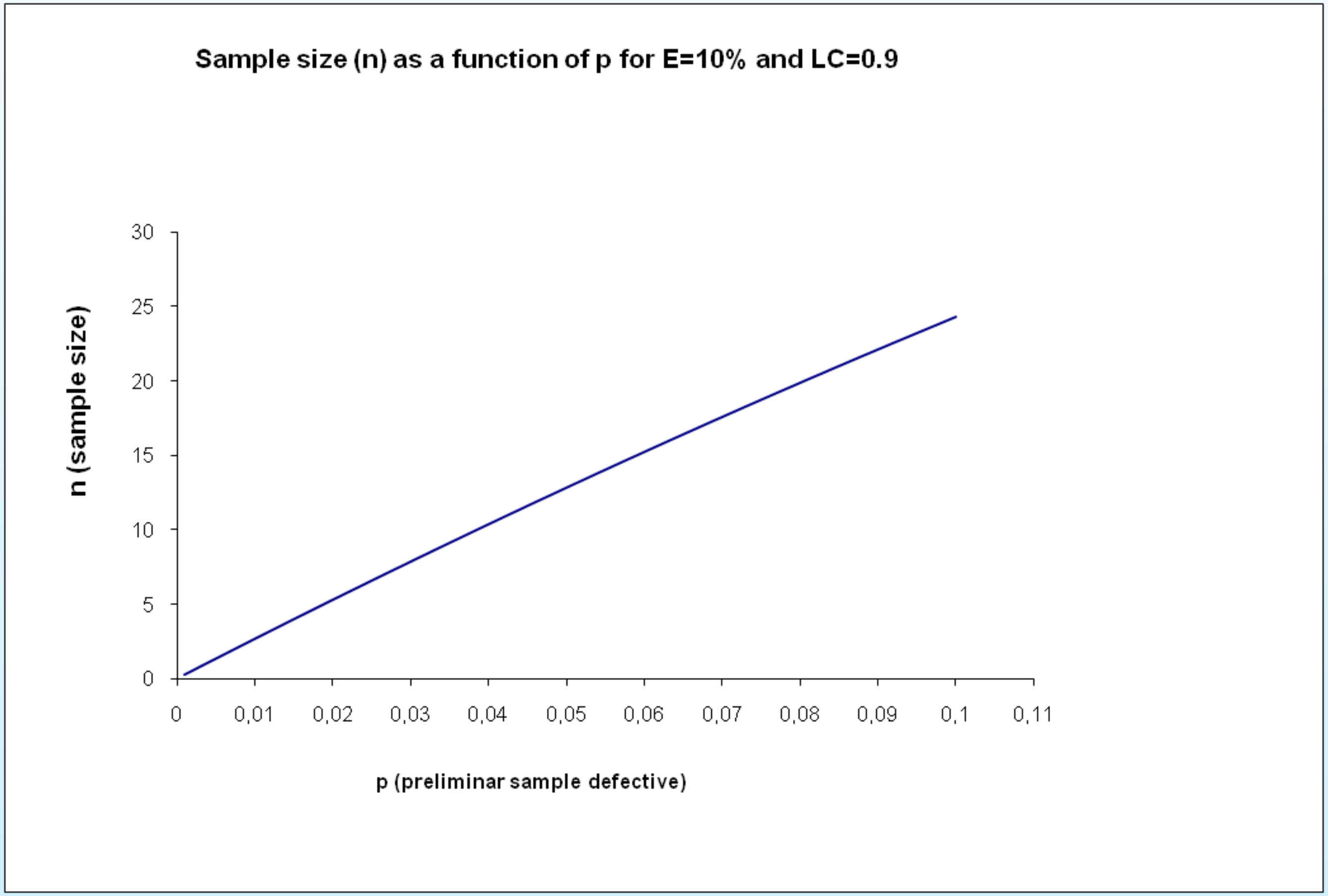
3. Sampling procedure

Sample size for E=10% and LC=0.95



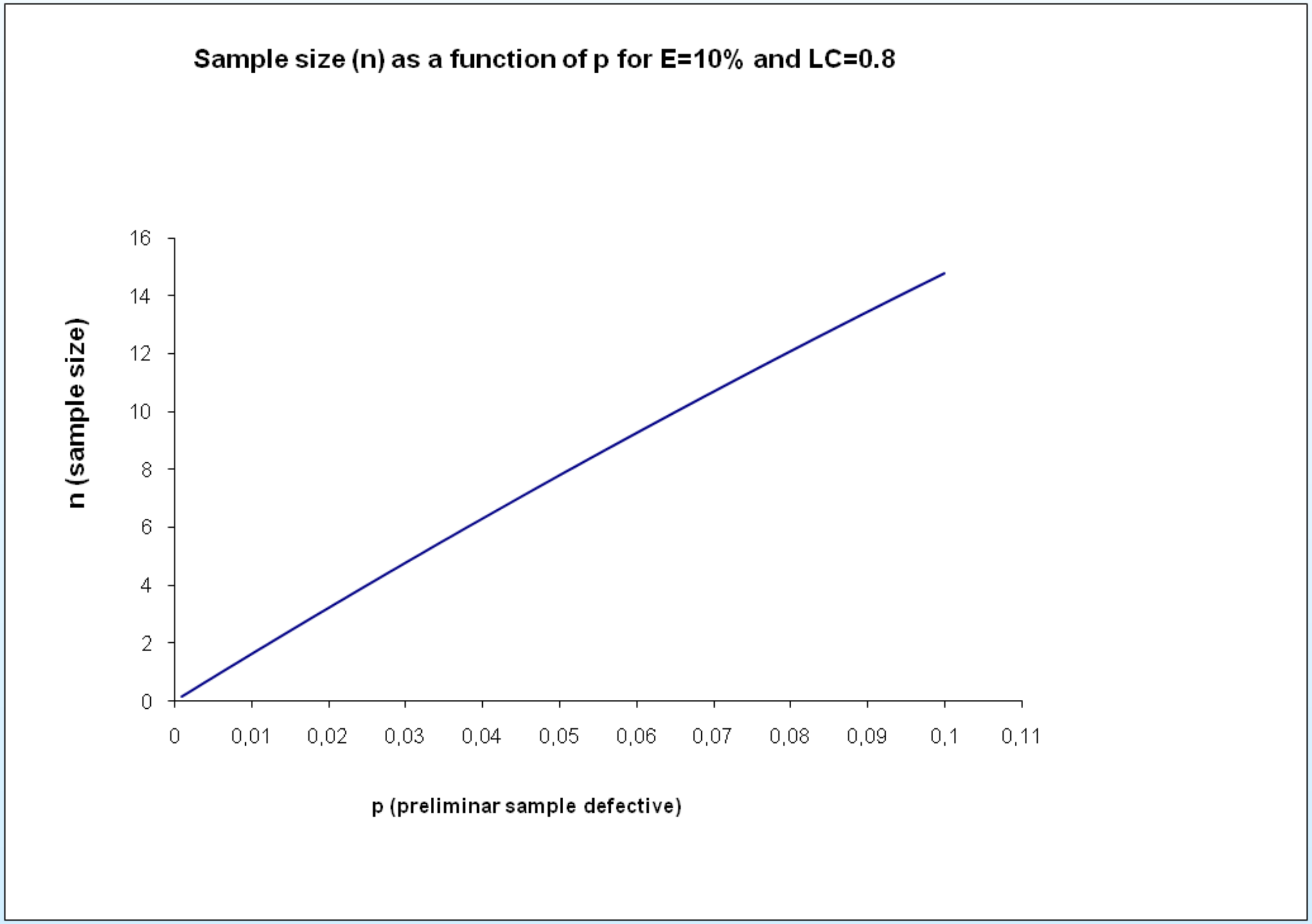
3. Sampling procedure

Sample size for E=10% and LC=0.90



3. Sampling procedure

Sample size for E=10% and LC=0.80



4. Example sampling procedure

Template for sampling

Step N°	data				Remarks
1	N = …………				Product category on market (#models, #manufacturers)
2	ER_{11}, ER_{12}, ER_{21},….. & related KU values				Essential requirements classification (electrical only)
3	Serious risk products KU < 1	High risk products 1>=KU<2	Medium risk products 2>=KU<3	Low risk products +rest KU>=3	
4	Preliminary sampling (on a limited number of products)				Technical assessments + use of existing data (MS database)
5	Q_{ps} = ……. (…………)	Q_{ph} = ……. (…………)	Q_{pm} = ……. (………)	Q_{pl} = ……. (………)	Estimated quantities (sum = 1)
6	P_{ps} = ………	P_{ph} = ………	P_{pm} = ………	P_{pl} = ………	Estimated probabilities of failures
7	N_s= …….. @ LC = 0,99	N_h= ……. @ LC = 0,95	N_m= ……. @ LC = 0,90	N_l= ……. @ LC = 0,80	Sampling size E=error= 5 or 10%
8	Final sampling				Final technical assessments
9	Evaluate results & adjust sampling model & add data to MS database				

4. Example sampling procedure

Suppose market surveillance action on n=100000 electrical equipment on the market.

Step	data				Remarks
1	$N = 100000$				Product category on market (#models, #manufacturers)
