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Appendix to the Regulations Relating to the Quality Seal for Condoms:

Statistical analysis of the results of inspections (Condoms drawn from the market)

Lucerne, 30 March 2004

A.1 Sampling

To begin with, at least 20 condoms are drawn at one or more randomly chosen vending points and tested. Whenever suspicion arises according to A.3 that the drawn condoms do not belong to the same batch as the condoms with the same batch number originally tested, then at least 105 additional condoms are drawn and a total of 125 condoms are tested from batches with a maximum size of 150 000 condoms. (With larger batches the number tested is increased to 200 or 315 for batch sizes of 500 000 or 1 500 000 respectively). The results of the condoms tested are analysed according to A.4. If the suspicion is not confirmed, no additional tests are done. If the suspicion is confirmed, and only a maximum of 5 are detected as "non conforming" according to section 4.1 out of 125 condoms, or a maximum of 10 are detected as "non conforming" according to section 4.1 out of 315 condoms, no additional tests are done. Otherwise an additional 125, or 200, or 315 condoms are drawn respectively and tested (see A.5).

A.2 Tests

The condoms are tested according to EN ISO 4074 for bursting pressure and bursting volume.

A.3 Analysis of the Distribution of a Small Sample

The analysis is done separately for bursting volume and bursting pressure. To begin with, the average value of the sample is adjusted to the average value of the originally tested condoms by multiplying each value of the sample with an appropriate factor, in order to take possible ageing processes, etc., into account. This factor must not deviate more than 10 % from 1.0.

The scale of values is divided into four classes:

smaller than m – 0.85s; m – 0.85s to m; m to M + 0.85s; Greater than m + 0.85s

where m = average value of the condoms originally tested

s = standard deviation of the condoms originally tested

The number of values in each class is counted and the testing value X² is calculated according to the following formula (chi square test with samples from multinomial populations)

$$X^{2} = (n_{1} + n_{2}) \cdot (-1 + \frac{1}{n_{1}n_{2}} \cdot \sum_{j=1}^{k} \frac{n_{2}b_{1j}^{2} + n_{1}b_{2j}}{b_{1j} + b_{2j}})$$

- where n_1 = number of condoms originally tested (125 or 250, for larger batches accordingly more condoms)
 - n_2 = number of condoms drawn from the market (maximal 100)
 - k = number of classes (= 4)
 - b_{1j} = frequency of condoms originally tested, in class j
 - b_{2j} = frequency of condoms drawn from the market, in class j

If the testing value X^2 for bursting volume and/or bursting pressure is greater than or equal to 6.25 (limiting critical value of chi square for a distribution with 3 degrees of freedom and a threshold of tolerance for error of 10 %), one can assume that the drawn condoms do not originate from the originally tested batch.

A.4 Analysis of the Distribution of a Large Sample

For a sample larger than 100 a procedure in analogy to A.3 is applied however the scale of values is divided into the following 11 classes:

smaller than m - 1.45s; m - 1.45s to m - 1.0s; m - 1.0s to m - 0.7s; m - 0.7s to m - 0.4s; m - 0.4s to m - 0.15s; $m \pm 0.15s$; m + 0.15s to m + 0.4s; m + 0.4s to m + 0.7s; m + 0.7s to m + 1.0s; m + 1.0s to m + 1.45s; greater than m + 1.45s

In the formula therefore k is equal to 11, n_2 has a value greater than 100.

If the testing value X² for bursting volume and/or bursting pressure is greater than or equal to 23.21 (limiting critical value of chi square for a distribution with 10 degrees of freedom and a threshold of tolerance for error of 1 %), one can assume that the drawn condoms do not originate from the originally tested batch. (Such a result may also appear because sampling in the market is unavoidably disproportionate if the batch is very inhomogeneous. However, one can assume that such an inhomogeneous batch does not conform to the definition of "batch" according to EN ISO 4074. An objection is therefore justified in any case).

A.5 Interpretation of the Numbers of "Non Conforming" Condoms

If a maximum of 5 are detected as "non conforming" according to section 4.1 out of 125 condoms, or a maximum of 7 are detected as "non conforming" according to section 4.1 out of 200 condoms, or a maximum of 10 are detected as "non conforming" according to section 4.1 out of 315 condoms, one can assume that the rate of non conforming units is consistent with an AQL of 1.5 (single sampling plan for normal inspection according to ISO 2859-1). If a maximum of 9 or 12 or 18 are detected as "non conforming" out of 250 or 400 or 630 condoms respectively, one can also assume that the rate of non conforming" out of 250 or 400 or 630 condoms respectively, one can also assume that the rate of non conforming" out of 250 or 400 or 630 condoms respectively, one can assume that the rate of non conforming" out of 250 or 400 or 630 condoms respectively, one can assume that the rate of non conforming units is larger than the AQL of 1.5 (double sampling plan for normal inspection according to ISO 2859-1).

A.6 Final provisions

This Appendix to the Regulations Relating to the Quality Seal for Condoms dated 30 March 2004 was agreed by the members of the Verein Gütesiegel on 30 March 2004 and replaces all previous Appendices. If any doubt should arise, the wording used in the German version of this Appendix applies.