

**GUIDANCE DOCUMENT FOR THE IMPLEMENTATION OF COMMISSION  
REGULATION (EU) No 519/2014 OF 16 MAY 2014 AMENDING REGULATION  
(EC) No 401/2006 LAYING DOWN THE METHODS OF SAMPLING AND  
ANALYSIS FOR THE OFFICIAL CONTROL OF THE LEVELS OF MYCOTOXINS IN  
FOOD**

**ENDORSED BY THE STANDING COMMITTEE ON THE FOOD CHAIN AND  
ANIMAL HEALTH SECTION TOXICOLOGICAL SAFETY OF THE FOOD CHAIN  
ANIMAL NUTRITION AT ITS MEETING ON 26 MAY 2014**

**IMPORTANT DISCLAIMER**

**This document has no formal legal status and, in the event of a dispute,  
ultimate responsibility for the interpretation of the law lies with the Court of  
Justice**

**NOTE**

This document is an evolving document and might be updated to take account  
of the experience gained by the competent authorities in the implementation  
of Regulation (EC) No 401/2006 or this guidance document

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# **GUIDANCE DOCUMENT FOR THE SAMPLING OF LARGE LOTS OR SPECIFIC CASES FOR MYCOTOXINS**

## **Introduction**

Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs, as last amended by Commission Regulation (EU) No 519/2014 of 16 May 2014, provides for a sampling procedure to be applied for the control of mycotoxins in various foodstuffs.

Specific rules for the sampling of very large lots or lots stored or transported in a way whereby the sampling throughout the lot is not feasible are established by Commission Regulation (EU) No 519/2014 of 16 May 2014 amending Regulation (EC) 401/2006. This document provides further guidance.

## **PART A: guidance on specific aspects of the sampling procedure**

### **I. Sampling and sample preparation**

- The lot (or sampled portion) shall be sampled by repeatedly taking incremental samples at various single positions in the lot (or sampled portion). These incremental samples shall be combined by mixing to form an aggregate sample.
- One aggregate sample per sampled portion (or lot).
- The aggregate sample of at least 10 kg shall be homogenised by grinding.
- Homogenisation by grinding means that the passes a sieve with size of 1 mm.

### **II. Guidance on sampled portion**

In the case of large lots (> 500 tons):

The sampled portion should be at least 10 % of the lot with a minimum portion of 500 tons, insofar accessible

If only a portion of a lot of feed is sampled, it shall be presumed that all of the food in the lot is so affected, unless following a detailed assessment there is no evidence that the rest of the lot fails to satisfy the EU requirements. The way how the detailed assessment has to be performed is to be agreed in advance with the competent authorities. An example of detailed assessment is to subdivide the lot into physically separated sublots of e.g. 500 tonnes and to sample and analyse the sublots separately to separate out the compliant from the non-compliant sublots.

### **III. Guidance on assistance/co-operation from food business operator to enable the inspector to perform the sampling correctly in acceptable conditions**

Food business operators have to provide assistance to the inspector to enable the inspector to perform the sampling correctly and under acceptable conditions.

Exact guidance is difficult to provide as it will largely depend on the ad hoc situation. The assistance can consist of:

- Unloading of the lot.
- Placing the pallets with bags as such that they are accessible from all sides.
- Providing a sheltered place for sampling.
- Separate the portion to be sampled (selected by the official inspector) from the rest of the lot.
- ...

## **PART B. Guidance on sampling of large batches /lots – silos**

### **1. Sampling equipment**

There are many different types of sampling equipment or devices. The most suitable equipment should be chosen taking into account the product to be sample, the quantity required and the containers to be used.

Examples of the equipment (non-exhaustive) to sample products in move (e.g. during loading or unloading) and static lots are provided for in Annex to the standard EN-ISO 24333-2009.

### **2. Sampling equipment and incremental samples**

When sampling with a spear (sampling probe/sampling device) with several apertures/openings, the food collected by a single aperture/opening can be considered as one incremental sample on the condition that in each aperture/opening the minimum quantity of incremental sample size is collected. Also a maximum of 1 incremental sample per 0.5 m length of spear can be accepted.

Examples:

Spear of 1 m with 2 apertures/openings, collected quantity 100-150 g per aperture/opening = 2 incremental samples.

Spear of 2 m with 1 aperture/opening, collected quantity 200 g = 1 incremental sample.

Spear of 2 m with 4 apertures/openings, collected quantity 100-150 g per aperture/opening = 4 incremental samples.

Spear of 6 m with 4 apertures/openings, collected quantity 250 g per aperture/opening = 4 incremental samples.

Spear of 3 m with 8 apertures/openings, collected quantity 100-150 g per aperture/opening = 6 incremental samples.

Vacuum spear of 9 meters length, sample taken over the complete length: 18 incremental samples

### **3. Sizes of bulk shipments and large batches in storage**

**Bulk shipments are transported in ships** – the size of the ships can vary from 500 t to cape size ships of more than 90.000 t. The holds also vary as depending on the constitution of the ship itself.

