Council Directive of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products (76/211/EEC)

[F1ANNEX II

Textual Amendments

F1 Substituted by Commission Directive of 28 September 1978 adapting to technical progress the Annexes to Council Directives 75/106/EEC and 76/211/EEC on prepackaging (78/891/EEC).

2. REQUIREMENTS FOR CHECKING BATCHES OF PREPACKAGES

The checking of prepackages shall be carried out by sampling and shall be in two parts:

— a check covering the actual contents of each prepackage in the sample,

— another check on the average of the actual contents of the prepackages in the sample.

A batch of prepackages shall be considered acceptable if the results of both these checks satisfy the acceptance criteria.

For each of these checks, there are two sampling plans:

— one for non-destructive testing, i.e., testing which does not involve opening the package,

— the other for destructive testing, i.e., testing which involves opening or destroying the package.

For economic and practical reasons, the latter test shall be limited to the absolutely essential minimum; it is less effective than the non-destructive test.

Destructive testing shall therefore be used only when non-destructive testing is impracticable. As a general rule it shall not be applied to batches of fewer than 100 units.

2.1. Prepackage batches

2.1.1. The batch shall comprise all the prepackages of the same nominal quantity, the same type and the same production run, packed in the same place, which are to be inspected. The batch size shall be limited to the amounts laid down below.

2.1.2. When prepackages are checked at the end of the packing line, the number in each batch shall be equal to the maximum hourly output of the packing line, without any restriction as to batch size.

In other cases the batch size shall be limited to 10 000.

2.1.3. For batches of fewer than 100 prepackages, the non-destructive test, where carried out, shall be 100 %.

2.1.4. Before the tests in 2.2 and 2.3 are carried out, a sufficient number of prepackages shall be drawn at random from the batch so that the check requiring the larger sample can be carried out.

For the other check, the necessary sample shall be drawn at random from the first sample and marked.

This marking operation shall be completed before the start of measuring operations.

2.2. Checking of the actual contents of a prepackage

The minimum acceptable contents shall be calculated by subtracting the tolerable negative error for the contents concerned from the nominal quantity of the prepackage.

Prepackages in the batch whose actual contents are less than the minimum acceptable contents shall be considered defective.

2.2.1. Non-destructive testing

Non-destructive testing shall be carried out in accordance with a double sampling plan as shown in the table below:

The first number of prepackages checked shall be equal to the number of units in the first sample, as indicated in the plan:

— if the number of defective units found in the first sample is less than or equal to the first acceptance criterion, the batch shall be considered acceptable for the purpose of this check,

— if the number of defective units found in the first sample is equal to or greater than the first rejection criterion, thebatch shall be rejected,

— if the number of defective units found in the first sample lies between the first acceptance criterion and the first rejection criterion, a second sample shall be checked, the number of units in which is indicated in the plan.

The defective units found in the first and second samples shall be added together and:

— if the aggregate number of defective units is less than or equal to the second acceptance criterion, the batch shall be considered acceptable for the purpose of this check,

— if the aggregate number of defective units is greater than or equal to the second rejection criterion, the batch shall be rejected.

Number in batch	**Samples**			**Number of defective units**	
	Order	**Number**	**Aggregate number**	**Acceptance criterion**	**Rejection criterion**
100 to 500	1st	30	30	1	3
	2nd	30	60	4	5
501 to 3 200	1st	50	50	2	5
	2nd	50	100	6	7
3 201 and over	1st	80	80	3	7
	2nd	80	160	8	9

2.2.2. Destructive testing

Destructive testing shall be carried out in accordance with the single sampling plan below and shall be used only for batches of 100 or more.

The number of prepackages checked shall be equal to 20.

— If the number of defective units found in the sample is less than or equal to the acceptance criterion, the batch of prepackages shall be considered as acceptable.

— If the number of defective units found in the sample is equal to or greater than the rejection criterion, the batch of prepackages shall be rejected.

Number in batch	**Number in sample**	**Number of defective units**	
		Acceptance criterion	**Rejection criterion**

Whatever the number (≥ 100)	20	1	2**]**

2.3. Checking of the average actual contents of the individual prepackages making up a batch

2.3.1. A batch of prepackages shall be considered acceptable for the purpose of this check if the mean value

$$\bar{x} = \frac{\sum x_i}{n}$$

of the actual contents x_i of n prepackages in a sample is greater than the value:

$$Q_n - \frac{s}{\sqrt{n}} \times t_{(1-\alpha)}$$

In this formula:

Q_n	=	the nominal quantity of the prepackage,
n	=	the number of prepackages in the sample for this check,
s	=	the estimated standard deviation of the actual contents of the batch,
$t_{(1 - \alpha)}$	=	0.995 confidence level of a Student distribution with ν = n — 1 degree of freedom.

2.3.2. If x_i is the measured value for the actual contents of the i-th item in the sample containing n items then:

2.3.2.1. the mean of the measured values for the sample is obtained by the following calculation:

$$\bar{x} = \frac{\sum_{i=1}^{i=n} x_i}{n}$$

2.3.2.2. and the estimated value of the standard deviation s by the following calculation:

— the sum of the squares of the measured values:

$$\sum_{i=1}^{i=n} (x_i)^2$$

— the square of the sum of the measured values:

$$\left(\sum_{i=1}^{i=n} x_i\right)^2$$

then

$$\frac{1}{n}\left(\sum_{i=1}^{i=n} x_i\right)^2$$

— the corrected sum

$$SC = \sum_{i=1}^{i=n} \frac{SC=\sum^{i=n} (x_i)^2 - 1}{n}\left(\sum_{i=1}^{i=n} x_i\right)^2$$

— the estimated variance:

$$v = \frac{SC}{n-1}$$

the estimated value of the standard deviation is:

$$s = \sqrt{v}$$

2.3.3. Criteria for acceptance or rejection of the batch of prepackages for checking the mean:

2.3.3.1. Criteria for non-destructive testing

Number in batch	**Number in sample**	**Criteria**	
		Acceptance	**Rejection**

100 to 500 (inclusive)	30	$x^- \geq Q_n - 0.503s$	$x^- < Q_n - 0.503s$
> 500	50	$x^- \geq Q_n - 0.379s$	$x^- < Q_n - 0.379s$

2.3.3.2. Criteria for destructive testing

Number in batch	**Number in sample**	**Criteria**	
		Acceptance	**Rejection**
Whatever the number (≥100)	20	$x^- \geq Q_n - 0.640s$	$x^- < Q_n - 0.640s$