L.N. 60 of 2006

FOOD SAFETY ACT
(CAP. 449)

Contaminants in Food (Sampling and Analysis Methods) (Amendment) Regulations, 2006

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health, the Elderly and Community Care has made the following regulations:-

Citation.

1. The title of these regulations is the Contaminants in Food (Sampling and Analysis Methods) (Amendment) Regulations, 2006, and they shall be read and construed as one with the Contaminants in Food (Sampling and Analysis Methods) Regulations, 2004, hereinafter referred to as "the principal regulations".

L.N. 488 of 2004.

Scope.

2. These regulations implement the provisions of Commission Directive 2005/4/EC of 19 January, 2005 and Commission Directive 2005/5/EC of 26 January, 2005.

Amends the Third Schedule to the principal regulations.

3. In the Third Schedule to the principal regulations, for point 5 there shall be substituted the following:-

"5. COMPLIANCE OF THE LOT OR SUBLOT WITH THE SPECIFICATION

The control laboratory shall analyse the laboratory sample for enforcement at least in two independent analyses, and calculate the mean of the results. The lot is accepted if the mean does not exceed the respective maximum level as laid down in Regulation (EC) No. 466/2001, taking into account the expanded measurement uncertainty and correction for recovery (*). The lot is rejected if the mean exceeds the respective maximum level beyond reasonable doubt, taking into account the expanded measurement uncertainty and correction for recovery.

The present interpretation rules are of application for the analytical result obtained on the sample for official control. In case of analysis for defence or referee purposes, the rules in the Maltese legislation shall apply.".

Amends the Fourth Schedule to the principal regulations.

4. In the Fourth Schedule to the principal regulations:-

(a) in point 3, 'Method of analysis to be used by the laboratory and laboratory control requirements', the following point 3.3.3. shall be inserted immediately after Table 4:-

"3.3.3. *Performance Criteria — Uncertainty Function Approach*

However, an uncertainty approach may also be used to assess the suitability of the method of analysis to be used by the laboratory. The laboratory may use a method which will produce results within a maximum standard uncertainty. The maximum standard uncertainty can be calculated using the following formula:

$$Uf = \sqrt{[\,(\mathrm{LOD}/2)^2 + (\mathrm{aC})^2\,]}$$

where:

Uf is the maximum standard uncertainty

LOD is the limit of detection of the method

C is the concentration of interest

α is a numeric factor to be used depending on the value of C. The values to be used are given in the table below:

C (µg/kg)	α
≤ 50	0,2
51-500	0,18
501-1000	0,15
1001-10 000	0,12
≥10 000	0,1

and U is the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

If an analytical method provides results with uncertainty measurements less than the maximum standard uncertainty the method will be equally suitable to one which meets the performance characteristics given above."; and

(b) for point 3.4 there shall be substituted the following:-

"3.4. **Estimation of the analytical trueness, recovery calculations and reporting of results.**

Wherever possible the trueness of analysis shall be estimated by including suitable certified reference materials in the analysis. The analytical result is to be reported, corrected or uncorrected, for recovery. The manner of reporting and the level of recovery must be reported. The analyst should note the "European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provisions in EU food legislation" (*). The analytical result has to be reported as x +/– U whereby x is the analytical result and U is the measurement uncertainty.

5. In the Fifth Schedule to the principal regulations,

Amends the Fifth Schedule to the principal regulations.

(a) for points 4.3, 4.4 and 4.5 there shall be substituted the following:-

"4.3. General survey of the sampling procedure for cereals, dried vine fruit and roasted coffee

Table 1: Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight or number of sublots	No of incremental samples	Aggregate sample weight (kg)
Cereals and cereal products	≥ 1500 > 300 and < 1500 ≥ 50 and ≤ 300 < 50	500 tonnes 3 sublots 100 tonnes -	100 100 100 3 – 100 ([8])	10 10 10 1 – 10
Dried vine fruit (currants, raisins and sultanas)	≥ 15 <15	15 – 30 tonnes -	100 10 – 100 ([9])	10 1 – 10
Roasted coffee beans, ground roasted coffee and soluble coffee	≥ 15 <15	15 – 30 tonnes -	100 10 – 100 ([9])	10 1 – 10

