

The need for adequate sampling in a well functioning market surveillance system

Keywords: Technical regulations, essential requirements, market surveillance, pre-standardization research, statistics, sampling methods

Introduction

In today's global product regulation regimes, it is of importance that the "putting on the market" of products becomes efficient and easy, this is to say the burden of regulatory compliance before putting the product on the market, is getting less involvement of the authority. This way of accessing the market by manufacturers or in general "economic operators" must be supported by an efficient and effective market surveillance system. This statement has been put forward by Market Surveillance Authorities but also their interested parties like the economic operators.

From a system level point of view, the main objective of the Market Surveillance Authorities is to make sure that the number of non-conforming products on the market is contained. In the ideal case, for seriously dangerous equipment, should be 0 (zero) %.

There have been created some regulatory documents¹ worldwide that put forward such a well functioning market surveillance system.

This paper discusses "the adequate scale" as is required in a well functioning MS system as it is said in clause 19 of 765/2008/EC:

«1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an **adequate scale**, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples.»

It may be not clear what 'adequate scale' means.

It is my understanding that Market Surveillance Authorities in countries are free in defining the contents of these terms.

In that situation, the adequate scale and other detailed market surveillance requirements will be defined by only 1 party: the Market Surveillance Authorities.

In the light of total harmonisation of regulations, this may induce problems such as that some member countries may require more serious requirements (e.g. larger sampling schemes, and so on). It may also make the Market Surveillance system less transparent hence not so acceptable by economic operators and finally the public.

The sampling procedure

In a previous document², about 5 sampling methods were investigated if they could be used for market surveillance purposes. These methods were:

¹ E.g. Regulation 765/2008/EC

1. Sample size based on binomial distribution,
2. Sample size based on test of hypothesis on a population proportion,
3. Sample size based on statistical quality control,
4. Sample size based on ISO 2859-1,
5. Sample size based on Bayesian statistics

It was concluded from this initial study that the determination of the sample size by means of the binomial distribution meets the needs of market surveillance in most efficient way, this means to get meaningful results using minimum sample size (e.g. ISO 2859-1 is not well suited for market surveillance actions as the required sample size is large).

Another step forward to get a more quantitative approach to market surveillance was the establishment of a “market surveillance sampling procedure” for use in market surveillance actions, refer to the flow chart below and referenced in the footnote below.

It is a 2-step approach in an endeavor to limit the number of samples as the resources of Market Surveillance Authorities are limited.

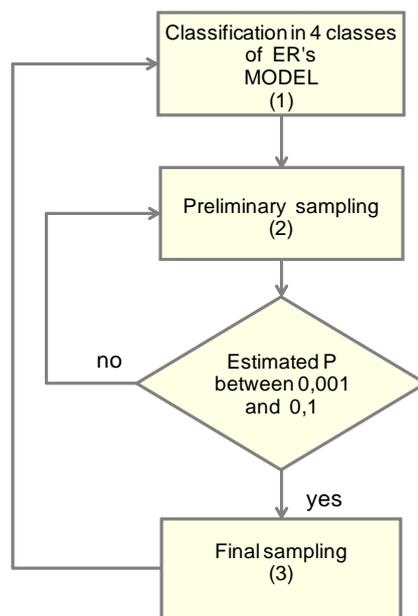


Figure 1: flow chart of the simplified sampling procedure

By classification of products and by doing some preliminary assessments, we can control the probability rate (P) of non-conforming products.

² Refer to the presentation on the UNECE WP6 web site : http://unece.org/trade/wp6/SectoralInitiatives/MARS/Slovakia_Oct10/BKDocs/Ivan%20Hendrikx%20MS%20sampling%20procedure.pdf

This presentation was based on the paper “Market surveillance sampling procedure” issued in june 2010 as a background document for the EMARS seminar of Malta, held in May 2010.

If we look at market surveillance as a system, it is needed to have some number for the total volume of products on the market, its safety features (may also be called 'Essential Requirements' or ERs), the classification of these ERs by risk assessment methods, so that an acceptable outcome becomes feasible. This is studied in blocks 'classification in 4 classes -MODEL' (1) and 'preliminary sampling' (2) of figure 1.

Therefore an initial model of the overall performance of a "well functioning market surveillance system" needs to know not only the volume of products and features (safety related) which are on the market but also it is needed to define the 'Non-Conformity Rate(s)' for the whole product population.

Example for the preliminary sampling requirement

A mathematical program was written in Matlab with the help of Matlab engineers, see below. As data of MSAs are not available and are partly confidential, it was decided to 'construct' the population of products on the market using a random number generation. As a first guess, we used a population number of 100000, of which we inserted at random 15 % non-conform products. This was the ultimate population on which the other statistical operations were effected.