Some examples of **transport by ship**:

- Panamax for about 60.000 metric tonnes in 7 up to 9 holds
- Handy-Max for about 35/45.000 metric tonnes in 5 up to 7 holds
- Handy for about 15/25.000 metric tonnes in 3 to 5 holds
- Coaster for about 2/5.000 metric tonnes in 2 to 3 holds
- River barges for 500 up to about 2.500 metric tonnes in 1 to 2 holds.

Consequently one hold can be from 2 to 10/12 meters deep.

## **Storage:**

Storage facilities (warehouses and silos) vary in size.

- Flat-(horizontal) warehouses have a size of 15/20 meters x 40 or 60 or 80 meters length or even more and cereals are stored 4 meters ( but very often more) high.
- Vertical silos (metallic or concrete) can have storage capacity between 500 to 20.000 tonnes per cell with 4 to 50 cells in the same building and the height can go from 10 to 50 meters.

## **4. General principles when sampling large batches**

In case the type/method of transport or batch storage does not allow for incremental samples to be taken across the whole batch, sampling of such batches should preferably be done when the product/batch is in flow. The lot to be sampled should be moved to another silo to enable sampling across the batch, if this is feasible.

In the case of large warehouses destined to store food, operators should be encouraged to install equipment in the warehouse enabling (automatic) sampling across the whole stored batch, in the presence of an official inspector.

## **5. Sampling of batches transported by ship**

### **5.1. Sampling of batches transported by ship by dynamic sampling**

The sampling of large batches in ships is carried out while the food is in move (dynamic sampling).

The sampling has to be done per hold (entity that can physically be separated). However to keep the balance of the ship, holds are emptied partly one after the other so that the initial physical separation does no longer exist after transfer into silos. So sampling can be performed related to the initial physical separation or related to the separation after transfer into storage.

The unloading of a ship of food can take several days: 50.000 tonnes with an unload capacity of 100 to 750 tonnes an hour can take 65 hours (3 days) to 500 hours (20 days).

Even if the sample is taken automatically, the presence of an inspector is necessary. Therefore it is not (always) feasible or appropriate (from resources and cost point of view) for an inspector to have to be present during the whole operation of unloading. Therefore sampling is allowed to be undertaken on a portion of the lot to be sampled and the result is considered representative for the sampled portion of the lot. It is presumed that all of the food in that lot is so affected, unless following a detailed assessment there is no evidence that the rest of the lot fails to satisfy the EU requirements.

The way how the detailed assessment has to be performed is to be agreed in advance with the competent authorities. An example of detailed assessment is to subdivide the lot into physically separated sublots of e.g. 500 tonnes and to sample and analyse the sublots separately to separate out the compliant from the non-compliant sublots.

Example:

Batch of 10.000 tonnes.

Unloading speed is 500 tonnes an hour: total unloading time = 20 hours.

Inspector decides to sample only part of the batch. He decides to sample 1000 tonnes which means that the sampling time is 2 hours (given that the unloading speed is 500 tons/hour).

The number of incremental samples is determined taking into account the size of the sampled portion of the whole batch and the substance to be controlled.

The sample must consist of 132 ( $100 + \sqrt{1000} = 132$ ) incremental samples of 100 grams, resulting in an aggregate sample of 13.2 kg.

This means that, in case of an automatic sampling, an incremental sample should be taken every 54 sec. or every 7.5 tonnes.

**5.2. Sampling of batches transported by ship by static sampling**

In case the sampling is done in a static way, the same procedure as foreseen for silos accessible from above has to be applied.

The length of the spear (sampling probe) to be used for the sampling of static batch/consignment stored in hold should be sufficient to sample at least a significant portion of the lot.

There has to be a representative sampling of the accessible part (from above) of the consignment/hold performed.

Example:

Hold of 20 m length and 20 m width and 10 m depth = 4000 m<sup>3</sup> = 3000 tonnes.

Insofar accessible from above with a spear of 1.5 m, the accessible part is 600 m<sup>3</sup> = 450 tonnes.

The number of incremental samples is determined taking into account the size of the sampled portion of the whole batch and the substance to be controlled.

The sample must consist of 100 incremental samples of 100 grams, resulting in an aggregate sample of 10 kg.

If the spear has 3 openings/apertures, the sample must be taken on at least 34 sampling points.

**6. Sampling of large batches stored in warehouses**

See point 4.

The length of the spear (sampling probe) to be used for the sampling of static batch/consignment stored in warehouse should be sufficient to sample at least a significant portion of the lot.

There has to be a representative sampling of the accessible part of the consignment performed.