[8] Depending on the lot weight – see Table 2 of this Schedule
[9] Depending on the lot weight – see Table 3 of this Schedule

4.4. *Sampling procedure for cereals and cereal products (lots ≥ 50 tonnes) and for roasted coffee beans, ground roasted coffee, soluble coffee and dried vine fruit (lots ≥ 15 tonnes)*

- On condition that the sublot can be separated physically, each lot must be subdivided into sublots following table 1. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may vary from the mentioned weight by a maximum of 20 %.

- Each sublot must to be sampled separately.

- Number of incremental samples: 100.

- Weight of the aggregate sample = 10 kg.

- If it is not possible to carry out the method of sampling described above because of the commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

4.5. *Sampling provisions for cereals and cereal products (lots < 50 tonnes) and for roasted coffee beans, ground roasted coffee, soluble coffee, dried vine fruit (lots < 15 tonnes)*

For cereal lots under 50 tonnes and for roasted coffee beans, ground roasted coffee, soluble coffee and dried vine fruit lots under 15 tonnes the sampling plan has to be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 10 kg. For very small lots (≤ 0,5 tonnes) of cereals and cereal products a lower number of incremental samples can be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg.

The figures in the following table can be used to determine the number of incremental samples to be taken.

Table 2: Number of incremental samples to be taken depending on the weight of the lot of cereals and cereal products

Lot weight (tones)	No of incremental samples
≤ 0,05	3
> 0,05 - ≤ 0,5	5
> 0,5 - ≤ 1	10
> 1 - ≤ 3	20
> 3 - ≤ 10	40
> 10 - ≤ 20	60
> 20 - ≤ 50	100

Table 3: Number of incremental samples to be taken depending on the weight of the lot of roasted coffee beans, ground roasted coffee, soluble coffee and dried vine fruit

Lot weight (tonnes)	No of incremental samples
≤ 0,1	10
> 0,1 - ≤ 0,2	15
> 0,2 - ≤ 0,5	20
> 0,5 - ≤ 1,0	30
> 1,0 - ≤ 2,0	40
> 2,0 - ≤ 5,0	60
> 5,0 - ≤ 10,0	80
> 10,0 - ≤ 15,0	100"; and

(b) the following point 4.6A shall be inserted immediately after point 4.6: -

"4.6A *Sampling provisions for wine and grape juice*

The aggregate sample shall be at least 1 kg except where it is not possible e.g. when the sample consists of 1 bottle.

The minimum number of incremental samples to be taken from the lot shall be as given in table 4. The number of incremental samples determined is function of the usual form in which the products concerned are commercialised. In the case of bulk liquid products, the lot shall be thoroughly mixed insofar as possible and insofar as it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous

distribution of ochratoxin A can be assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.

The incremental samples, which might frequently be a bottle or a package, shall be of similar weight. The weight of an incremental sample should be at least 100 grams, resulting in an aggregate sample of at least about 1 kg. Departure from this procedure must be recorded in the record provided for in point 3.8.

Table 4: Minimum number of incremental samples to be taken from the lot

Form of commercialisation	Weight of lot (in litres)	Minimum number of incremental samples to be taken
Bulk (grape juice, wine)	…	3
Bottles/packages grape juice	≤ 50	3
Bottles/packages grape juice	50 to 500	5
Bottles/packages grape juice	> 500	10
Bottles/packages wine	≤ 50	1
Bottles/packages wine	50 to 500	2
Bottles/packages wine	> 500	3”.

References

(*) European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provisions in EU food legislation, 2004

(http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/sampling_en.htm).

Ippubblikat mid-Dipartiment ta’ l-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugh fl-Istamperija tal-Gvern — *Printed at the Government Printing Press*

Prezz 24ċ – *Price 24c*