A. Creation of a random population of products and testing it

```
equipment=100000;
OK = 85000;
E1=ones(1,equipment);
while (sum(E1) >= OK);
E1(randi([1 equipment]))=0;
end;
sum(E1)
ans =
    84999
mean(E1)
ans =
    0.8500
std(E1)
ans =
    0.3571
N=100; alpha=0.05; p0=0.15; p1=0.20; cutoff=binoinv(1-alpha, N, p0)
cutoff =
    32
1 - binocdf(cutoff,N,p0)
ans =
    0.0446
```

B. Estimating the sample size when having established a Non-Conformity Rate of 15% (p0)

```

Nvec = 50:50:2000;
DesiredPower = 0.80;
power = sampsizepwr('p',p0,p1,[],Nvec,'tail','right');
plot(Nvec,power,'bo-',[0 2000],[DesiredPower DesiredPower],'k:');
xlabel('N = sample size')
ylabel('Power');
title('Power function for the alternative: p = 0.20')

```

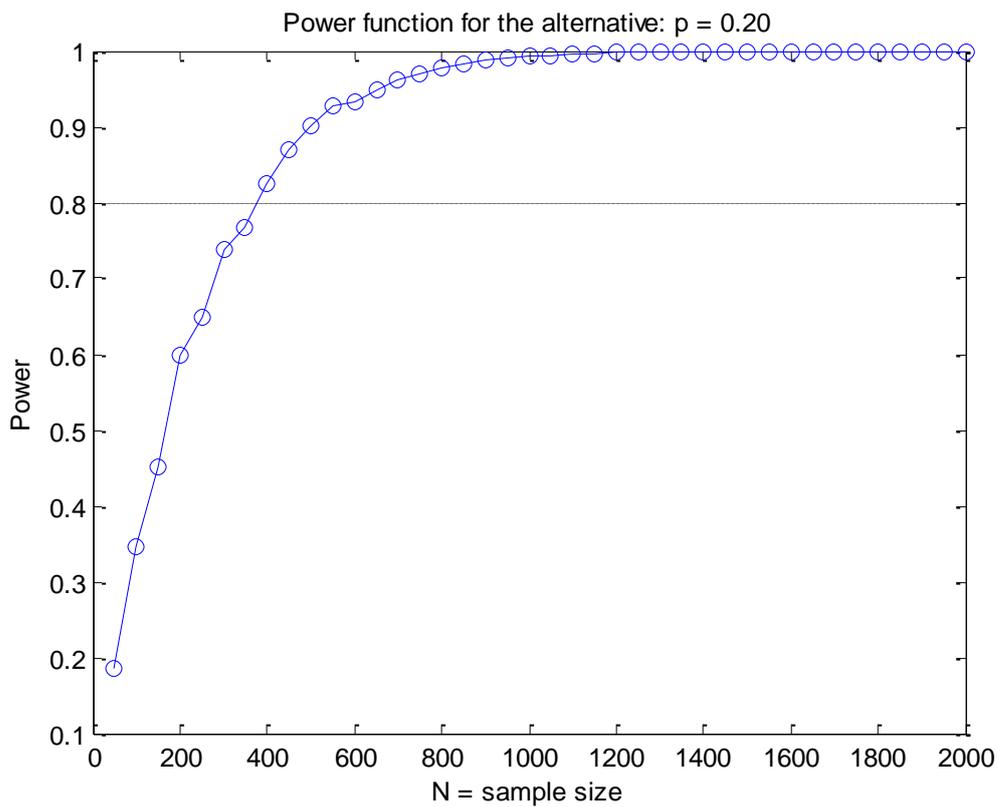


Figure 2: sample size required for verifying that the Non-Conformity Rate is not 20 % (target set at 15 %)

```

approxN = sampsizepwr('p',p0,p1,0.80,[],'tail','right')

```

approxN = 376

This means that we need to have a sample size of 376 products out of a population of 100000 products to be reasonable confident (80 %) that the Non-Conformity Rate is not 20%, having set 15 % as the target.

Preliminary conclusions

The testing of an arbitrary volume of products on the market using a random number generating algorithm and as first selection parameter the maximum allowed 'Non-Conformity Rate' of products, shows that the sampling volume is quite large.

The proposed statistical approach i.e. using a power function to test an arbitrary population of products, provides for a base to answer the question of clause 19 of 765/2008/EC: "on an adequate scale".

The preliminary sampling process should study the interaction between the actual Non-Conformity Rate of products on the market and the effects of Market Surveillance Actions (simply said: sampling). The results of these studies can be used to further develop the market surveillance model, i.e. the interaction between essential requirements, risk assessment, conformity assessment incl. measurement uncertainty, statistical techniques (like sampling schemes) and non-tangible effects (like visibility).

It is obvious that stakeholder inputs should be included in the work of market surveillance in an attempt to create requirements/procedures generally accepted by anyone in the market place.

Next work

Having showed the importance of the sample size in a well functioning market surveillance system, the next work will need to concentrate on the 'Non-Conformity Rate' selection parameter.

Pre-standardization research projects can be used as a vehicle to further develop the Non-Conformity Rate and other market surveillance procedures/methods, to be integrated, once accepted by interested parties, into the 'model'.

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