The analytical result of this sample is decisive to determine the compliance/non-compliance of the whole batch. If only a portion of a lot of food is sampled, it shall be presumed that all of the food in the lot is so affected, unless following a detailed assessment there is no evidence that the rest of the lot fails to satisfy the EU requirements. The way how the detailed assessment has to be performed is to be agreed in advance with the competent authorities. An example of detailed assessment is to subdivide the lot into physically separated sublots of e.g. 500 tonnes and to sample and analyse the sublots separately to separate out the compliant from the non-compliant sublots.

#### Example 1:

Cereals stored at a warehouse 30 m large – 50 m deep – 4 m high = 6000 m<sup>3</sup> = about 4500 tonnes accessible from 1 side (30 meter side).

- **Possibility to sample with spear of 2m:** 30 m x 2 m x 4m = 240 m<sup>3</sup> = about 180 tonnes. As the sampled portion is not 10 % of the total lot size, the possibility of the use of a longer spear (of about 5 metres) must be considered.  
100 incremental samples of 100 grams – resulting in 10 kg sample  
(if the spear has 4 apertures/openings: the batch has to be sampled at 25 sampling points representatively located along the accessible side).
- **Possibility to sample with spear (with engine) of 5 metre long:** 30 m x 5 m x 4 m = 600 m<sup>3</sup> = about 450 tonnes  
100 incremental samples of 100 grams – resulting in 10 kg sample  
(if the spear has 10 apertures/openings: the batch has to be sampled at 10 sampling points representatively located along the accessible side).

#### Example 2:

Cereals stored at warehouse 30 m large – 30 m deep – 4 m high = 3600 m<sup>3</sup> = about 2700 tonnes accessible from 4 sides (120 meter side).

- **Possibility to sample with spear of 2m:** 120 m x 2 m x 2m = 480 m<sup>3</sup> = about 360 tonnes.  
100 incremental samples of 100 grams – resulting in 10 kg sample  
(if the spear has 4 apertures/openings: the batch has to be sampled at 25 sampling points representatively located along the accessible side).
- **Possibility to sample with spear (with engine) of 5 meter long:** 120 m x 5 m x 2 m = 1200 m<sup>3</sup> = about 800 tonnes.  
 $100 + \sqrt{800} = 128$  incremental samples of 100 grams – resulting in 12.8 kg sample  
(if the spear has 4 apertures/openings: the batch has to be sampled at 32 sampling points representatively located along the accessible side).



## **7. Sampling of silos**

### **7.1. Sampling of silos (easily) accessible from above**

See point 4.

The length of the spear (sampling probe) to be used for the sampling of static batch/consignment stored in silo should be sufficient to sample at least a significant portion of the lot.

There has to be a representative sampling of the accessible part of the consignment performed.

The analytical result of this sample is decisive to determine the compliance/non-compliance of the whole batch. If only a portion of a lot of food is sampled, it shall be presumed that all of the food in the lot is so affected, unless following a detailed assessment there is no evidence that the rest of the lot fails to satisfy the EU requirements. The way how the detailed assessment has to be performed is to be agreed in advance with the competent authorities. An example of detailed assessment is to subdivide the lot into physically separated sublots of e.g. 500 tonnes and to sample and analyse the sublots separately to separate out the compliant from the non-compliant sublots.

For examples see point 6.

### **7.2. Sampling of silos not accessible from above (closed cylindrical silos)**

See point 4.

#### **7.2.1. Sampling of silos not accessible from above (closed cylindrical silos) with size >100 tonnes**

Food stored in such silos cannot be sampled in a static way and therefore in case the food in the silo has to be sampled and there is no possibility to move the consignment, the agreement has to be made with the operator that he has to inform the inspector when the silo will be unloaded in order to enable sampling when food is in flow.

#### **7.2.2. Sampling of silos not accessible from above (closed cylindrical silos) with reasonable size (< 100 tonnes)**

Sampling procedure involves the release into a recipient of a quantity of 50 to 100 kg and to take the sample in a representative way from this 50 -100 kg.

Example for a silo of 25 tonnes of cereals:

Silo of 25 tonnes / 50 – 100 kg to be released in recipient / sample taken from this 50 – 100 kg // size of aggregate sample relates to whole consignment (25 tonnes) → means 10 kg sample – number of incremental samples relate to quantity released → 5 incremental samples of about 2 kg.

The analytical result of this sample is decisive to determine the compliance/non-compliance of the whole batch. If only a portion of a lot of food is sampled, it shall be presumed that all of the food in the lot is so affected, unless following a detailed assessment there is no evidence that the rest of the lot fails to satisfy the EU requirements. The way how the detailed assessment has to be performed is to be agreed in advance with the competent authorities. An example of detailed assessment is to subdivide the lot into physically separated sublots of e.g. 500 tonnes and to sample and analyse the sublots separately to separate out the compliant from the non-compliant sublots.

**8. Sampling of bulk consignments in closed containers**

Can only be sampled when unloaded. In many cases not possible to sample at point of import and therefore in such cases where containers are to be sampled, the sampling must take place during unloading at the point of destination.

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