2	ER_{11}, ER_{12}, ER_{21} & related KU values				Essential requirements classification (electrical only)
3	Serious risk products KU < 1	High risk products 1<=KU<2	Medium risk products 2<=KU<3	Low risk products+rest KU>=3	
4	Preliminary sampling (on a limited number of products)				Technical assessments + use of existing data (MS database)
5	$Q_{ps} = 0{,}04$ (4000)	$Q_{ph} = 0{,}06$ (6000)	$Q_{pm} = 0{,}1$ (10000)	$Q_{pl} = 0{,}8$ (80000)	Estimated quantities (sum = 1)
6	$P_{ps} = 0{,}005$	$P_{ph} = 0{,}008$	$P_{pm} = 0{,}004$	$P_{pl} = 0{,}002$	Estimated probabilities of failures
7	$N_s = 4$ (15) @ LC = 0,99	$N_h = 4$ (13) @ LC = 0,95	$N_m = 2$ (5) @ LC = 0,90	$N_l = 1$ (2) @ LC = 0,80	Sampling size E = error = Constant = 10 (5) %
8	Final sampling				Final technical assessments
9	Evaluate results & adjust sampling model & add data to MS database				

5. Summary

- **Preliminary comparison of sampling techniques indicates to start with binomial distribution (using common spreadsheet tools)**
- **Merit of other advanced techniques (e.g. Bayesian) should be studied (ideally in a research project, e.g. AMSUM)**
- **Classification of Essential Requirements: a technique has been proposed**
- **A sampling procedure has been proposed:**

  a 2-step approach based on binomial distribution. It should be further developed, with feedback from UNECE and PROSAFE.